

THE ETHICAL CONSIDERATIONS IN THE HEALTH-RELATED
RESEARCH ACTIVITIES CONDUCTED DURING ARMED
CONFLICTS: CASE STUDY OF DARFUR, WEST SUDAN (2004-
2012)

By

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ABSTRACT

The aim of this thesis is to conduct an empirically informed and philosophically robust ethical analysis of health-related human research undertaken during armed conflicts using the case study of Darfur, west Sudan (2004-2012). It adopts an empirical bioethics approach that combines the collection and analysis of empirical data with traditional philosophical analysis. The empirical data were collected using a systematic review of the studies that were conducted in Darfur during the chosen study period, followed by a qualitative project in Sudan. The qualitative findings were used to inform the philosophical discussion where the lines of arguments suggested by the project participants¹ and the literature were scrutinized. This empirically-informed approach was chosen to overcome some of the shortcomings of the use of an abstract philosophical theorization when applied alone to an applied ethics field like humanitarian (research) ethics.

Four main themes emerged and are discussed in the light of the relevant literature. The overall thesis is that the mainstream research ethical governance models are inadequate to ethically guide humanitarian activities as they lack the needed moral representativeness and operational feasibility. To overcome these problems, I argue that ethical oversight should shift from individualistic autonomy-based bioethics to relational autonomy and trust-based bioethics and from committee-based to community- situated governance models.

¹ Throughout the thesis, 'participants' refer to the participants in this project, unless stated otherwise.

DEDICATION

To the greatest woman in my life my wife, Hajir Mohamed, for all the love and the endless support she gave me without hesitation. Without you, it would have been impossible for any of this to happen.

To my people in Darfur who inspired me all through this work.

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LIST OF ABBREVIATIONS

3Ws	Who's Doing What Where
ACF	Action Contre La Faim
AIDS	Acquired Immune Deficiency Syndrome
COHRED	Council on Health Research for Development
CPA	Comprehensive Peace Agreement
CPI	Transparency International Corruption Perceptions Index
EMRO	Eastern Mediterranean Regional Office (of WHO)
ERC	Ethics Review Committee
FAO	Food and Agricultural Organisation of the UN
FMOH	Federal Ministry of Health, aka National Ministry of Health
GBV	Gender-Based Violence
GDP/GNP	Gross Domestic/National Product
GoS	Government of Sudan
HAC	Humanitarian Aid Commission
HAP	Humanitarian Accountability Partnership
HIV	Human Immunodeficiency Virus
HQ	Headquarters
IASC	Inter-Agency Standing Committee
ICRC	International Committee of the Red Cross
IDPs	Internally Displaced Persons
IFRC	The International Federation of Red Cross and Red Crescent Societies
INGO	International Non-Governmental Organisation
IOM	International Organisation for Migration
IRB	Institutional Review Board
ISDR	International Strategy for Disaster Reduction (UN)
MMR	Maternal Mortality Ratio

MOU	Memorandum of Understanding
MSF	Médecins Sans Frontières
NGOs	Non-governmental organisations
NHRC	National Health Research Council
NISS	National Intelligence and Security Services
NMPB	National Medicines and Poisons Board
NNGO	National Non-Governmental Organisation
NREC	National Research Ethics Committee
OCHA	UN Office for the Coordination of Humanitarian Affairs
OHCHR	Office of the High Commissioner for Human Rights
RA	Research Assistant
FMOH-RD	Directorate of Health Research at the Federal Ministry of Health
REC	Research Ethics Committee
RRFs	Rapid Response Forces
SAF	Sudan Armed Forces (Sudanese army)
SHHS	Sudan Household Health Survey
SMOH	State Ministry of Health
SOPs	Standard Operating Procedures
SPHERE	Project on Humanitarian Charter and Minimum Standards in Disaster Response
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNAMID	United Nations African Mission in Darfur
UNDP	United Nations Development Programme
UNDSS	United Nations Department of Safety & Security
UNFPA	United Nations Population Fund
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund

UNJLC	United Nations Joint Logistics Center
USAID	United States Agency for International Development
WASH	Water, Sanitation, and Hygiene
WFP	World Food Programme
WHO	World Health Organisation
WoA	Warrant of Arrest

GLOSSARY OF TERMS

Term	Definition ²
Birth rate, crude (per 1,000 people)	Crude birth rate indicates the number of live births occurring during the year, per 1,000 populations estimated at midyear. Subtracting the crude death rate from the crude birth rate provides the rate of natural increase, which is equal to the rate of population change in the absence of migration.
Chapter VII of the UN Charter	This Chapter provides the framework within which the Security Council may take enforcement action. It allows the Council to "determine the existence of any threat to the peace, breach of the peace, or act of aggression" and to make recommendations or to resort to non-military and military action to "maintain or restore international peace and security" (United Nations, 1945)
Corruption Perceptions Index (CPI)	The CPI scores and ranks countries/territories based on how corrupt a country's public sector is held to be. It is a composite index, a combination of surveys and assessments of corruption, collected by a variety of reputable institutions. The CPI is the most widely used indicator of corruption worldwide (Transparency International, 2015).
Death rate, crude (per 1,000 people)	Crude death rate indicates the number of deaths occurring during the year, per 1,000-population estimated at midyear. Subtracting the crude death rate from the crude birth rate provides the rate of natural increase, which is equal to the rate of population change in the absence of migration.
Health expenditure per capita (current US\$)	Total health expenditure is the sum of public and private health expenditures as a ratio of total population. It covers the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health but does not include the provision of water and sanitation. Data are in current U.S. dollars.
Health expenditure, total (% of GDP)	Total health expenditure is the sum of public and private health expenditure. It covers the provision of health services (preventive and curative), family planning activities, nutrition

² All definitions are from World Development Indicators, URL <http://databank.worldbank.org/data/>. Last Updated: 09/09/2015. Date Accessed [19/09/2015], unless indicated otherwise.

Term	Definition ²
Infant mortality rate	activities, and emergency aid designated for health but does not include the provision of water and sanitation. IMR is the number of infants dying before reaching one year of age, per 1,000 live births in a given year.
Mortality rate, under-5 (per 1,000 live births)	Under-five mortality rate is the probability per 1,000 that a new-born baby will die before reaching age five, if subject to age-specific mortality rates of the specified year.

GENERAL INTRODUCTION

The aim of this thesis is twofold. First, I aim to study the ethical considerations that were encountered during the ethical review, the actual undertaking of, and participation in the health-related research activities involving humans in an armed conflict setting, as expressed by those who reviewed, conducted, or participated in them. My case study is the region of Darfur, west Sudan from the beginning of the conflict in 2004 until 2012. Second, I aim to use the findings of the empirical project to produce an empirically-supported and philosophically robust ethical framework for the conduct of research involving humans during armed conflicts.

To this end, this project started by mapping the ethical concepts relevant to this project. This mapping is achieved through the review of the literature related to health research conducted during humanitarian contexts with a focus on armed conflicts. The various approaches to the concept of research and its ethically-relevant features are discussed in Chapter Two. Given the lack of agreement on what constitutes health research that involves humans; two identifying key ethical features issues pertaining to how 'research' is expressed in this project are suggested: the collection of identifiable personal data and/or biosamples³.

The conceptual mapping is followed by an attempt to explore the current situation in terms of how the ethical aspects of the studies conducted in Darfur were considered and reported. This exploration was done through a systematic review that included the studies involving humans conducted in Darfur between

³ Biosample refer to any biological sample taken from any human participating in any of the included studies, e.g. urine, blood, stool, throat swab, etc.

2004 and 2012, which is fully described in Chapter Seven. The findings of the systematic review, along with the relevant literature, helped in formulating the empirical qualitative project that was conducted in Sudan. This empirical project involved representatives of the relevant stakeholders, namely the internally displaced persons (IDPs), the humanitarian sector, and the governmental bodies responsible for the governance of research and humanitarian activities. The methods used in the different phases of the project are described and justified in Section Three.

One of the main empirical findings of this project is a clear discrepancy between two narratives. The 'official narrative' is reflected by the representatives of the governance bodies, which emphasised the existence of regulatory documents, procedures, and structures through which the research activities in the whole of Sudan, including Darfur, should be regulated. In contrast, the 'field narrative' represented by the humanitarian agencies and the IDPs described a community- situated , multi-tier, local governance system that applies to all the humanitarian activities, not only research.

There are many ways to interpret the discrepancy between the official and the field narratives. One way, which is emphasised by the representatives of the governance bodies, is that the humanitarian agencies failed to abide by the national research guidance, and so should be asked (and sometimes forced) to comply with that research governance system. I refer to this position as the *narrative of failure*. Alternatively, however, the field representatives can be seen to be describing a community-oriented and trust-based governance system for

humanitarian activities, including research. I refer to this alternative approach as the *local narrative*, which represents the backbone of the discussion.

The final section of the thesis discusses the empirical findings and how they informed the normative analysis and the development of an ethical framework for the guidance of research conducted in conflict settings. The thesis concludes with philosophical and operational recommendations. The overarching recommendation is the need to re-orientate and restructure the current humanitarian and research governance systems to complement and not supersede the community-oriented, trust-based, local decision-making system.

I. SECTION ONE: INTRODUCTION AND BACKGROUND

To facilitate the understanding of this project and the interpretation of its findings, this introductory section aims to briefly describe the demographic and the socio-political context of the study area. This is done in Chapter One. As I am aware of how lengthy this could be, I limit myself to the extent of information needed to help in contextualising the Methods, the Results, and the Discussion to make them easier to follow and understand. Additionally, the situation in Darfur is politically controversial, thus I tried to avoid taking sides or defending a viewpoint, despite my personal views that I will explain in 'Reflexivity'.

I have avoided controversial political issues related to the armed conflict in Darfur for two main reasons. First, this project takes Darfur as a case study, so it explores some of the general characteristics that other conflicts share regardless of their local features. Therefore, extensive historical or political elaboration on the conflict is not needed and there is already an abundant literature on the armed conflict in Darfur. Second, such elaboration would bring the risk of bias without a worthwhile corresponding benefit.

After the geopolitical and sociocultural introduction, Chapter Two provides the conceptual introduction, where I outline and discuss the main concepts and terminologies that will be used throughout the thesis. Further discussion and more detailed arguments on why these definitions were chosen will also be made in Chapter Nine.

At the end of this section, I will outline the thesis' rationale, objectives, and research questions.

1 CHAPTER ONE: BACKGROUND

This chapter outlines some background information about Sudan, Darfur, and the health service and research set up in Sudan. As justified earlier, the level of details will be kept to the extent needed to understand the context that this project is using as a case study.

1.1 Sudan: Country in transition

1.1.1 Geopolitical and demographic overview

Sudan is a northern-east African country with a surface area of 1.8 million square kilometres and an estimated population of 36 million (Central Intelligence Agency, 2013).

Sudan has a rich tribal structure with an estimated 300 tribes and more than 100 indigenous spoken languages

(Abu-Manga, 2009), though Arabic and English are the official languages of the country (National Assembly and Sudan, 2005).

Since its independence from the joint Anglo-Egyptian colonial rule in 1956, it had been mostly ruled by military leaders who seized power by military coups from 1958-1964, 1969-1985, and from 1989 to date (BBC, 2015b). The latest military coup was led by Colonel (then Major General) Omar Al-Bashir who has been the president and the leader of the ruling National Congress Party (NCP) since then.



Figure 1-1 Political map of Sudan

He won elections for five-year presidential terms in 1996, 2000, 2010, and 2015, all of which involved allegations of corruption (James C., 1996; Abdelaziz, 2015).

Prior to independence, British colonisation attempted to keep the two peoples of the dominantly Arab Muslim north and the predominantly African polytheist south separate (Ibrahim, 2014). On independence, Sudan was administratively divided into five regions (central, eastern, western, northern, and southern), until the implementation of the federal system in 1991, when it was divided into 9 states. In 1994, the country was then administratively divided into 25 states, each of which has a governor, known as Wali, assigned by the president; a locally-elected legislative council; and a state's ministers' cabinet.

The number of Sudanese states has changed again after the separation of the 10 southern states as an independent state (see 1.1.4). This left the north (now the Republic of Sudan) with 15 states by the end of 2011. In 2012, the two states of East Darfur and Central Darfur were created, and in 2013 an additional state was created in Kordofan, bringing the total number of states (at the time of writing) to 18 (Central Intelligence Agency, 2013).

Each Sudanese state is divided into smaller administrative units, known as localities (Mahaliya), the number of which has changed with every change in the number of states. Currently, there are 134 localities, each of which includes various numbers of neighbourhoods, which have the so-called 'Neighbourhood Committees', also known as the People's Committees. These committees usually represent the community leaders of these neighbourhoods and have the authority to provide some local official authorizations. Additionally, in the rural areas, they

have roles related to allocation of local resources, like irrigation or fodder, and sometimes resolving conflicts and tribal disputes.

1.1.2 Developmental and health indicators:

Sudan shares some developmental and health indicators comparable to those of sub-Saharan Africa (SSA) (Table 1-1). Sudan is considered among the least developed countries, ranking 166th (out of 195) on the UN Human Development Index, with about 46.5% of the population living below the poverty line, earning less than US\$ 1 a day, while 8% are living in extreme poverty (Programme, 2014). Sudan's Transparency International Corruption Perceptions Index (CPI) has been extremely low, ranking 174th and 173rd (out of 175 countries) in 2013 and 2014, respectively, thus classified among the most corrupt countries in the world (Transparency International, 2015). Similarly, Sudan has ranked 177th (out of 190) in the Freedom of Press Score (Freedom House, 2015) and ranked 174th (out of 180) in the 2015 Reporters Without Borders press freedom index (Reporters Without Borders, 2015).

Table 1-1: Sudan's key health and developmental indicators

Indicator*	Value (2012, unless stated otherwise)		
	SSA	Sudan	Arab World
Health expenditure per capita (current US\$)	96.1	113.3	321.7
Health expenditure, total (% of GDP)	5.7	6.7	4.2
Life expectancy at birth, total (years)	56.4	61.9	69.9
Mortality rate, under-5 (per 1,000 live births) (2013)	92.9	76.3	40.2
Maternal mortality ratio (2013)	510	36	160
* SSA: Sub-Saharan Africa; GDP: Gross Domestic Product			

1.1.3 Natural disasters and armed conflicts

The climate in pre-separation Sudan along with other geopolitical factors was often blamed for natural disasters, mainly droughts and famines. The famine of 1984 is considered the most significant in Sudan's contemporary history for two reasons. First, it led to the demographic restructuring of Sudan when many affected people, especially from Darfur, left their region and moved towards Khartoum. Second, it was the first time that foreign humanitarian aid entered the country, mainly the United States Agency for International Development (USAID) through the so-called 'Operation Lifeline Sudan' (Ibrahim, 2014). The GoS established a governmental department to organise the foreign humanitarian aid, following the opening of an office for the World Food Program (WFP) for the first time (Mccarthy, 1986; Ibrahim, 2014). International humanitarian and non-governmental agencies have been increasingly working in Sudan since then.

1.1.4 Armed conflicts

Sudan has suffered from a continuum of violent conflicts, beginning before its independence in 1956. It witnessed two distinct civil wars between southern rebels and the consecutive governments in Khartoum. The first southern rebellion started in 1955 amid fears of the central and northern dominance of the independent state-to-be. This initiated a series of political and military events that made the southern rebellion grow, and it was not until 1972 that it temporarily ended with the Addis Ababa agreement that promised political autonomy for the South.

The second war started following another southern rebellion led by the late Dr John Garang, the leader of the main rebel group, Sudan People's Liberation Movement/Army (SPLM/A), in 1983. In 2005, the Comprehensive Peace Agreement (CPA) was signed ending this civil war and giving a semi-autonomous status to the 10 southern Sudanese states at that time with the right to self-determination in a referendum, which was held in January 2011 and led to the independence of the south and the formation of the Republic of South Sudan on 9 July 2011 (Central Intelligence Agency, 2013).

1.2 Darfur and other on-going armed conflicts: Overview

To understand the context which this project presents as a case-study, I will highlight Darfur's administrative structure and outline the nature and impact of armed conflicts on its population. Later, I will highlight examples of other on-going, smaller-scale conflicts in the southern areas of Kordofan and the Blue Nile.

1.2.1 Darfur: Demographic and conflict-related overview

The region of Darfur, west Sudan has a surface area of 510,888 square kilometres, an area equal to that of France, and its pre-conflict population was estimated to be 6.7 million (World Health Organization and Federal Ministry of Health, 2005b). The population in the region is mostly rural (about 80%), and about 25% of whom are nomads. Darfur's health and socio-demographic indicators are among the poorest in Sudan. For example, maternal mortality rate (MMR) in the three states of Darfur was between 178-335/100,000 live birth, infant mortality rate (IMR) ranged 58-64/1000 live birth, and literacy rates were as low as 16% (Health and Statistics, 2010; Abbas, 2012).

Since 2003 an armed conflict has been taking place in Darfur, mainly between the rebel groups (mostly non-Arabic-speaking tribes) and Sudan Armed Forces (SAF) or their allegedly allied militias, known as Janjaweed believed to be mostly from Arab tribes. Other conflicts have been taking place between and among the different rebel groups, and among different Arab tribes (Muthee, 2007).

Over the recent years, there was a shift in the nature of the armed conflicts in the region. They became mostly inter-tribal, especially among the Arab tribes themselves over disputes on resources, like the order of irrigating lands, or minor incidents, like accidentally killing cattle belonging to another tribe.

As a result, the UN estimated that 2.3 million Darfuri people were internally displaced within Sudan (Refugees and United Nations High Commissioner for, 2013), and hundreds of thousands had become refugees in Chad (over 300,000), Egypt (around 24,000) and other countries like Israel (about 1200) and Europe (Meffert and Marmar, 2009; Refugees' Rights, 2009). These figures change continuously depending on the situation on the ground. For example, the number of people in Darfur who were newly displaced due to insecurity in 2013 is three times higher than in 2012 and is more than in any single year since the height of the conflict in 2004 (UN Office for the Coordination of Humanitarian Affairs, 2014).

The IDPs within Darfur are usually gathered in camps, which have their own local administration and receive humanitarian aid from the international non-governmental organisations (INGOs) in their respective sectors, known as clusters (see subsection 1.2.4). As of August 2015, the UN estimates that over 2.55 million people remain displaced, among whom 51,000 were newly displaced people since

the beginning of 2015 (Figure 1-2) (UN Office for the Coordination of Humanitarian Affairs, 2015).

The conflict in Darfur has attracted the attention of the international community since 2004 and has led to an influx of about 100 INGOs working in Darfur (Valenciano *et al.*, 2004). The number of humanitarian workers in Darfur grew from more than 10,000 (of which more than 900 were international) in 2005 to 17,100 in 2008 then dropped to 12,658 aid workers following the expulsion of 13 INGOs. The UN agencies reported that only 6,850 aid workers in INGOs remain in Darfur, as of 30 November 2013 (UN Office for the Coordination of Humanitarian Affairs, 2014).

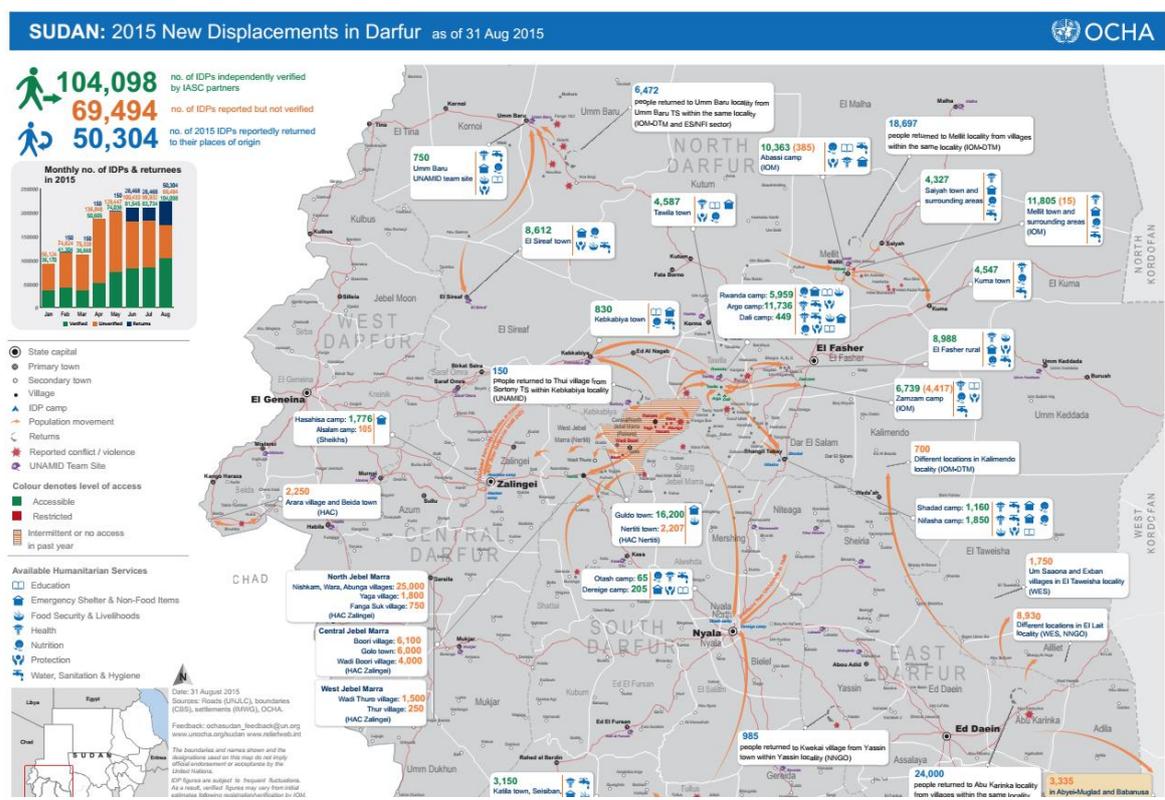


Figure 1-2 2015 New Displacements in Darfur as of 31 August 2015 (OCHA, 2015b)

As part of their work, the humanitarian aid agencies undertake several activities that involve the collection of personal data and/or biological samples (hereafter referred to as biosamples) from those affected by the conflict, mostly in the form of household surveys and needs' assessments. These surveys aim to assess the humanitarian impact of the conflict by looking for a multitude of epidemiological indicators, like morbidity, mortality, and malnutrition. The Complex Emergency Database (CEDAT) recorded more than 800 mortality, nutrition, and vaccination surveys that were undertaken in Darfur between 2004 and 2012 (CEDAT, 2013). Degomme has estimated that the surveys that were undertaken in Darfur between 2003 and 2008 included more than 56,000 households, more than 100,000 children and more than 130,000 adults (Degomme and Guha-Sapir, 2010).

Apart from the humanitarian-related objectives of these studies, some results were also politically and legally significant. For instance, the conclusion of the WHO's Crude Mortality Survey (CMS) in 2004 (Morgan *et al.*, 2004) that the mortality rates in Darfur's conflict exceeded the emergency threshold were cited as baseline evidence for further claims of genocide (US Department of State, 2004; Hagan, Raymond-Richmond and Parker, 2005; Straus, 2005).

There were also several studies of violence-related mortality and gender-based violence (GBV) in Darfur (Depoortere *et al.*, 2004; Woodruff and Kaiser, 2004; Hagan and Palloni, 2006), and these were used, *inter alia*, by the UN Security Council (UNSC) to issue a number of resolutions under Chapter VII of the UN Charter, the most significant of which is the UNSC Resolution 1593, in which,

“the Security Council decided to refer the situation prevailing in Darfur to [...] the International Criminal Court (ICC).” (United Nations Security Council, 2005)

Later, on 4th of March 2008, Al-Bashir became the first president in power to be issued a Warrant of Arrest (WoA) (The International Criminal Court, 2009) by the ICC, which was blamed by the GoS for the INGOs’ activities and studies.

1.2.2 Other armed conflicts (besides Darfur):

Before concluding this part of the chapter, it is worth noting that there are other foci of smaller scale armed conflicts in the southern areas of Kordofan and Blue Nile between the government and the so-called SPLM-North (SPLM-N). The GoS repeatedly accused the southern Sudanese government of providing a haven for the SPLM-N militias. Since July 2011, the Nuba Mountains in South Kordofan have also witnessed rebel attacks against the GoS, which was accused of marginalising the people of the region and denying them their basic rights.

1.2.3 Who is doing what in Darfur?

There are 5 categories of humanitarian-related stakeholders in Darfur, which also represent the categories of participants (Table 1-2).

Table 1-2: Categories and roles of humanitarian-related players in Darfur

Categories, subcategories, and examples	Main roles			
	Service providers	Coordination	Oversight	Other
Governmental (Federal & States) ⁴				
HAC			X	
Line ministries and governmental departments	X	X		

⁴ Each of which has both federal and state entities; the federal entities work with the HQs of the humanitarian agencies in Khartoum, and coordinate with their state counterparts.

Categories, subcategories, and examples	Main roles			
	Service providers	Coordination	Oversight	Other
Military authorities (NISS, SAF, RRFs)				X
United Nations/ African Union				
FAO	X	X		
OCHA	X	X	X	
UNAMID	X			X
UNDP	X	X		
UNDSS				X
UNFPA	X			
UNHCR	X	X		
UNICEF	X	X		
UNJLC		X		X
WFP	X	X		
WHO	X	X		
International Organisations				
Bilateral organisations (IOM and IFRC)	X	X		
INGOs				
Countries' Red Cross/Crescents	X			
Countries' MSF, OXFAM, etc.	X			
Other INGOs	X			
NNGOs	X			
Local communities' committees	X			
Armed (rebel) groups		X		X
<p>FAO: UN Food and Agriculture Organization, ICRC: International Committee of the Red Cross, INGO: International Non-Governmental Organisation, IOM: International Organisation for Migration, MSF: Médecins Sans Frontières, NGOs⁵: Non-governmental organisations, NISS: National Intelligence and Security Services, NNGO: National Non-Governmental Organisation, SAF: Sudan Armed Forces, RRFs: Rapid Response Forces, HAC: Humanitarian Aid Commission, OCHA: Office for the Coordination of Humanitarian Affairs, UNAMID: United Nations African Mission In Darfur, UNDP: United Nations Development Programme, UNDSS: United Nations Department of Safety & Security, UNFPA: United Nations Population Fund, UNHCR: United Nations High Commissioner for Refugees, UNICEF: United Nations Children's Fund, UNJLC: United Nations Joint Logistics Center, WASH: Water, Sanitation, and Hygiene, WFP: World Food Programme, WHO: World Health Organisation</p>				

⁵ If not specified as national or international, then it indicates both.

Though the categorisation in the above table has been stable since the beginning of the humanitarian intervention in Darfur, the players within each category have been subject to constant change. For instance, the number of INGOs and humanitarian workers has changed, either due to budget constraints, the inaccessibility of some areas or due to tensions with the GoS. These tensions resulted in the expulsion of 13 INGOs in 2009 (Wakabi, 2009), in senior UN officials being asked to leave in 2014, and in the suspension of the ICRC's activities in Sudan in February 2015 (BBC, 2015a). In early 2015, the government asked the UN African Mission in Darfur (UNAMID) to leave the country (Alnugomi, Charbonneau and Nebehay, 2014).

Most of the basic services in Darfur are provided by the UN specialised agencies and their national and international partner organisations. For example, as of March 2015, less than half of the health facilities in Darfur were fully managed by the SMOH; the NGOs ran and supported approximately 47% of them (World Health Organization and Federal Ministry of Health, 2015).

The NNGOs are under-resourced and lack much of the technical capacity needed to perform the humanitarian work. An assessment of the Civil Society Organisations (CSOs) in Darfur has suggested that they are small in size, tribally- or geographically-oriented, politically polarised, and donor-dependent (Partners in Development Services, 2010).

1.2.4 The Cluster Approach to humanitarian coordination

The humanitarian intervention in Darfur, among other UN-led humanitarian missions globally, has been subject to many assessments and criticisms that were

reported elsewhere (Bellamy and Williams, 2006; Kahn and Lucchi, 2009; Daley, 2013; Jirouskova, 2014).

In response to these criticisms, the UN introduced the Cluster Approach to coordinate the humanitarian intervention. This was recommended in 2005 by an independent committee commissioned to assess the UN humanitarian system and was introduced in 2006 as part of the UN Humanitarian Reform in response to the weaknesses of the UN humanitarian system, particularly in Darfur (Office for the Coordination of Humanitarian Affairs *et al.*, 2005; Mcnamara, 2006).

In a humanitarian context, a cluster is “a group of agencies that gather to work together towards common objectives within a particular sector of emergency response”. Each cluster has a designated Cluster Lead (Figure 1-3 and Table 1-3), which is “an agency/organisation that formally commits to take on a leadership role within the international humanitarian community in a particular sector/area of activity, to ensure adequate response and high standards of predictability, accountability and partnership” (WHO, 2007).

Currently, the main role of these clusters is to coordinate the humanitarian interventions in a so-called “3 Ws” (who, where, when) approach, where each organisation within each cluster is responsible for specific services in a geographical sector.

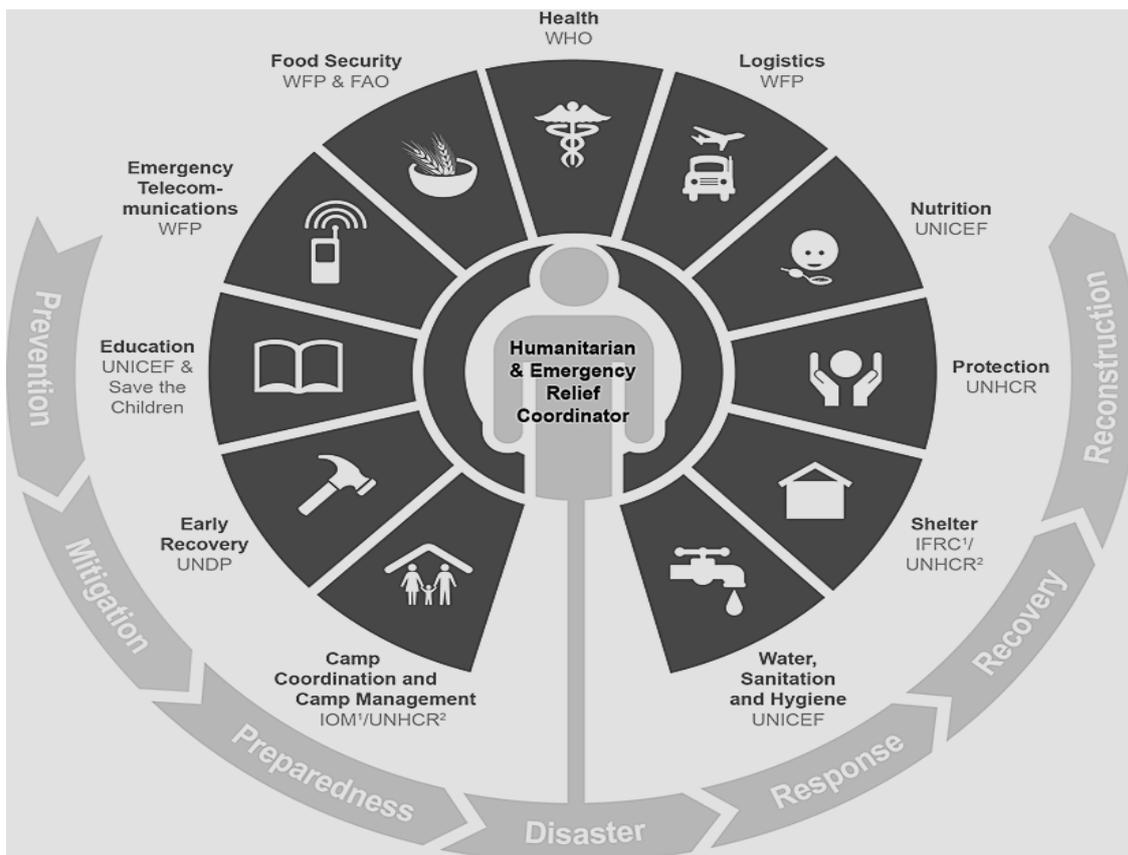


Figure 1-3: Global Cluster Leads (as of June 2012)

Source: IASC, URL:

http://reliefweb.int/sites/reliefweb.int/files/resources/map_2809.pdf

Table 1-3: Global Cluster Leads (United Nations Inter-Agency Standing Committee, 2006)

Sector or Area of Activity	Global Cluster Lead
Technical areas:	
1. Nutrition	UNICEF
2. Health	WHO
3. Water/Sanitation	UNICEF
4. Emergency Shelter:	UNHCR
	IFRC (Convener)*
Cross-cutting areas:	
5. Camp Coordination/ Management:	UNHCR IOM

Sector or Area of Activity	Global Cluster Lead
6. Protection:	UNHCR
	UNHCR/OHCHR/UNICEF
7. Early Recovery	UNDP
Common service areas:	
8. Logistics	WFP
9. Emergency Telecommunications	OCHA/UNICEF/WFP
<p>UNICEF: United Nations Children Fund, WHO: World Health Organisation, UNHCR: United Nations High Commissioner for Refugees, IFRC: International Federation of Red Cross, IOM: International Organisation for Migration, OHCHR: Office of the High Commissioner for Human Rights, UNDP: United Nations Development Program, WFP: World Food Programme, OCHA: United Nations Office for the Coordination of Humanitarian Affairs</p> <p>* IASC Principals agreed that, in cases of natural disaster, IFRC acts as a convener for Emergency Shelter (taking into account the IFRC's obligations and independence) (Office for the Coordination of Humanitarian Affairs, 2006). IFRC has committed to be a 'convener' rather than a 'cluster lead'. In an MOU between IFRC and OCHA, it was agreed that IFRC would not accept accountability obligations beyond those defined in its Constitutions. It has therefore not committed to being 'provider of last resort' nor is it accountable to any part of the UN system.</p>	

1.2.5 Health research in Sudan

1.2.5.1 Historical overview of research in Sudan

The aim of this subsection is to give a brief historical overview of health research and research governance in Sudan. This overview, in turn, aims to give a better contextual understanding of the views of those representing the research governance bodies (RGBs). This overview is also helpful to assess whether these views could be extended to other contexts that share similar research governance features beyond Sudan.

Health (medical) research in Sudan started as early as 1903 (Bayoumi, 1975). However, there was no entity clearly responsible for it, even after the establishment of the Ministry of Health in 1947. It was not until 1970 that the National Council for Research which included a Medical Research Council was established, as the first attempt to institutionalize research governance, which is “the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve research quality...” (Clinical Trials Research Governance, 2015).

Following the 1989 military coup, the entity responsible for health research within the Federal Ministry of Health (FMOH) went through a number of transitions⁶ (Table 1-4) (Abdur Rab and Mamdouh, 2004; Esayed *et al.*, 2007; Hussein, 2008). The impact of these transitions on the status quo and the future possible alternatives for ethical review are discussed later.

Table 1-4: Timeline of the landmark events in the progress of research governance in Sudan (1991 - 2015)

Year	Landmark event	Notes
1991	The National Council for Research became the National Research Centre and the sub-councils were renamed institutes.	
1996	Program of Health Systems Research was established	The objective was to provide information from non-clinical research to the different departments in FMOH
1997	The program became the Health System Research Unit	
1998	The Unit was upgraded into the	It was directly affiliated to the Under-secretary of the FMOH; and “became

⁶ Some of the notes and events were added from the interview with a representative of a research governance body, which are put between quotation marks “...”.

Year	Landmark event	Notes
	Research Directorate	responsible for formulating research policies and work-plans, following up their implementation, facilitating collaboration between health and related sectors and ensuring optimal use of resources available for health research. It is also responsible for setting priorities.” (RGB-1)
1999-2000	Setting of the National Research Priorities	With support from Council on Health Research and Development (COHRED), it carried out an extensive priority-setting exercise that included all the northern Sudanese states at the time
2000	Endorsement of the National Research Priorities	This was done at a national conference in September 2000
2002	The (re-)formation of the National Health Research Council (NHRC)	This was done by a ministerial decree; NHRC comprised two national committees: 1) the National Research Ethics Review Committee (NREC); and 2) the National Technical Review Committee.
	The Research Directorate became under the Directorate General of Health Planning and Policy	
2003	National Health Research System Mapping survey	This was done as part of a WHO-EMRO study to assess HRS in 5 EMRO countries.
2004	Cancellation of the old composition of the NHRC, and the establishment of the Council of Health Research	The ‘new’ council still had the same composition of NHRC, i.e. a national ethics committee, a national technical committee, with the addition of the Research Directorate as the Secretariat of the Council
2006	The issuance of the Regulations of the National Research Ethics Committee	NHRC began its regular meetings and had its subcommittees

Year	Landmark event	Notes
2007	The delegation of the technical and ethical review to local committees in states MOH, universities, and hospitals	Three ministerial resolutions were issued to delegate three entities to have their local research review committees: 1) the States, 2) the Federal hospitals; and 3) the research institutes
2008	Publication of the National Guidelines for Ethical Conduct of Research Involving Human Subjects	
	The Public Health Act was issued	It legalised the formation of the National Health Research Council and its committees and indicated that no research on humans should be conducted without ethical approval
2012	The Research Directorate became a Department under the Directorate of Health Economics and Information	
	The Public Health Act was enacted	
2015	Proposal to re-establish a national research council is submitted to the federal minister of health for discussion	
COHRED: Council on Health Research and Development; FMOH: Federal Ministry of Health; HRS: Health Research Systems; MOH: Ministry of Health; NHRC: National Health Research Council; NREC: National Research Ethics Committee; RGB: representative of research governance bodies (see 6.3); WHO-EMRO: World Health Organization – East Mediterranean Regional Office		

Currently, the Research Directorate at the FMOH is the health-related governance body responsible for research that involves humans, including the development of the National Guidelines for Ethical Conduct of Research Involving Human Subjects (National Ministry of Health, 2008). As far as the focus of this

project is concerned, the guidelines do not provide any specific guidance for epidemiological or sociological studies. There are only some references to research on vulnerable populations and the possible social risk of some studies.

1.2.5.2 Legal aspects of research governance

Legally, health research in Sudan is governed through two Acts: The Public Health Act (2008, enacted in 2012) and the Medicines and Poisons Act (2009). In regard to experimentation on humans, the Public Health Act empowers the Health Research Council to “oversee the medical research conducted on humans and assure their accordance with the professional ethics” [Public Health Act (2008)], while the Medicines and Poisons Act states that “no one can conduct any trial for any pharmaceutical product or medicine except with the approval of the [National Medicines and Poisons] Board” [Drugs and Poisons Act (2009)].

Clinical trials are one of the three categories of research that have to be reviewed by the NREC, in addition to externally-funded research and studies done in more than one state (Government of Sudan, 2008). Any research category apart from these three can be reviewed by a local (state or university) research ethics committee.

1.2.5.3 Comparison of research and humanitarian governance systems

The Research Ethics Review Bodies (RERBs) seem to be the mainstream mechanism through which the ethical oversight of research is thought to be achieved. These bodies work in accordance with regulatory documents (e.g. guidelines and application forms) and are given the regulatory authority to review the scientific and ethical aspects of research. For example, the “Common Rule” requires that research must be reviewed and approved by an IRB (U.S.

Department of Health and Human Services and Office for Human Research Protections, 2009) before being conducted, and the EU has a similar requirement (European Commission, 2015). The RERBs should also have clear functions and responsibilities, including providing guidance, education and assistance to researchers and other research-related stakeholders, as well as monitoring on-going research to maintain the public's trust in science and scientific research.

However, among all these functions, the focus seems to be on ethical review, where researchers submit their research proposals to the RERBs that have the authority to approve, reject or require amendments to the submitted proposal "to ensure that they conform to internationally and locally accepted ethical guidelines" (World Health Organization, 2009). Despite the variation in the RERBs' powers, remits and agendas, these bodies share the mandate to ensure the proposed research's ethical acceptability as measured against the principles stated in their respective guidelines.

Their roles also include "safeguarding the rights, safety, and well-being of the research subjects" (Council for International Organizations of Medical Sciences and World Health Organization, 2002) and to "take into account potential risks and benefits for the community in which the research will be carried out" (World Health Organization, 2009). The RERBs should be independent, multi-disciplinary, multi-sectoral, and pluralistic in nature to ensure the broadest possible coverage of protection for potential research participants (World Health Organization, 2000).

Before ending this chapter, an important comparison between the two governance systems that regulate the activities under study in this thesis must be

made. These are the humanitarian governance bodies that regulate humanitarian activities and the research governance bodies that regulate research activities in the country, including the conflict-affected areas. This comparison will help in understanding the views expressed by the representatives of each system, as reported in the results of the empirical project.

Table 1-5 outlines the governance frameworks which regulate research and humanitarian activities. It also shows that the humanitarian governance bodies (HGBs) have more legal power over humanitarian activities compared to the regulatory power that the research governance bodies (RGBs) have over research.

Table 1-5: The governance frameworks regulating research and humanitarian activities in Sudan

Field	Governance body	Affiliations	Areas of oversight	Guiding law	Regulatory documents & bylaws
Health Research	Health Research Council: - Technical Review Committee - Ethical Review Committee - Research Directorate	Federal Ministry of Health (FMOH) ⁷	Reviews: multi-state studies; externally funded; clinical trials ⁸	Public Health Act (2008)	<ul style="list-style-type: none"> • National Research Ethics Guidelines • Standard Operating Procedures (SOPs)
	National Medicines & Poisons Board	FMOH	Reviews animal experimentation; & drugs clinical trials	Medicines & Poisons Acts (2009)	Under formulation
	Universities	Ministry of Higher Education	Studies done by its affiliated staff or students		<ul style="list-style-type: none"> • National Research Ethics Guidelines • Research Ethics Committee Standard Operating Procedures
	Hospitals	State Ministry of Health ⁹	studies done by its affiliated staff		<ul style="list-style-type: none"> • National Research Ethics Guidelines

⁷ By law, these bodies are 'independent' bodies but practically they are run by the FMOH staff and hosted in its buildings.

⁸ Oversight of clinical trials is overlapping with the same role given to the National Medical Poisons Board (NMPB)

⁹ There were 17 hospitals, the biggest in the country, which were affiliated to the Federal Ministry of Health until 2011, when a presidential decree to affiliate them to the states in which they exist. Most of them were in Khartoum. The fate of these hospital RECs is not clear. No REC was established in any Darfur state.

Field	Governance body	Affiliations	Areas of oversight	Guiding law	Regulatory documents & bylaws
			or trainees		<ul style="list-style-type: none"> • Research Ethics Committee Standard Operating Procedures (SOPs), if present
Humanitarian	Humanitarian Aid Commission: - Federal HAC - States HAC	Ministry of Welfare & Social Security	Humanitarian activities in any state of Sudan	Voluntary and Humanitarian Work (Organisations) Act that replaced the preceding Humanitarian Aid Commission Act (1996)	<ul style="list-style-type: none"> • Sudanese Voluntary and Humanitarian Work Act 2006 • Directives for Humanitarian Work 2015 • Country Agreement between Government of Sudan (GoS) and International Non-Governmental Organisations (INGOs) Operating in Sudan¹⁰ • Unified Guide to humanitarian work, aka the General Directory of Procedures (2007)¹¹ • Additional international documents¹²

¹⁰ http://hac.gov.sd/picture_library/report/Last%20Country%20Agreement.pdf

¹¹ http://www.hac.gov.sd/picture_library/report/Unified%20guide%20procedure.pdf

¹² For example, the Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I), 8 June 1977 (http://hac.gov.sd/picture_library/report/Protocol%20Additional%20to%20Geneva%20Conventions.pdf) and the Convention (I) for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field. Geneva, 12 August 1949 (http://hac.gov.sd/picture_library/report/Geneva%20Convention_E.pdf)

1.3 Aim and objectives

The overall goal of this project is to study the ethical considerations that were encountered during the ethical review, the actual undertaking of, and participation in the health-related research activities in order to achieve the goal of answering the project's research questions. Accordingly, the objectives of the thesis are:

- 1- To outline the international and Sudan's national¹³ ethics guidelines and governance models for health research involving humans, with a focus on humanitarian settings. This is achieved through a critical review of the literature on research ethics and humanitarian ethics.
- 2- To explore the reporting of the ethical considerations related to the studies conducted during the conflict in Darfur. This is achieved through a two-phase systematic review of eligible studies that mention two of these considerations: ethical review and informed consent. The first phase included the reports publicly available online, while the second phase involved a hand search of the hardcopies of the reports of eligible studies. These hardcopies are archived in the Centre for Research on the Epidemiology of Disasters (CRED) in Brussels.
- 3- To assess whether research conducted in the context of the conflict adhered to the national and international research ethics guidelines and governance regulations. This is achieved by conducting an empirical qualitative study in Sudan involving interviews and focus groups with the relevant stakeholders.

¹³ Any reference to 'national' guidelines refers to the Sudanese guidelines, unless stated otherwise.

1.4 Research questions

The project aims to answer one overall question. It also addresses two empirical sub-questions and one central normative sub-question.

The overall research question is: How ought 'research' to be ethically undertaken during armed conflicts? This question is discussed with a focus on the case study of Darfur, western Sudan (2004–2012). The answer to this question is sought mainly through a review of the relevant literature and an empirical bioethics project that uses qualitative methods to formulate the key arguments and conclusions of this project.

The empirical research questions are:

1. What were the ethical issues encountered and reported during the undertaking of research involving humans in Darfur during the study period?
2. What ethical standards and procedures were used to provide guidance and oversight for research undertaken in Darfur during the study period?

The central normative research question is: What ethical standards and procedures ought to guide research that involves humans in situations of armed conflict?

It should be noted here that what constitutes "research" is one of the issues discussed in this project. Due to the lack of an agreed-upon definition, I use this

term conservatively. In the next chapter I propose a working definition, which is critiqued later in the discussion.

Summary points

- This chapter aimed to set the socio-political stage for the study area of the thesis, which is essential to understanding the selection of the participants and to contextualising the study's findings and discussion.
- Sudan has suffered a series of natural disasters and armed conflicts, including the conflict in Darfur which has been ongoing since 2003, along with other potential conflicts in other parts of Sudan.
- As a result, Sudan hosts a wide range of humanitarian actors, mostly UN specialised agencies and INGOs, which are the de facto providers of many basic services in most of the conflict-affected regions.
- The relations between the GoS and the humanitarian actors are not stable and are often tense.
- The health research governance bodies have been subject to a succession of changes in their structures and affiliations. They are also less powerful than the humanitarian governance bodies.

2 CHAPTER TWO: CONCEPTS AND TERMS USED IN THIS THESIS

The previous chapter outlined the geopolitical context of the study. This chapter completes the contextual background of the project by introducing the main concepts and terms used in this thesis.

Two main concepts need to be explained before exploring the ethical issues related to health research involving humans during armed conflicts. These concepts are ‘health research involving humans’ (hereafter referred to as “research”); and ‘disasters, with a focus on armed conflicts’. As these concepts may be understood differently in different settings, it is important to clarify what they mean in this thesis.

In providing this clarification, I present the various ways in which these concepts are approached in the relevant literature, with a focus on “research”. I then introduce the working definition of “research” used in the thesis.

2.1 Definition of ‘health research involving human participants’

Defining “research” is a controversial yet essential starting point, as it must be clarified which activities this thesis addresses. The controversy arises because of the various definitions and uses of the term “research” within the health-related domain. I approach this variability in three stages.

First, I briefly summarise some of the definitions of “research” in the main international and national research ethics guidelines, focusing on three necessary conditions that are usually used to define “research”. Second, I present and critique the working definition of “research” used in this thesis. Lastly, I select

some ethically relevant characteristics to be used to classify an activity as “research” and then argue that these characteristics as more appropriate indicators to identify “research” as far as the ethical oversight of research is concerned.

2.1.1 Characterisations of “research” in mainstream research ethics guidelines

According to Swartz (2010), “a 'proper' intentional definition states in the *definiens* (i.e. the word or phrase that defines) the logically necessary and sufficient conditions for the application of the *definiendum* (i.e. what is being defined)”. If we apply this criterion to the definition of “research”, then those who define the term should specify all the necessary and sufficient conditions required to conclude that a specific activity is a research activity.

A comprehensive list of definitions of “research” should ideally be compiled by means of a systematic review of the (preferably qualitative) literature, with clear search strategies that are used by more than one reviewer. A relevant example that was published after the completion of this project¹⁴ is the systematic qualitative review of ethical guidelines done by Mezinska et al. (2016) to “systematically and qualitatively review the existing ethical guidelines for disaster research” (Mezinska *et al.*, 2016).

Although a review similar to that of Mezinska et al. (2016) would have added a more comprehensive approach to the definition of “research”, I believe the lack thereof does not necessarily imply a lack of depth or systematicity. Such a broad

¹⁴ I came across it while doing the corrections needed by the examiners following the viva.

review is useful in exploring various aspects of a body of literature (as I have done in the systematic review in a later phase of this project) and not a single concept, which in this case is the definition of “research”. In the initial (mostly exploratory) phase of the project, this task would have expanded the scope of the project beyond the preliminary task of defining the term “research”.

Moreover, the term was defined at an early stage of the project as an intermediate step and not as an objective per se. Therefore, extensive elaboration on these definitions of “research” would not have contributed to answering the project’s questions and would in that sense have been an unnecessary distraction from the project’s objectives.

Nonetheless, I tried to make the search for the definition of “research” in the research ethics guidelines as systematic as possible through three main steps. First, I matched the guidelines I included in this review with the stakeholders involved in this project. To explain, this project involved three main categories of participants, which include the governmental bodies responsible for the oversight of studies that involve humans, the organizations that plan for and conduct these studies, and the individual researchers.

To understand how this project’s participants perceived “research”, their respective guidelines seem an appropriate reference point. It is expected that these guidelines influence, if not fully represent, what they consider as “research”. Accordingly, the documents included in the search were the guidelines developed by the WHO as the lead of the health cluster (Subsection 1.2.4), the national guidelines for research ethics, and the international research ethics guidelines.

Second, as international research guidelines may not be specific enough, I confined myself to the list of international guidelines in the International Compilation of Human Research Standards, hereafter referred to as “the compilation”. This list is compiled by the Office for Human Research Protections at the U.S. Department of Health and Human Services. The compilation was chosen as it has been annually updated since 2010. In addition, the codes and guidance are identified and selected by more than 70 contributing experts and list over 1,000 laws, regulations, and guidelines on human subjects protections from more than 100 countries and from many international organizations (Department of Health and Human Services, 2012b). For each country, there is a list of its key organizations, legislation, regulations and guidelines. This makes this compilation a reliable and comprehensive list of research guidelines and related regulations.

Third, as the compilation is divided into two main parts—the International Guidelines, followed by each country’s list of documents—I have confined myself to its first section. The International Guidelines section is further sub-divided into the following subsections: General, Drugs and Devices, Research Injury, Protection, Genetic Research, Embryos, Stem Cells, and Cloning, Human Biological Materials, and Privacy/Data (Table 2-1). I included the guidelines listed under the ‘General’ section, which includes the guidelines that are applicable to almost any type of research. The guidelines mentioned in the specialized subsections were excluded. The guidelines listed in the other sections have been excluded because they are too specialized and refer to kinds of studies that are seldom used in a humanitarian setting. Each eligible guideline is included once. If

the document is repeated under other subsections of the compilation, the duplicate is excluded.

Following the international guidelines mentioned in the compilation, I present other guidelines, which are widely considered as key documents in research ethics literature along with the national research ethics guidelines of Sudan.

Table 2-1 International research guidelines listed in the International Compilation of Human Research Standards (Department of Health and Human Services and Services, 2012)

Guidelines	Definition of research, if present
General	
WHO: Operational Guidelines for Ethics Committees that Review Biomedical Research (2000)	“[...] biomedical research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records, and biological samples, as well as epidemiological, social, and psychological investigations” (World Health Organization, 2000, p. v).
International Guidelines for Ethical Review of Epidemiological Studies (2009)	“[...] involving activities that are designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference” (Council for International Organizations of Medical Sciences, 2008, p. 7).
WHO: Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants	“This document has been developed for individuals and organizations involved in health-related research with human participants, including biomedical, behavioural, social science, and epidemiological research (throughout this document, the term

Guidelines	Definition of research, if present
	“research” is meant to include, and refers to, all of these domains)” (World Health Organization, 2011).
WHO: Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002)	“Any proposal relating to human subjects including healthy volunteers that cannot be considered as an element of accepted clinical management or public health practice and that involves either (i) physical or psychological intervention or observation, or (ii) collection, storage and dissemination of information relating to individuals” (World Health Organization, 1996, p. 3).
Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)	No specific definition
Research ethics committees: basic concepts for capacity-building (WHO, 2009)	<p>“[A]ny social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings:</p> <ul style="list-style-type: none"> • are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment; or • become individually identifiable through investigator’s collection, preparation, or use of biological material or medical or other records” (World Health Organization, 2009, p. 7).
UNAIDS: Ethical Considerations in Biomedical HIV Prevention Trials (2007)	No specific definition

Guidelines	Definition of research, if present
<p>WMA: Declaration of Helsinki (2008)</p>	<p>No clear definition. Two articles make reference to “research”:</p> <p>“Medical research involving human subjects includes research on identifiable human material or identifiable data” (Article 1).</p> <p>“The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments)” (Article 6).</p>
<p>ICH: E6 Good Clinical Practice: Consolidated Guidance (1996)</p>	<p>“1.12 Clinical Trial/Study:</p> <p>Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy” (International Conference on Harmonization, 1996, p. 7).</p>
<p>Devices</p>	
<p>GHTF: SG5/N2R8: 2007 Clinical Evaluation SG5(WD)/N3R6: 2007 Clinical Investigations GHTF SG5/N1R8: 2007 Clinical Evidence – Key Definitions and Concepts</p>	<p>The three guidelines adopt the same definition of Clinical Investigation:</p> <p>“Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device”; “This term is synonymous with ‘clinical trial’ and ‘clinical study’” (Global Harmonization Task Force,</p>

Guidelines	Definition of research, if present
	2007, p. 7).
<i>Privacy/Data Protection</i>	
Declaration on Ethical Considerations Regarding Health Databases (2002)	“the collection, storage and use of identifiable data and biological material beyond the individual care of patients” (World Medical Association (WMA), 2002).
<i>Human Biological Materials</i>	
WHO: Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003)	There is no specific definition of research, but it is indicated that “Clinical research frequently involves, and in many cases depends on, the use of human tissues, cells and fluids, including sperm, eggs, blood, urine and saliva” (World Health Organisation, 2003, p. 1).

In addition to the list provided in the international section of the compilation, there are other commonly cited research ethics documents that I highlight. These documents are the Belmont Report (US), the Tri-Council Policy Statement (TCPS2) (Canada) and the Research Governance Framework for Health and Social Care (UK). Indeed, this list is not inclusive; it may not be representative of the global research guidance documents, and it is not meant to be. The aim of exploring these documents is to include additional views that may not have been well covered in the documents in the international section of the compilation.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The National Commission for the Protection of Human Subjects, 1979) defined research involving human subjects as:

“[...] well-designed and critical investigations of therapeutic techniques with unknown efficacy and/or risks or an attempt to find the aetiology of a disease having for its aim the discovery of new facts associated with the accepted and routine practice of medicine” (The National Commission for the Protection of Human Subjects, 1979, pp. 13–14)

Also in the US, the ‘Common Rule’ (45 CFR Part 46) defines it as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (U.S. Department of Health and Human Services and Office for Human Research Protections, 2009, p. 4)

In Canada, the Tri-Council Policy Statement (TCPS 2, 2014) defines “research involving humans” as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation” (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014, p. 209).

In the UK, the Research Governance Framework for Health and Social Care defines “research” as “the attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods, including studies that aim to generate hypotheses as well as studies that aim to test them” (Department of Health, 2001) All three of these qualifying statements must be fulfilled to classify as an activity as “research”.

Finally, in Sudan, the Guidelines for Ethical Conduct of Research Involving Human Subjects (2008) state that “the term “research” refers to a class of activity

designed to develop or contribute to general knowledge. General knowledge consists of theories, principles, or relationships, or the accumulation of information on which they are based” and “any social science, biomedical, behavioural or epidemiological act that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings are involved” (National Ministry of Health, 2008, p. 3)

Before critiquing the definitions provided in the reviewed guiding documents, the limitations of this review should be highlighted. As mentioned earlier, the included guidelines were not part of a full-range systematic review. Hence, I could have missed one or more definitions of “research” in a document that was not included in the search. Second, given the reliance on one main list, the conclusions of other reviewers might differ from mine if a comprehensive qualitative systematic review were conducted. Nevertheless, the abovementioned definitions represent a sample which, although not exhaustive, is reflective of how most of the international research ethics guidelines approach the term “research”. A comprehensive qualitative systematic review of how international research regulatory documents define “research” is recommended for future work.

Despite the differences in wording and emphasis in the above definitions, four main recurring features are systematically used to characterise “research”:

- 1- It is systematically conducted;
- 2- It generates knowledge that can be applied beyond those from whom the data were collected;

- 3- It is experimental, i.e. it includes some deviation from common practice to test either the current practice or the experimental one; and
- 4- It involves humans, mainly in the form of their personal or health-related data or biosamples.

In the remainder of this subsection, I outline why these conditions are not jointly sufficient to define “research” in humanitarian settings such as conflict zones.

As a systematic enquiry, “research” entails using rigorous methods for the systematic collection, analysis and interpretation of data. Through the use of systematic methods, the outcome of this activity is made reliable, credible, and cost-effective. However, the use of rigorous methods is not specific to “research”. Most professional activities that entail the collection and/or analysis of data should be systematic. In humanitarian contexts, these systematic enquiries are also a part of many activities, such as clinical care (as in taking medical history), surveillance, or in relation to logistical requirements, such as assessing vaccine coverage to estimate the necessary vaccine stock.

Second, though commonly cited, the condition of generating *new* knowledge seems problematic, as it is not clear when to describe a piece of knowledge as “new”. Researchers expect to contribute to the body of knowledge in their field. This contribution is measured against what is already known about their area of study. In a humanitarian context, there are many occasions where the demarcation between existing investigations and treatments provided to patients

and research done on the same persons to develop new/advanced treatments or investigations becomes blurred (Hunt, Anderson and Boulanger, 2011).

Generalization of the produced knowledge is defined by Polit and Beck (2010) as “an act of reasoning that involves drawing broad conclusions from particular instances—that is, making an inference about the unobserved based on the observed” (Polit and Beck, 2010, p. 1451). In humanitarian contexts, most systematic enquiries are conducted for local organisational or humanitarian purposes focused on a local population in a specific area and so are not readily generalizable beyond this population. Nevertheless, these findings may be used to make the humanitarian interventions evidence-informed (Gerdin *et al.*, 2014; O’Mathúna, 2015). For example, the CRED has an online database of mortality and malnutrition rates, the Complex Emergency Database (CE-DAT), which has more than 3,000 surveys involving populations affected by complex emergencies globally (CEDAT, 2013). The humanitarian intervention studies have also been reviewed to assess the evidence base that informs humanitarian public health programming globally (Clarke *et al.*, 2014).

Lastly, some of the definitions emphasise the experimental nature of “research”, i.e. the use of novel or non-standard methods in comparison to standard health care or services. This emphasis relies on the assumption that routine healthcare follows well-established procedures, usually by following clinical guidelines.

Such a clear distinction between experimental and standard care is difficult to establish, whether in clinical or public health interventions. Clinically, many

surgical practices are experimental, innovative and validated mainly by experience (Bernstein and Bampoe, 2004; Stirrat, 2004; Willis-Owen, 2009; Rogers *et al.*, 2014; Schwartz, 2014). These innovations are often subject to self-regulation (Hunt *et al.*, 2016) rather than to formal ethical review, as is the case with “research”. For other clinical disciplines, there is evidence of wide variation in adherence to evidence-based clinical guidelines, which are supposed to serve as the benchmark to standardise care (Greenhalgh *et al.*, 2014).

In humanitarian contexts, due to their complexity, the humanitarian sector has adopted various decision-making models (Darcy *et al.*, 2013). There have been some efforts to standardise humanitarian practice, such as the SPHERE Project, which aims to introduce considerations of quality and accountability into the humanitarian response (Sphere Project, 2011). As for clinical guidelines, the humanitarian-related guidelines like those of the SPHERE Project, UNICEF and the WHO are interpreted and implemented in different ways, whether in terms of the outbreak thresholds, i.e. the number of cases needed to declare an outbreak of a given disease; surveillance methods; diagnostic tools; or treatment modalities (Seal and Kerac, 2007; Brown *et al.*, 2008; Bilukha *et al.*, 2012; Bhutta *et al.*, 2013).

In the following sub-section, I present a different approach to thinking about “research” in a humanitarian context that draws from the idea of operational research (OR).

2.1.2 Operational Research (OR) as an alternative approach to defining “research” in the humanitarian context

The reason to pursue another avenue in defining “research” in relation to this project is the lack of obvious reference to specific humanitarian activities in the mainstream research guidelines. Some humanitarian activities could fit within the mainstream definition of “research”, such as a clinical trial to test a new vaccine for the Ebola virus (Rid and Emanuel, 2014). However, conducting clinical trials is not common in conflict settings, either because of the lack of facilities, the difficulty of maintaining a strictly controlled environment (Ford, 2009), or simply because the questions raised in humanitarian situations are best answered by other research designs.

More commonly, activities central to the humanitarian setting are more difficult to categorise as “research”, such as when the collection of personal data and/or biosamples is done as a part of planning, managing, or providing a humanitarian service. Here, the utility of the mainstream research ethics guidelines becomes questionable, because these activities share some features of “research” but not others. For example, these activities include a systemic collection of data that are later analysed and utilized. Nevertheless, unlike pure research, the humanitarian workers can use the collected data for other short-term, mission-specific, and organisation-oriented purposes.

I have thus chosen to look at other specific approaches to “research” which seem relevant to humanitarian situations, such as Operational Research (OR). Operational Research is defined as “research into strategies, interventions, tools

or knowledge which enhance programme effectiveness” (Harries, 2003, p. 146) by “applying advanced analytical methods, including mathematical models, to help make better decisions” (Zachariah *et al.*, 2009, p. 711).

The OR approach is relevant to the humanitarian context because the interventions conducted are implemented within programs and operations. Zachariah *et al.* (2010) suggest that OR is relevant to NGOs in humanitarian contexts for three reasons: “(i) to improve effectiveness of interventions, (ii) to assess the feasibility of implementing new models of care, and (iii) to gather evidence to support advocacy for health policy change” (Zachariah *et al.*, 2010, p. 2). Unlike clinical research, OR assesses effectiveness within settings outside of the (complete) control of the researchers. Taking these factors into consideration, MSF, for example, has adopted an OR approach in its Operational Research Policy Framework and its ethical guidance document, the Research Ethics Framework (MSF Ethics Review Board, 2013a).

The MSF’s guidelines describe OR in the humanitarian sector as “the search for knowledge on interventions, strategies or tools that can enhance the quality, effectiveness or coverage of programmes in which the research is being conducted” (Zachariah *et al.*, 2010, p. 2).

In conclusion, it is not possible to adopt one definition or approach to “research”. While mainstream research ethics guidelines focus on clinical and quasi-clinical research models, the humanitarian sector often focuses on the OR model. Both models exist in the humanitarian setting, and thus both approaches are under study in this project.

2.2 A working definition of “research”

A working definition of “research” in this thesis is needed to define the conceptual boundaries of what this project aims to study. To this end, I have tried to consider the features of “research” shared by the mainstream guidelines and OR.

My working definition of health research involving humans in Darfur, hereafter referred to as “research”, refers to any health-related intervention that involves the systematic collection of human personal data and/or biosamples from the people of Darfur affected by the on-going conflict, not solely for the clinical benefit of a patient.

At this stage, I outline an initial justification for selecting the two criteria of collecting personal data and/or biosamples as the defining features of “research”. This is followed by a critique of this initial definition.

At the beginning of the project, neither the mapping of the humanitarian activities nor the presence (or absence) of ethical oversight mechanisms in Darfur was clear. Therefore, I tried to make the definition as inclusive of as many humanitarian activities as possible.

Second, the collection of data and/or biosamples is a common feature in the definition of “research”, so no activity can be called “research” if it does not include the collection of data and/or samples, although not all data collection activities are considered “research”.

Here, I need to acknowledge that the choice of these two features was also based on an initial conceptual position, which I later changed after conducting the empirical project in Sudan. Initially, I assumed the presence of a conceptual barrier between the researchers in Darfur and ethical review. By this, I mean that researchers in conflict settings do not submit their planned data/biosample collection activities for ethical review, because these activities do not fit within their understanding of what “research” is. I then tried to make the working definition broader than this assumed narrow scope of “research”, so I aimed at as inclusive a definition of “research” as possible.

Such a position assumes that all kinds of data/biosample collection are ethically equivalent when they are not. Obviously, the collection of biosamples, especially blood, is associated with more potential harm than completing questionnaires, for example, and therefore apparently warrants greater precautions. Moreover, the selected features referred to a point that is difficult to define, which is related to the sole purpose of clinically benefitting a specific patient. Generally, it would be expected that some clinical practices in humanitarian settings may not follow the standard practice used elsewhere and would be likely to include extra interventions, which may be similar to research. The demarcation point, though, is that whatever ‘innovative’ intervention the practitioner does will always remain with this specific patient treated at the time of the innovation and not as a large-scale trial. The latter approach would fall under any possible definition of “research”. In addition, if the “extra” intervention occurs and turns out to be potentially harmful with no clinical benefit or no benefit to

patients, the central ethical point will shift from research ethics to the humanitarian clinical ethics arena.

Nevertheless, the use of this definition did not affect the overall validity of the findings, because it was mainly used to help the project's participants understand what I was referring to when I used the term "research". More importantly, the participants were asked for their views on what counts as "research" in the humanitarian context. Their views are thoroughly reported and discussed later (in the Results and Discussion sections, respectively).

2.3 Disasters and armed conflicts

2.3.1 Disaster

The United Nations' Department of Humanitarian Affairs (DHA) defines a disaster as:

"A serious disruption of the functioning of society, causing widespread human, material or environmental losses which exceed the ability of affected society to cope using only its own resources" (United Nations Department of Humanitarian Affairs, 1992, p. 27).

Traditionally, disasters are classified according to their cause into either "natural" or "man-made". However, it is acknowledged that disasters result from "a combination of the exposure to a hazard; the conditions of vulnerability that are present; and insufficient capacity or measures to reduce or cope with the potential negative consequences" (UNISDR, 2009, p. 9). Man-made disasters include complex emergencies/conflicts, industrial accidents, and transport accidents

(Below *et al.*, 2009; International Federation of Red Cross, 2015). Disasters are usually associated with a negative impact on human well-being, including significant loss of life, together with damage or loss of property and services.

2.3.2 Complex (humanitarian) emergencies (CHEs)

Among the different types of disasters, CHEs are particularly relevant to this project. A CHE is defined as:

“A humanitarian crisis in a country, region or society where there is a total or considerable breakdown of authority resulting from internal or external conflict and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the on-going UN country program” (United Nations Inter-Agency Standing Committee (IASC), 1994).

The key characteristics of CHEs are (United Nations Inter-Agency Standing Committee (IASC), 1994; International Federation of Red Cross, 2015):

- extensive violence and loss of life;
- displacement of populations;
- widespread damage to societies and economies;
- the need for large-scale, multi-faceted humanitarian assistance;
- the hindrance or prevention of humanitarian assistance by political and military constraints; and
- Significant security risks for humanitarian relief workers in some areas.

These characteristics are fulfilled in the case of Darfur.

2.3.3 Conflicts and armed conflicts

Generally, the term “conflict” refers to “violent fighting between two or more parties that threatens the safety and security of communities or of the general population” (Project, 2011, p. 3).

Armed conflicts are further defined in two main ways: legal and technical. Legally, the International Humanitarian Law (IHL) distinguishes two types of armed conflicts, namely international armed conflicts, between two or more states; and non-international armed conflicts, between governmental forces and non-governmental armed groups, as in Darfur, or between non-governmental groups only (International Humanitarian Law, 2010).

Technical definitions tend to provide a threshold within the definition. For example, Strand et al. (2003) define an armed conflict as “a contested incompatibility that concerns government and/or territory where the use of armed force between two parties, of which at least one is the government of a state, results in at least 25 battle-related deaths” (Strand, Wilhelmsen and Gleditsch, 2003, p. 3). A more detailed account is given by Smith (2004), who defines armed conflicts as “open, armed clashes between two or more centrally organised parties, with continuity between the clashes, in disputes about power over government and territory” (Smith, 2004, p. 3) He subdivides his definition into inter-state conflicts, wars of independence, trans-national (civil) wars, and multi-state (international) wars.

The term “civil war”, which could be used to describe the armed conflict in Darfur, is defined as “any armed conflict that involve[s]; (1) military action internal to the metropole of the state system member; (2) the active participation of the national government; (3) effective resistance by both sides; and (4) a total of at least 1,000 battle-deaths during each year of the war” (Sarkees, 2010, p. 5).

Armed conflicts are known to impact the physical and social structures of affected communities, mainly by forcing people to migrate to areas either within their country or outside of it. These groups are referred to as “internally-displaced persons” (IDPs) and “refugees”, respectively (Reliefweb, 2008). The third category of those affected by armed conflict is the “host community”, which refers to the population that receives the refugees and/or the IDPs. The host community may not be directly involved in the conflict itself. Migrations during armed conflicts are usually associated with attempts to resettle in the nearest secure area in temporary camps. These camps are often administered by community leaders and served by the UN specialised agencies.

2.4 Summary points

- “Research”, “health research”, and “human participants/subjects” are terms frequently used in the literature, with some reference to one or more characteristics, but to date, there seem to be no agreed-upon definitions of these terms.
- The situation in Darfur is considered an armed conflict (civil war) which led to a complex humanitarian emergency, justifying the involvement of the international community, mainly represented by the UN agencies and

INGOs, to help those affected by the conflict. The humanitarian interventions were associated with activities that involved the collection of data and/or biosamples from the people of Darfur.

- For the purpose of this project, any health-related intervention that involves these activities, where not solely for the clinical benefit of a patient, is referred to as “research”.

II. SECTION TWO: REVIEW OF LITERATURE ON HUMAN RESEARCH IN CONFLICT SETTINGS

INTRODUCTION

The introductory part of the thesis, contained in Sections One and Two, presented the geopolitical features of the study area (Section One) and the conceptual mapping of the area of literature within which this project fits. In this section, I present the conceptual framework, using the literature related to the conduct of research on humans during conflicts. This review of the literature aims to identify the gaps that this project seeks to fill. Finally, this section also provides some lenses through which the empirical findings may be viewed and discussed.

Humanitarian and specifically conflict-related research ethics represents an intersection of at least four fields: public health ethics, humanitarian ethics, research ethics, and disaster ethics (Figure 3-1). A full review of these fields is beyond the scope of this section. The focus is rather on how the three other fields could affect research ethics in relation to humanitarian contexts.

With this in mind, this section is divided into two chapters. Chapter Three briefly highlights the ethically relevant aspects in some of the technical and legal documents commonly used in humanitarian settings. Chapter Four lays out the literature addressing the key ethical considerations in research during humanitarian interventions, especially in conflict areas. In both chapters, the relevant gaps in the literature gaps are highlighted.

3 CHAPTER THREE: REGULATORY APPROACHES TO HUMANITARIAN INTERVENTIONS IN DISASTERS AND CONFLICTS

This chapter presents an overview of humanitarian regulatory documents. The focus is on how ethical issues related to humanitarian interventions are discussed in these documents. Generally, there are three intertwined levels of regulation for humanitarian interventions. Internationally, there is the widely accepted International Humanitarian Law (IHL); at the organisational level, there are the NGOs' guidelines and codes of conduct; and finally, there are the regulations of the country in which the humanitarian organisation is working.



Figure 3-1: Diagram representing the position of conflict-research ethics in the relevant literature

3.1 Laws and legal documents

The IHL is the main legal framework that applies to armed conflicts, including humanitarian interventions therein. It is composed of a set of rules that are contained in the four Geneva Conventions of 1949, which are endorsed by almost every country (International Committee of the Red Cross, 1949). The IHL is based on two main principles: protecting those who are not participating in the hostilities and setting limits for the methods and means of warfare.

Article 3 common to the four Geneva Conventions establishes an important distinction between international armed conflicts, which are between two or more states, and non-international armed conflicts, which “are those restricted to the territory of a single State, involving either regular armed forces fighting groups of armed dissidents, or armed groups fighting each other” (International Committee of the Red Cross, 1949). The conflict in Darfur is considered an example of a non-international armed conflict. Rules 25-30 are devoted to the protection of medical and religious personnel, while Rules 31 and 32 are related to the duty to respect and protect humanitarian relief personnel and objects.

Alongside these international regulations, humanitarian organisations must abide by the local regulations of the countries in which they work. In Sudan, the voluntary and non-governmental organisations are regulated by the Voluntary and Humanitarian Work (Organisation) Act, 2006. The act states six principles that should govern humanitarian work. These are (a) Non-discrimination, (b) Chastity [*sic*], (c) Accountability, (d) Sustainability, (e) Having due regard to the desires of the local community, and (f) Non-interference of foreign voluntary organisations in

the internal affairs of Sudan. Table 3-1 summarises the definitions of these principles.

Table 3-1: Principles governing humanitarian work as stated in the Voluntary and Humanitarian Work (Organisation) Act, 2006 (*The Voluntary and Humanitarian Work (Organization) Act, 2006*)

Principle	Definition
(a) Non-discrimination	Non-discrimination on the ground of race, gender, ethnicity, political affiliation or religious beliefs
(b) Chastity [sic]	Chastity in the selection of project sites, taking into consideration the areas having the greatest need
(c) Accountability	Accountability before beneficiaries, donors and public bodies having a connection, who are responsible for services in the area, and such bodies as the basic rules of the organisation may specify
(d) Sustainability	Sustainability of remedial programmes, for preparation of such circumstances, as may enable local communities to depend on upon themselves in the long run
(e) Having due regard to the desires of the local community	Having due regard to the desires of the local community at all stages of the project, through the participation of local communities at all stages of implementation of the project
(f) Non-interference	Non-interference of foreign voluntary organisations in the internal affairs of Sudan, in such way as may affect the sovereignty of the country

3.2 Humanitarian Guidelines and Codes of Conduct

Given the IHL's lack of specificity regarding the work of humanitarian agencies, these agencies tend to develop their own codes and guidelines. They mostly rely on the so-called "Humanitarian Principles", namely humanity, impartiality, neutrality, and independence (Table 3-2).

Table 3-2: Examples of the codes of conduct and core values set by some international organisations

Organisation	Document title	Scope and examples of core values
The United Nations (UN)	They stem from United Nations' General Assembly (GA) resolutions number GA 46/182 (1991) and GA 58/114 (2003) (United Nations General Assembly, 1991, 2003)	<p>Humanitarian Principles</p> <ol style="list-style-type: none"> 1. Humanity: Human suffering must be addressed wherever it is found. The purpose of humanitarian action is to protect life and health and to ensure respect for the human being. 2. Impartiality: Humanitarian action must be carried out based on humanitarian need alone, giving priority to the most urgent cases of distress and making no distinctions based on nationality, race, religious beliefs, class or political opinions. 3. Neutrality: Humanitarian actors must not take sides in hostilities or engage in controversies of a political, racial, religious or ideological nature. 4. Independence: Humanitarian action must be autonomous from the political, economic, military or other objectives that any actor may hold regarding areas where humanitarian action is being implemented.
International Committee of Red Cross and Red Crescent (ICRC)	The Fundamental Principles of the Red Cross and Red Crescent (The International Federation of Red Cross and Red	<p>These include the four abovementioned Humanitarian Principles (and three additional ones of relevance to the Red Cross Red Crescent Movement, i.e. Unity, Voluntary Service and Universality)</p> <ol style="list-style-type: none"> 1. Voluntary service: It is a voluntary relief movement not prompted in any manner by desire for gain. 2. Unity: There can be only one Red Cross or one Red Crescent Society

Organisation	Document title	Scope and examples of core values
	Crescent Societies (IFRC), 1965)	<p>in any one country. It must be open to all. It must carry on its humanitarian work throughout its territory.</p> <p>3. Universality: The International Red Cross and Red Crescent Movement, in which all Societies have equal status and share equal responsibilities and duties in helping each other, is worldwide.</p>
IFRC, ICRC, and NGOs	The Code of Conduct for the Red Cross and Red Crescent Movement and NGOs in Disaster Relief, 1994 (The International Federation of Red Cross and Red Crescent Societies (IFRC), 1994)	<p>The signing of this code is a condition for membership in that consortium. The Code attempts to regulate the action of the organisation in their disaster relief operations. The Code of Conduct is a voluntary code which is self-enforced by each of the signatory organisations. It has no mechanism for checking compliance; therefore, there is no formal sanction when the conduct of a signatory does not conform to the Code (United Nations Inter-Agency Standing Committee (IASC), 2010).</p> <ol style="list-style-type: none"> 1. The humanitarian imperative comes first 2. Aid is given regardless of the race, creed or nationality of the recipients and without adverse distinction of any kind 3. Aid will not be used to further a particular political or religious standpoint 4. We shall respect culture and custom 5. We shall attempt to build disaster response on local capacities 6. Ways shall be found to involve programme beneficiaries in the management of relief aid

Organisation	Document title	Scope and examples of core values
		7. In our information, publicity and advertising activities, we shall recognise disaster victims as dignified humans, not hopeless objects
The SPHERE Project	Humanitarian Charter and Minimum Standards in Humanitarian Response (Sphere Project, 2011)	The fundamental moral principle of humanity: that all human beings are born free and equal in dignity and rights. Other common rights include the right to life with dignity, to receive humanitarian assistance, and the right to protection and security
UN Office for Coordination of Humanitarian Affairs (OCHA)	OCHA Orientation Handbook on Complex Emergencies (United Nations Office for the Coordination of Humanitarian Affairs, 1999)	<ol style="list-style-type: none"> 1) Humanitarian assistance is of fundamental importance for the victims of natural disasters and other emergencies. 2) Humanitarian assistance must be provided in accordance with the principles of humanity, neutrality and impartiality. 3) The sovereignty, territorial integrity and national unity of the State must be fully respected in accordance with the Charter of the United Nations. 4) Each State has the responsibility first and foremost to take care of the victims of natural disasters and other emergencies occurring in its territory. 5) Primary responsibility for the protection and well-being of a civilian population rests with the government of the state or authorities that control the territory in which the population is located. 6) In situations of armed conflict, civilians are protected under international law against attacks and other violations of international humanitarian law.

Organisation	Document title	Scope and examples of core values
		7) The parties to the conflict must respect and apply the spirit and letter of the international humanitarian law and human rights, and established principles relating to humanitarian assistance.

Despite the variety amongst these sets of principles, a few common features can be identified. First, they are mostly based on the UN Humanitarian Principles, which have been endorsed by the UN General Assembly, which is fundamentally a political body and not an academic or a humanitarian one. This explains the principles' generality and legalistic formulation. Second, their focus is on the organisations' interaction with those affected by the humanitarian condition as beneficiaries and patients, not as research participants. This gap makes these principles an inadequate reference for the ethical oversight of research in humanitarian contexts.

Lastly, the values and principles mentioned in the various codes and guidelines are mentioned in the abstract. There is no moral reasoning or justification provided regarding the choice of one set of (ethical) principles over another. There is however one exception, which is the Humanitarian Charter of the Sphere project.

The Humanitarian Charter of the Sphere project provides some moral claims regarding its principles. For example, it claims that its principles are universal and so should apply "to all those affected by disaster or conflict wherever they may be". The Charter also claims moral primacy for the humanitarian imperative, i.e. "action should be taken to prevent or alleviate human suffering arising out of disaster or conflict, and... nothing should override this principle" (The Sphere Project, 2011, p. 20). However, the Charter does not justify why the humanitarian imperative should override any other principle or why its principles should apply wherever there is a disaster.

In summary, humanitarian laws and codes provide general guidance that, though relevant, is not specific to research. In the next chapter, I summarise the literature relating specifically to research in conflict settings.

4 CHAPTER FOUR: ETHICAL AND PHILOSOPHICAL APPROACHES TO RESEARCH DURING CONFLICTS

The previous chapter outlined the ethically relevant principles mentioned in the main humanitarian guidelines and codes of conduct. This chapter presents an overview of the literature on humanitarian research ethics, with a focus on the conflict context. However, I do not discuss the literature on pandemics and natural disasters, despite its potential relevance. Arguably, armed conflict settings constitute a more complicated context than any other humanitarian condition. For example, in non-military (natural) disasters, the governments of the affected regions usually help the affected population, sometimes by deploying the army. Such deployment is usually welcomed, or at least not opposed by the affected population. This involvement of the national army was seen in Pakistan's earthquake (2005), in Mozambique's cyclone (2007) and in the Haiti hurricane (2008) (Ferris, 2012; Cecchine *et al.*, 2013), despite criticisms of the efficiency of civilian-military humanitarian coordination (Hofmann and Hudson, 2009; Boon and Allen, 2014).

In contrast, in an armed conflict setting like that in Darfur, governmental interventions, even by civilian staff, may not always be welcomed. Governmental armed forces, in such conditions, are often part of the combat, and humanitarian interventions are provided in a tense atmosphere, usually through difficult negotiations with combatants on both sides.

Moreover, in non-military humanitarian conditions, international humanitarian interventions are usually done in coordination and collaboration with the local governments. In many conflict-related humanitarian situations, however, humanitarian interventions need to be imposed by pressure from the international community, sometimes by means of UN Security Council resolutions. With this in

mind, the focus of this chapter is on the literature related to research in conflict settings and not in other settings.

The chapter does however highlight the milestones that have marked the development of research ethics discipline and the main shared ethical principles in research ethics guidelines. It is important to discuss whether mainstream research ethics guidelines are applicable to conflicts. Following this, the literature on ethical considerations in research during conflicts is categorised and summarised, citing some examples for each category.

4.1 Introduction

Since World War II, national and international efforts have been made to develop, specify, and regulate research on humans through guidelines, legislation and ethical review systems (Chalmers, 2013; Hussein, 2015b). I have demonstrated above that the ‘compilation’ enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research (Subsection 3.1). In contrast, ethical issues related to public health emergencies and disasters have only recently attracted global interest, and this interest has been comparatively minor.

Notably, some of the widely cited ethical guidelines were developed as consequences of scandals in relation to publicised research misconduct, such as the Nuremberg Code following the Nazi experiments on inmates during World War II; the Declaration of Helsinki following the controversies surrounding the use of placebo; and the Belmont Report following the Tuskegee study (Emanuel and Menikoff, 2011). Levine has described the field of research ethics as “born in scandal and reared in protectionism” (Levine, 1988).

Despite some variations among the different research ethics guidelines, some ethical considerations are common to almost all of them. Table 4-1 summarises these common considerations and their disaster-related applications.

Table 4-1: Core ethical principles and issues covered by the main guidelines and examples of their application in public health emergencies (Hussein, 2015a)

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
Respect for people's autonomy	The duty to respect people's ability to make decisions on issues related to their health and their body, if they are competent to make such decisions; and the duty to protect individuals with impaired or diminished autonomy	Obtaining informed consent from people affected by an emergency before their identifiable personal information or biosamples are collected and processed for research purposes	CIOMS (General principles), Tri-Council Policy Statement (TCPS) (Article 1.1), Belmont Report (Basic ethical principles)
Informed consent	A process whereby the potential research participant decides whether they want to participate in the proposed study after receiving information about it. The requirements for consent considered to be valid vary by guideline and regulation. In general, they agree that decisions must be made free from coercion, by a competent person who	Participants in certain emergency-related activities should give their informed consent, especially when their identifiable information or biosamples are to be collected. Such	CIOMS (General principles, and guidelines 4–6), Declaration of Helsinki (Articles 25–32), TCPS (Chapter 3, The consent process)

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
	can understand the information given and appreciate the associated risks. The information given to the participant should be in a language and format suitable to the participant's ability to comprehend it.	consent can be given collectively (following community consultations) and/or individually ¹⁵ .	
Beneficence	The moral duty to pursue actions that promote the well-being of others and the ethical obligation to maximise benefit and to minimise harm	To benefit from and have access to results of research e.g. to a vaccine in a pandemic	CIOMS (General principles), Belmont Report (Basic ethical principles)
Non-maleficence	The moral duty not to cause harm to others through interventions	Vaccine trials should involve the smallest number of human subjects and the smallest number of tests on those subjects that will ensure scientifically valid data.	CIOMS (General principles), Declaration of Helsinki (Articles 16–18)

¹⁵ Different format of consent is discussed in further detail later in the thesis.

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
Justice	Primarily distributive justice, which requires equitable distribution of benefits and burdens, i.e. distribution such that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it	Collecting samples from citizens of a developing country affected by a pandemic to develop a vaccine rapidly and ensure that the vaccine is made available locally	CIOMS (General principles and guidelines 10 and 12), Declaration of Helsinki (Articles 16–18), TCPS (Article 1.1 and Chapter 4)
Vulnerability	A status in which some people may struggle to protect their interests or be at greater risk of being exploited. This situation is usually linked to specific physical, financial, educational or social circumstances. Groups considered as vulnerable vary by guideline, but children, mentally and/or physically disabled individuals, prisoners, refugees, terminally ill patients and women are often cited as the primary vulnerable groups.	Targeting women and children for surveillance during emergencies without epidemiological or methodological justification	CIOMS (General principles and guidelines 13–16), Declaration of Helsinki (Vulnerable groups and individuals, articles 19 and 20), Common rule (Subparts B, C and D), TCPS (Chapter 9, Research involving the First Nations, Inuit and Métis peoples of Canada)

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
Privacy	The right or expectation not to be interfered with or to be free from surveillance or, more generally, a moral right to be left alone. In practical terms, privacy is for instance concerned with the setting in which a person's health-related information is acquired.	Taking precautions to interview victims of a public health emergency in private places (i.e. where those not related to the study cannot see or hear them)	TCPS (Chapter 5), Declaration of Helsinki (Article 24)
Confidentiality	The principle that ensures that identifiable information is kept out of reach of others. All identifiable information about individuals, whether recorded (written, digital, visual, audio) or simply held in the memory of health professionals, is subject to confidentiality.	Ensuring that identifiable data from surveillance activities are secured and not accessible by irrelevant persons (e.g. locked in filing cabinets or in encrypted files)	CIOMS (Guideline 18, Safeguarding confidentiality), TCPS (Chapter 5, Privacy and confidentiality)
¹ Modified from a module entitled "Learning objective 1.3: Demonstrate understanding of the ethical principles and requirements addressed in current normative instruments relative to research and surveillance in public health emergencies" (Hussein, 2015a)			

As I have argued elsewhere (Hussein, 2015b), the current normative instruments have shortcomings when applied in disaster situations, and alternatives should be developed. One of the main concerns is that “most research ethics guidelines were written for clinical research, which is usually undertaken in a stable context in which adequate resources are available” (Hussein, 2015b, p. 43). In contrast, disasters often lead to or aggravate disrupted healthcare and research systems, particularly in places with limited resources. In conditions such as humanitarian emergencies, disasters can make it “nearly impossible to abide by the letter of mainstream research ethics guidelines” (Hussein, 2015b, p. 43).

The call for a disaster-specific ethical governance system is not new and a growing body of literature has argued for conflict-specific research ethics guidance. In the remainder of this chapter, I summarise the main trends of this literature and then identify the gaps that this project could help to fill.

4.2 Categorisation and summary of the literature on conflict research ethics

In conflict settings, researchers work within a multitude of unpredictable parameters and face inter-related logistical, methodological, and ethical challenges. These parameters include *inter alia* the state of insecurity, lack of resources, and urgency of the need for the humanitarian aid. Each of these challenges gives rise to important ethical considerations. For example, the insecurity resulting from combat may limit researchers’ access to some areas, which in turn has methodological and ethical implications. Examples of the latter include issues related to the vulnerability of the inaccessible population, the just

distribution of benefits that could result from the research activities, and the humanitarian agencies' duty to protect their staff.

The literature discussing these ethical considerations in conflict settings can be categorised into conceptual literature, field experience, and literature relating to operational concerns. The conceptual literature focuses on the philosophical and theoretical conceptualisation of the moral aspects of research in conflict settings. The field experiences also discuss some related ethical issues, but mostly as personal or institutional reflections based on the authors' field experiences. The operational literature proposes frameworks and tools to be used for ethical research in humanitarian settings. Examples of each category follow below.

First, the conceptual literature discusses various ethical concepts related to research in emergency settings. For example, Black (2003) attempts to differentiate two types of research conducted during conflicts: "research conceived and commissioned by humanitarian agencies in order to answer operational questions, and broader research independently conceived to understand and explain an evolving humanitarian context and the actions of those involved" (Black 2003, p.97). This differentiation is useful in directing the ethical guidance for each type. Black calls for a broader engagement of the research community in the realities of complex emergencies that fall outside of the guidelines developed in academic settings (Black, 2003).

Goodhand (2000) outlines the main challenges faced by conflict zone researchers and suggests standards that should be followed (Goodhand, 2000). He makes an important reference to the inadequacy of the universal guidelines for

making ethical decisions during conflicts, which are context-specific (although this could be objected to as a misunderstanding the purpose of such guidelines).

Kilpatrick (2004) identifies four critical considerations in relation to post-disaster research, which are (a) the decision-making capacity of potential participants; (b) vulnerability; (c) the risks and benefits of participation; and (d) informed consent (Kilpatrick, 2004). Similarly, Giarratano et al. (2014) also emphasise the vulnerability of disaster survivors, yet suggest following the established guidelines and having the study approved by institutional review boards (IRBs) (Giarratano *et al.*, 2014).

One of the effects of the fragile security situation is on the accessibility of the conflict-affected areas. Aiga (2007) discusses how the accessible areas may become over-researched. For example, between February and September 2004, there were 107 communities in Darfur covered by 44 surveys. Of these communities, 33 (31%) partook in two or more surveys and two (2%) partook in five or more surveys (Aiga, 2007).

Another approach to the conceptualization of ethical issues in humanitarian contexts is to suggest research agendas, i.e. research areas that should be given priority in the humanitarian context. For example, the Humanitarian Health Ethics Forum (HHE Forum) has identified priority areas for research that are needed to inform the policy and practice of international responses to humanitarian crises (Hunt *et al.*, 2014). They suggest key research questions for five topic areas related to humanitarian health ethics: how research is perceived, the necessary training, support for humanitarian health workers, the impact of policies and

project structures, and research-related theoretical frameworks. This project falls within more than one of these areas. For example, it explores how some of the ethical issues in humanitarian health research are perceived, and the study's findings can help in considering necessary revisions in the current policies and structures.

Additionally, there is literature reflecting on humanitarian field experiences. This literature varies from individual researchers or practitioners sharing moral reflections on personal experiences (Gately, 2005; Wood, 2006) to institutions (mostly *Médecins Sans Frontières* (MSF)) sharing their 'lessons learned' (Schopper *et al.*, 2009; Zachariah *et al.*, 2010; Sheather and Shah, 2011; Karunakara, 2013).

Lastly, some literature showed wider variation in suggestions regarding how to manage ethical issues related to research in unstable conditions. For example, Ferreria and colleagues (2015) discuss the concept of vulnerability in disaster research and suggest an approach for ethical analysis that incorporates utilitarianism and social justice. These authors also recommended some modifications to the currently existing ethical guidance (Ferreria, Buttell and Ferreria, 2015). O'Mathúna (2015) uses the seven principles that Emanuel (2000) suggests for ethical clinical research (Emanuel, 2000) to justify and analyse ethical issues in disaster research (O'Mathúna, 2015). These seven principles were also the benchmarks for the first MSF REB framework (Giacomini, Kenny and DeJean, 2009; MSF Ethics Review Board, 2013b), yet were excluded in the second version of the framework, as they may "suggest that ethics is a series of inflexible and

absolute rules, and it can be unclear how the different elements relate to each other” (MSF Ethics Review Board, 2013a).

Being aware of the key differences between normal and disaster settings, other authors have departed in various ways from the mainstream approach to ethical research conduct. They suggest new frameworks and tools for ethical research conduct in humanitarian contexts and specifically in conflict situations. Nevertheless, this departure from the mainstream guidelines has left a few gaps in these innovative guidelines. For example, using the mainstream guidelines as the standard (from which they claim to depart) inherently acknowledges that the international research ethics guidelines represent (or can represent) the conflict-affected communities, morally speaking. They also have what Black (2003) describes as an inherent weakness in humanitarian codes, namely they may be respected and followed “by actors who have not been involved in developing [them], or who have not experienced the specific difficulties that the code tries to address” (Black, 2003, p. 97).

Additionally, this literature lacks empirical evidence to support any related moral claims. The provision of such empirical evidence is the key contribution of this project. However, it was important to refer to this literature to help in formulating the research questions for the thesis by identifying the main ethical issues and principles previously discussed in the literature. In the following paragraphs, I present some examples of this literature. Later, in the Discussion chapter, I discuss the same literature in relation to the findings of this project.

Clarival and Biller-Andorno propose a ten-step approach to ethical decision-making to assist humanitarian workers (Clarival and Biller-Andorno, 2014). Their approach focuses on resource allocation and is not specific to research. O'Mathúna (2010) points out that the ethical priority in disaster research should be protecting the participants from exploitation, then suggests an approach that includes cross-cultural collaboration and communication and protecting researchers (O'Mathúna *et al.*, 2010).

Two recently published frameworks are particularly relevant to this project. The *Humanitarian Health Ethics Analysis Tool (HHEAT) Handbook* (Fraser *et al.*, 2014) is an ethical analysis tool designed to help humanitarian healthcare workers make ethical decisions by means of a six-step process (Table 4-3). This framework is meant to guide disaster-related humanitarian decisions; it does not provide ethical guidance for disaster research.

Table 4-2: Summary of the HHEAT six-step ethical analysis process (Fraser *et al.*, 2014)

Step	Description
1. Identify/Clarify the Ethical Issue	Determine whether an ethical issue exists and summarise it clearly and concisely. This summary should highlight pertinent features of the situation as well as principles and moral values in an objective manner.
2. Gather Information	Collect data and consider three sources of information that are especially relevant in humanitarian aid contexts:
a) Resource Allocation and Clinical Features	In all healthcare contexts, ethical decisions relating to the care of individual patients require a comprehensive understanding of relevant clinical features. This analysis should include data gathering on diagnosis, prognosis, treatment options, and patient and family preferences on goals of care. In humanitarian contexts, data gathering might extend to considerations of public health concerns and the allocation of scarce resources. Determining what resources are available and how

Step	Description
	resources ought to be allocated merits considerable attention and may demand critical thinking and a creative approach.
b) Participation, Perspectives and Power	Humanitarian healthcare aid occurs in contexts where socioeconomic inequalities, colonial histories and violence and oppression may operate on a variety of different levels. This step of analysis involves consideration of how multiple perspectives are integrated into the decision-making process. This includes considering the position, relationships and participation of various stakeholders.
c) Community, Projects and Policies	In humanitarian contexts, it is important to question how cultural frameworks and personal and collective histories affect how the issue is understood. The analysis could also include exploration of the impact of staff turnover, organisational culture, clarity of program and organisational objectives, and structures of accountability and responsibility.
3. Review the Ethical Issue	Assess all the information that has been gathered, identify important knowledge gaps as well as obstacles or impediments that may hinder or make potential courses of action difficult or impossible. If necessary, reformulate or re-articulate the ethical issue considering these emerging considerations.
4. Explore Ethics Resources	A variety of ethical resources is available to help support ethical decision-making in humanitarian contexts. This step of analysis promotes consideration of ethical arguments in greater detail and facilitates more robust ethical justification. Ethical resources include: (a) professional moral norms and guidelines for healthcare practice; (b) human rights and international law; (c) ethical theory; and (d) local norms, values and customs.
5. Evaluate and Select the Best Option	Generate as many options as possible to respond to the ethical issue and identify the positive and negative consequences that may result from each course of action. The values, principles and moral arguments justifying each course of action should be analysed and compared. Considering this analysis, options should be weighed, and the 'best' option, or cluster of options, selected. An implementation plan should be formulated.
6. Follow Up	Follow up on the decision taken so that ethical choices can be evaluated considering outcomes.

The second relevant framework is “[A]n ethical framework for the development and review of health research proposals involving humanitarian contexts” (Curry, Waldman and Caplan, 2014). This framework resulted from an extensive review of the relevant literature. It proposes six clusters which incorporate relevant questions that can be utilised by researchers and reviewers (Table 4-4).

Table 4-3: Research for Health in Humanitarian Crises (R2HC) Ethical Framework and Key Questions (Curry, Waldman and Caplan, 2014)

<p>Cluster A: Emergency Context Requirement/Benefits-Harms-Risks</p> <ul style="list-style-type: none"> • Why must this research be conducted in a humanitarian crisis or emergency context – in short, explain why the expected evidence and benefit cannot be gained from implementation of the protocol in more stable (non-emergency) settings. • What are the known and potential harms and risks to individuals and the subject population overall by involvement in the proposed research? • What are the relevant analyses of harm-benefit “ratios”? What mitigating strategies and associated costs (planned and potential) have been defined and projected?
<p>Cluster B – Protocol Design: Scientific Validity/Feasibility; Research Focus: Relative Priority; Team Strength: Competence/Collaborative Structure; Declared Interests</p> <ul style="list-style-type: none"> • What is the relative importance/priority that this protocol should enjoy in the larger context of evidence-building for the humanitarian response? • Why are the institutions and individuals involved in the proposed team—including local (in-country) researchers and supporting staff—uniquely qualified to conduct this research? What are the weaknesses or “holes” in the team structure that might be strengthened before the research is implemented? • How are the declared interests of all investigators and institutions involved in the research relevant to the conduct of the research? Do any these interests

represent “conflicts” that might compromise the integrity of the research, the team or the evidence sought?
Cluster C: Independent Ethical Review/Oversight; Safeguards/Security/Exits
<ul style="list-style-type: none"> • What ethical review processes and review entities (REBs/IRBs: institutional/internal, independent, contracted, local/in-country) will be involved in approving this protocol? • What are the known and anticipated strengths and weakness of these review bodies, including their capacity to provide initial, continuing and summary oversight of the protocol? • Are there any mitigating strategies around weaknesses and are there costs associated with addressing them? • What safeguards, security, exit strategies, and associated costs have been developed regarding research subjects (both those involved in the intervention and those in “control” groups) and the research team itself over the proposed duration of the project?
Cluster D: Community Engagement; Cultural Context/Norms/Values
<ul style="list-style-type: none"> • What community engagement strategies have been undertaken to date, and what engagement actions are planned? • How does the protocol address the unique cultural context(s), norms and values of the population(s) involved?
Cluster E: Community/Individual Benefit; Confidentiality/Data Security
<ul style="list-style-type: none"> • How will the research directly benefit—with reasonable immediacy—the community and individuals involved? If it will not, who will benefit and when? By what process were benefits presented to and affirmed by the research subjects and their community? • How does the protocol address data confidentiality and security? What are the anticipated risks and mitigation strategies/costs?
Cluster F: Informed Consent
<ul style="list-style-type: none"> • What informed consent strategies and processes are proposed for subjects of the research as well as the research staff involved? • Are these strategies credible, and is adequate documentation planned?

Finally, there is the literature produced at the institutional level. I could identify two distinct lines of operationally-oriented ethical guidance. The first is that related to pandemics, especially influenza (Kinlaw, Barrett and Levine, 2009; World Health Organization, 2015) and Ebola (WHO, 2014), which as noted earlier is not included in this review.

The second, which I find more relevant to this project, is the “MSF Research Ethics Framework – Guidance Document”. It was developed by the Ethical Review Board (ERB) of MSF (2013) as a series of open-ended questions that “seek to encourage researchers to think critically about their proposed protocols and justify their methods, think about possible harms and benefits, and consider what the implications of their research might be” (MSF Ethics Review Board, 2013b, p. 2). The relevance of this framework to this project is twofold. First, it is organized in as a sequence of step-wise questions, rather than claiming to be a set of universally accepted ethical principles without providing any empirical evidence to support this claim. Second, MSF is an international federation that works actively in almost all disasters worldwide. This makes its framework closer to the humanitarian realities than those frameworks prepared by experts who may not have such extensive humanitarian experience. Table 4-5 summarises the main questions under each of the sections of the MSF Research Ethics Framework.

Table 4-4: Sections and main questions of the MSF Research Ethics Framework – Guidance Document (MSF Ethics Review Board, 2013a)

Section	Section title and main questions
Section 1	Research Question and Methodology

Section	Section title and main questions
	(1.1) What is the research question? Why is it important?
	(1.2) How are the methodology and proposed analysis appropriate given the research question(s)?
	(1.3) What is the context in which the research will be conducted? How has this influenced the research design?
	(1.4) Are there any other parties involved in the research? What potential interests of these parties might conflict with MSF's mission and values?
	(1.5) Are all relevant resources for the research secured?
	(1.6) Have the research staff the relevant training and protections?
Section 2.	Respecting and Protecting Research Participants and Communities
	(2.1) What are the anticipated harms and benefits?
	(2.2) What are your plans for obtaining consent?
	(2.3) How do you plan to protect confidentiality?
	(2.4) How do you plan to access, store, and distribute any collected biological material?
Section 3.	Implications and Implementation of the Research Findings
	(3.1) What will happen when the research is either stopped or is complete?
	(3.2) How will the findings be disseminated?
	(3.3) How will the findings be implemented?

4.3 Gaps in the literature on humanitarian research ethics

In this subsection, I identify the gaps in the main types of literature I use in this thesis: research ethics guidelines and literature published in peer-reviewed journals.

4.3.1 Critique of international and national research ethics guidelines

In this subsection, I argue that both national and mainstream international guidelines are not appropriate for the review of humanitarian research. To support this conclusion, I provide three main reasons. The first is an overview of how these guidelines were developed, with emphasis on their derivation from mostly Western regulatory systems and ethical values. The second is an argument as to why the current approach to developing these guidelines renders them both morally and operationally inappropriate for providing ethical guidance for these activities. In particular, the guidelines seem to be focused on clinical research conducted in stable settings. In the humanitarian context, clinical studies are not a common form of research, and the settings are not stable.

The discussion of the research ethics guidelines is specifically relevant to this project for a number of reasons. First, these guidelines are the main source of ethical research guidance in Sudan and beyond. We ought to ensure their appropriateness to the intended task of providing ethical guidance. Second, the guidelines' ethical guidance should be reflective of the moral values of the communities within which the guided research is conducted. In the case of Sudan, I explain that this was not the case and conclude that the national guidelines were not as national as their name would suggest. Third, the methodology of developing these guidelines requires some conditions, discussed below, to be morally reflective of the communities for which they were developed. These conditions seem to be missing in the case of Sudan.

Many of the commonly cited research ethics guidelines and literature produced since the Nuremberg Code have been developed in reaction to incidents where research participants in a given study were abused or coerced (Dhai, 2014). Remarkably, most of these infamous incidents occurred in scientifically advanced Western countries, and most of the international research ethics guidelines that were subsequently developed or amended were from these countries. As would be expected, the guidelines reflect the mainstream moral values of the countries within which they were developed, with a clear emphasis on an individualistic approach to the basic guiding ethical principles (Petrini, 2010). The most cited ethical principles are the three principles of autonomy, beneficence, and justice, proposed by the Belmont report in the US (The National Commission for the Protection of Human Subjects, 1979), to which a fourth principle (non-maleficence) was added by two US philosophers, Beauchamp and Childress (Beauchamp and Childress, 1994).

These four principles are also the guiding ethical principles in the Sudanese national guidelines (National Ministry of Health, 2008). The adoption of these principles seems to have overlooked two features that differentiate the Sudanese context from the original context in which these principles were developed, namely the absence of freedom of speech and the unique hierarchical community structures.

The governments in most of Western countries are democratically chosen by their people and are held accountable to them. These governance systems are

supported by a democratically established legal system and free media that facilitate public debates around most ethical issues.

In contrast, there was a lack of meaningful public engagement in the development of the national guidelines. Unlike some key research ethics guidelines and regulations that were made available for public comment, such as the CIOMS (Council for International Organizations of Medical Sciences (CIOMS), 2015), the Tri-Council Policy Statement in Canada (Interagency Advisory Panel on Research Ethics, 2013), and the 'Common Rule' in the US (Protections, 2015), the national guidelines in Sudan were not even shared with other academics for comment, let alone the general public.

The development of the national guidelines did not seem to go beyond a group of experts assigned by an authorised body to draft these guidelines based on a review of relevant literature and their expert opinions. As such, it would be difficult to defend the ethical principles in the national guidelines as a true moral reflection of the Sudanese people, who were not given the opportunity to evaluate them. The empirical findings presented later in this thesis reveal a lack of awareness and compliance with these guidelines.

To be fair, there are reasons to believe that this lack of moral relevance and the subsequent lack of adherence to the guidelines could be a developing world phenomenon and not only a Sudanese one. Most of the literature that discusses the ethical review of research in developing countries focuses on the presence or absence of guidelines and rarely addresses how these guidelines were developed (Kass *et al.*, 2007; Rwabihama, Girre and Duguet, 2010; Motari, Ota and Kirigia,

2015). The top-down approach, where a group of experts proposes ethically relevant principles, is easier and cheaper than making the process more inclusive.

Other socio-political, logistic, and financial barriers to implementing a more inclusive approach should not be ignored as background factors that have led to the absence of a tradition of inclusion. For example, Adlan (2015) suggests that there is a relationship between the ability to hold this sort of consultation and the general standard of education in the population, since to engage meaningfully in the debate one has to understand what research is and what it means to commit to evidence-based practice (Adlan, 2015).

Second, there are clearly demarcated relationships among the individuals living in most Western countries and between the people and their governments. For example, there are clear duties and rights that are protected by the constitution and the law in these countries. These can be represented in a flowchart whose shapes are connected by straight lines that do not cross one another, which I call 'linear relationships'. Research governance is seen within this rights-duties balance. In this sense, these legalistic guidelines are morally and practically aligned with these communities.

Contrarily, relationships at the various levels in Sudan are never linear. Consider the example of who counts as a 'family members', which might be assumed to be one of the easiest human relationships to define. In Sudan and many southern hemisphere countries, a male cousin is called a "brother", a father's male cousin is called an "uncle", a father's uncle is called a "grandfather", and so on. Such complexity creates similar complexity when it comes to making

and taking decisions. There is an inherent expectation amongst family members (in the wider sense) to be part of many of the decisions taken by other family members. These expectations are often respected and hence the general tendency to make the important decisions jointly.

The lack of democratically elected governments, the complicated web of relationships, and the subsequent lack of clarity as to who owes what to whom make any 'copy and paste' approach to research ethics guidelines simplistic and unjustifiable on a moral and practical basis. Morally, the imported research governance systems are based on ethical principles that flourish in communities with significantly clearer rights-duties distinctions. Hence, priority is given to such principles as autonomy, usually understood in its individualistic meaning; and ethical principles are evaluated in terms of their value to the individual human being. These Western interpretations of the core foundational ethical principles vary from what many people in the developing countries may believe and be able to apply under their mostly non-democratic political regimes.

It is also important to re-orientate the moral role of ethical oversight committees to interpret the moral values of the communities in which they function. In so doing, the ethics committees would be safeguarding values, not only following rules. However, for this to happen, these bodies ought to be led by ethical guidelines that represent the communities they serve and work within the community's structures. Both conditions are missing from the national guidelines. The national guidelines are a slightly modified version of the international

guidelines, and the central structure of the research ethics oversight overrides the roles of the community members and structures.

Furthermore, the national guidelines adopt a narrow clinical research model, with scant reference to non-clinical studies. Most of the ethical principles mentioned in the national guidelines refer to “biomedical research” (Principles 5 and 8) and “medical research” (Principle 6). They state that “experimental procedure[s] involving human subjects should be clearly formulated in an experimental protocol” (Principle 8) and that “the responsibility for the human subject must always rest with a medically qualified person” (Principle 10) (National Ministry of Health, 2008). I could not find any reference to any other form of research apart from the experimental clinical model. Thus, it would not be possible to establish these guidelines as the reference with which to review humanitarian activities, even if this were desired.

4.3.2 Overview of the non-guidelines literature on humanitarian research ethics

Although there is extensive literature on disaster research ethics, it still has a few significant limitations when it comes to research during conflicts. First, little of this literature directly addresses research during conflicts. Most of the focus is on humanitarian decision-making in mostly non-military disasters. There are essential differences between conflict and non-conflict disasters, as mentioned earlier.

Second, most of the moral and procedural bases in the literature are modifications of the current research ethics guidelines, and only a few authors suggest more context-specific approaches to ethics in studies such as those

conducted during conflicts (Demi and Warren, 1995; Ford *et al.*, 2009; MSF Ethics Review Board, 2013a). The mainstream research ethics guidelines were not developed to address the exceptional circumstances of conflicts, which may need non-conventional approaches to anticipate and manage their related ethical issues.

Lastly, most of the existing literature is based on personal experiences of the authors or their organisations, which may not reflect the researched communities' perspectives on these ethical issues.

This project aims to enrich the philosophical discussion of the relevant ethical issues by integrating an empirical qualitative research component to help in understanding the local perspectives of the communities affected by the humanitarian condition. This understanding would help in developing frameworks that can represent and integrate the local values of the researched communities. Studying the community's views through systematic research methods is necessary to seek a consensus from community members and researchers on which ethical principles seem relevant and how to apply them. Such moral agreement will ultimately help to provide research ethics guidelines that are philosophically defensible, socially acceptable, and operationally applicable. Otherwise, any ethical framework to guide research during conflicts can be challenged based on its inherent assumption that its ethical standards and moral references are globally acceptable.

SUMMARY

The literature on ethical issues in conflict-related research has developed steadily over the last 25 years (Curry, Waldman and Caplan, 2014). However, at least three gaps in this literature could be identified. First, most of the literature is written by experts who happen to have experience in ethics and/or humanitarian interventions. Arguably, these guidelines should be adapted based on the context of each country and its socio-cultural peculiarities. Second, most of the literature identifies and assesses these ethical issues using various ethical principles that may or may not reflect local moral values.

Finally, the literature relies mostly on personal and sometimes institutional reflections, though some frameworks were developed to be empirically informed using empirical bioethics approaches.

Having defined the gaps in the current literature on conflict-related research ethics, I now explain the rationale for this project.

RATIONALE

The consistent flow of literature on ethical considerations in research in humanitarian contexts reflects the need to find the most appropriate approach to ethically guide such research. A project that marries empirical and philosophical approaches is needed for three reasons. First, any guidance addressing the humanitarian context should involve those in the field to explore how they have interpreted the currently available regulations and guidance. This exploration will help in understanding the abovementioned moral gaps in the available guidance. These moral gaps can have practical implications. Researchers in humanitarian

settings might find it difficult to apply these guidelines for a variety of logistical or operational reasons that may have been absent from the current humanitarian research guidance. Moreover, there could be community resistance to the application of the available guidance if it is morally irrelevant to the community members.

Second, the project aims to gain an understanding of the potentially complex research setup in Darfur as an example of a conflict-affected area. Research activities during conflicts are unlikely to be stand-alone activities. They are usually integrated with other humanitarian activities, and so research-related decisions ought to be studied within the overall complexity of the humanitarian setting. This understanding is important to establish how and why ethically relevant decisions are made about the conduct of research, which is needed to provide realistic guidance that can be practically implemented.

Lastly, as things stand, there is no national or international 'standardised' approach to anticipating and managing the ethical issues related to health research activities undertaken in Darfur or other conflict areas. Nationally, the only available guiding document for research in Sudan is the National Ethical Guidelines for the Conduct of Research that Involves Human Subjects in Sudan (National Ministry of Health, 2008). None of its chapters make any reference to special situations or humanitarian settings. Internationally, there is no standardised ethical oversight guidance mechanism for research in armed conflict settings, and there is considerable inconsistency in the quality and extent of the

evidence base that informs humanitarian interventions in disasters, including conflicts (Caplan and Curry, 2015).

A unified or standardised approach to ethical analysis is not meant to be founded on 'one size fits all' guidelines that are readily replicable and applicable in all conflict-affected areas. Such a minimal set of common standards and/or guiding principles is meant to guide the identification and analysis of ethical issues that could be encountered during the planning and conduct of research activities during conflicts. Unlike the existing guidelines, it does not provide a predetermined set of ethical principles to be universally followed. It rather presents an exploratory systematic approach that could be used to integrate local moral values with those in the literature and the guidelines, depending on the area where it is applied. This project presents only one example of Darfur, whose community may hold moral values different from those in other conflict zones. Nevertheless, the provision of a uniform approach to ethical analysis is expected to help the researchers in such a context in the same way that other 'technical' guidelines assist in the methodological aspects of research in conflicts (Dilley and Boudreau, 2001; ACF International, 2010; Checchi, 2010; Prudhon *et al.*, 2011; Alix-Garcia, Bartlett and Saah, 2012).

The use of qualitative methods, though it produces data not readily generalizable, facilitates an in-depth understanding of the nuances of relevant stakeholders' experiences and opinions. This will help to ensure that the conclusions drawn in this project are not purely abstract (Ives and Draper, 2009)

and are considerate of the stakeholders' views, including those of the conflict-affected researched communities and not only the researchers'.

Finally, this project provides some empirical input into this under-researched area, aiming to develop of a provisional, empirically informed and philosophically argued ethical framework. The integration of these two main components would make the framework not only morally defensible but also practically viable. This provisional framework can be validated, developed and adapted to help governmental and non-governmental institutions and donors in reviewing, undertaking, or funding research in conflict-affected areas that share the features of the conflict in Darfur.

III. SECTION THREE: METHODS

To produce an empirically supported and philosophically robust framework, this project uses multiple methods, building upon a critical review of the related literature, which is then used to develop an ethical argument based on the views of the relevant stakeholders.

The aim of this chapter is to describe and justify the project's initially proposed methods and the changes that were made to them during the project. These changes resulted from two main factors. Some changes were prompted by concerns raised by the University of Birmingham's ethics committee in relation to my personal safety should I have undertaken the fieldwork in Darfur as originally planned. The committee requested to move the fieldwork from Darfur either to another location outside Sudan or to Khartoum, the capital. Working in Khartoum was the better choice methodologically and practically. Other changes were necessary to comply with the preconditions of the National Intelligence and Security Service (NISS) in Sudan (see below) in order to be granted security clearance to access the areas housing the IDPs in Khartoum.

In each of the following sections, I describe and justify the original proposal followed by the changes made, if any. These methodological changes are discussed in Chapter Nine in relation to two dimensions. First, how my empirical project itself became a case study of the issues it aimed to discuss, especially in terms of the practical and ethical considerations in planning and conducting research in conflict-affected settings. Second, what the implications of these changes to my thesis could be.

5 CHAPTER FIVE: STUDY DESIGN AND METHODS

The implementation of this project involved two phases of empirical work, followed by a third and final normative phase. The first phase included two types of review. First, I conducted a review of the literature discussing the ethical aspects pertinent to the conduct of research during armed conflicts (Section II). Second, I conducted a systematic review of the reports resulting from research activities that were undertaken in Darfur (2004–2012) (subsection 5.1.1). The second and the third phases used the qualitative data collection and analysis methods described below.

5.1 Phase I: Literature and Systematic Reviews

The review of the relevant literature is reported in the previous section (see Chapters Two, Three, and Four).

5.1.1 Phase Ia: Systematic Review

A systematic review is an exhaustive review of the literature addressing a clearly defined question, which uses a systematic and explicit methodology to identify, appraise and synthesise all the empirical evidence that meets eligibility criteria that have been pre-specified in order to minimise bias (Abalos et al. 2001; Green et al. 2011).

A systematic review was conducted in the first phase of the project (2013) to explore how the ethical issues are reflected in the reports and manuscripts that report on the health research activities, as defined within this project, conducted in Darfur during the study period.

There are many ethical issues related to the conduct of research that the mainstream research ethics guidelines have considered and set standards for (Hussein, 2015a). For example, to publish a study that involves humans in a peer-reviewed journal, the authors should explicitly state whether consent was given by the participants and whether any of the authors have conflicts of interest. In addition, the authors must state that ethical approval for the execution of the reported study was obtained (International Committee of Medical Journal Editors, 2013). Whether the reports of the studies conducted in Darfur would follow the same standards was not clear. Thus, I focused on only two ethical issues as an easily checkable proxy for a minimal consideration of ethical issues. The first was whether the published reports of the studies that were undertaken in Darfur mentioned that they had obtained ethical approval, and the second was if they mentioned obtaining informed consent from their participants.

These two issues were chosen only as examples of ethical issues that could be encountered in research involving humans during conflicts. Accordingly, the data extraction form was left open to the possibility of other ethical issues being recorded; for example, if the authors of the study disclosed any conflicts of interest or described how privacy or confidentiality was maintained, this could be mentioned in the results. The two examples were chosen because they were expected to be mentioned in the eligible reports. This expectation was based on two main assumptions. First, the main international research ethics guidelines, as well as those of Sudan, unanimously hold that any research that involves humans ought to obtain ethical approval (Nilstun, 1994) (for example, Guidelines 2 and 20 in the Declaration of Helsinki (World Medical Association, 2014); Common Rule,

subpart A, especially articles 46.107, 46.108 and 46.109 (U.S. Department of Health and Human Services and Office for Human Research Protections, 2009)), and that research participants should give voluntary informed consent (for example CIOMS General principles, guidelines 4–6 (Council for International Organizations of Medical Sciences and World Health Organization, 2016)). These requirements are meant to be followed regardless of whether the researcher intends to publish the research in a scientific journal. Second, these two issues are among the main requirements for publication of research that involves humans in medical journals (International Committee of Medical Journal Editors, 2013). Therefore, it is reasonable to expect them to be mentioned more often than other issues.

5.1.2 Selection criteria and literature search

This systematic review (SR) sought to include all studies published between 2004 and 2012 that involved the collection of human personal data and/or biosamples from the people of Darfur within or outside Darfur. Human personal data refers to any kind of information that could be used to identify a person or information pertaining to a person's health-related conditions. These data include but are not limited to name, age, sex, address, and contact information. Biosamples refer to any human biological sample taken from Darfuri persons for purposes not solely related to their care, including but not limited to samples of tissue, blood, urine, and stool.

The SR included two main sources. The first was the reports that were publicly available online of the eligible studies published within the study period in

English and/or Arabic with no limit to the participants' group or the study methodology. The second were the results of a hand search of the hardcopies of the reports of the health-related studies conducted in Darfur during the study period archived in the CRED. The CRED's archive contains the reports of studies undertaken during disasters worldwide. These reports are received from the INGOs responding to the disasters (Degomme and Guha-Sapir, 2007) and include studies conducted in Darfur during the relevant time period.

5.1.3 Hand search of the CRED's archive

The purpose of the hand search was to complement and validate the findings of the online systematic review. It involved a hand search of the reports of the studies that met the inclusion criteria for the online systematic review but were only available offline. The hand search was meant to complement the online search in case some reports were only available in hardcopy. It is also reasonable to believe that the hardcopies of the full reports may have included details about ethical issues not mentioned in the published reports and manuscripts available online, which are usually limited by word counts.

Originally, this manual review was planned to be conducted at the offices of selected INGOs in Khartoum. The relevant INGOs would be selected based on the results of the online SR. The INGOs with the highest number of eligible retrievable studies in the SR would be selected as subjects for the desk review. This phase was dependent upon whether the selected INGOs would grant access to these reports, which was sought in the preparatory visit to Khartoum.

This part of the study was done differently than planned in terms of location and representativeness. The hand search of the eligible studies was done at the CRED in Brussels, not at the INGOs' offices in Khartoum. Furthermore, the original plan aimed to achieve representativeness by considering a sample of research reports in proportion to those found in the SR. However, the CRED search included all the available eligible reports on Darfur in CRED's archive. It included not only all the reports but also the studies' protocols shared by the INGOs who worked in Darfur at any point between 2004 and 2012.

Shifting the desk review from Khartoum to the CRED was justified by three main reasons. First, it was more inclusive to search for the reports of various organisations in one place. Second, the CRED's archive includes reports from the 13 INGOs that were expelled from Sudan in 2008, which would not have been available if the search were done in Khartoum. Finally, it was more representative of the targeted reports, given that the search in Khartoum would have been proportional to the NGO's share in the online search. The hand search of the CRED archive granted access to all the available reports of all the NGOs that had worked in Darfur within the study period. Likewise, if the desk review had been done in Khartoum, it would have represented only the organisations that agreed to participate.¹⁶ Any mention of ethical issues found in the desk review was reported in the form and was used to inform later phases of the project, mainly the interviews and the FGDs.

¹⁶ This proved to be a safer option given that two main UN agencies (WHO and UNICEF) refused to participate in the project as will be detailed in the results (Chapter Eight).

The study period was chosen with the aim of capturing all studies undertaken from the beginning of the influx of international aid agencies to Darfur in 2004, with the end of 2012 being the point at which it is reasonable to assume that any studies that had been completed would have been published¹⁷. Table 5-1 summarises the eligibility criteria for inclusion in this SR.

Table 5-1: Eligibility criteria used for screening, inclusion and exclusion of studies

	Included	Excluded
Topic	Any study that addressed any topic related to the health of the people of Darfur and involved the collection of personal data and/or biosamples from its participants was included, provided its full report or manuscript was retrievable from the online search and/or the CRED archive.	News, updates, political documents and retrospective studies analysing secondary data only
Types of studies and data items	Surveys, assessments, evaluations, situation reports and any study type that included the collection of personal data and/or biosamples directly from the participants or through reviewing records that contained their identifiable personal data	Infographics, manuals and guidelines, maps, news and press releases, and UN documents (e.g. legal documents and UN Security Council resolutions)
Types of participants	Darfuri people who were affected by the armed conflict, whether living inside or outside Darfur at the time of the study, whether IDPs, refugees or affected host communities	Studies on NGOs' or GoS' staff, general non-Darfur community, and studies on non-human participants
Types of interventions	Any study that was carried out on Darfuri persons during the study period, whether aimed at assessing the humanitarian impact of the crisis or not and regardless of whether it had a section or a statement on ethical review, ethical guidelines or consent	Studies that aimed at environmental or animal-related interventions
Settings	Any setting in which those affected by the Darfur conflict could be found, including but not	Any armed conflict

¹⁷ The systematic review was conducted in 2013, the second year of the PhD.

	Included	Excluded
	limited to IDPs, refugee camps, and host communities	setting outside Darfur
Types of publications and publication status	Any full report or manuscript that was retrievable from the online search or the CRED archive and published between 2004 and 2012 about findings from research that involved the collection of personal data and/or biosamples regardless of the purpose, the methodology, or the place of publication	Abstracts only, summary only reports, incomplete or inaccessible articles or reports, conference proceedings, meta-analyses, and reports on other activities that do not include the collection of human data and/or biosamples
Language of publication	English and Arabic	Reports published in any language other than English and Arabic
Publication date	1-1-2004 until 31-12-2012	Reports published before 1-1-2004 or after 31-12-2012

5.1.4 The search terms

The search terms that were used for the online search included a combination of Medical Subject Headings (MeSH) terms, free text, and synonyms to capture as many of the relevant publications as possible. The search terms that were used were: “Humanitarian aid”, “Assessment”, “Surveys”, “Nutrition”*, “Darfur”, “Sudan”, “Refugees”, “Camps”, “Internally displaced persons (IDPs)”, “Child*”, “United Nations”, “Non-Governmental Organisation”, “Ethics Committees”, “ethic”*, and “Informed Consent”.

The online search included two main search areas (Figure 7-1). Firstly, operational and humanitarian-related studies were retrieved from the Complex Emergency Database (CEDAT, <http://cedat.be/>), which is managed by the CRED (ReliefWeb, 2013). The CEDAT provides key humanitarian indicators from humanitarian studies but does not offer the full text of their reports. The full text of the eligible studies was then searched for in ReliefWeb (<http://reliefweb.int>), which is a specialised digital service of the UN Office for the Coordination of Humanitarian Affairs (OCHA). If the full text was not found on ReliefWeb, other sources were sought (Table 5-2). Secondly, the clinical and non-epidemiological studies were searched for in PubMed, Biomedcentral, and Google Scholar.

Table 5-2: Sources of specialised search to retrieve full-text reports or manuscripts when not found in ReliefWeb

-
- a. United Nations Sudan Information Gateway (UNSIG): <http://www.unsudanig.org> has published weekly 'Humanitarian Action in Darfur' reports since 2006,
 - b. WHO's IRIS (World Health Organisation Institutional Repository for Information Sharing): <http://apps.who.int/iris/>
 - c. MSF field research database: <http://fieldresearch.msf.org/msf/>
 - d. Google Scholar
-

The main source of the full-text reports for the screened studies was ReliefWeb (<http://reliefweb.int>); where the full report was not available, the websites of the respective humanitarian organisations were searched. Google Scholar was the main source of grey literature.

For the CRED archive search, I reviewed the database of titles that was provided by CRED and all eligible studies with full reports were included.

Each of the eligible studies, whether found online or in the CRED archive was appraised based on two main indicators: whether there was mention of

obtaining ethical approval and whether there was mention of obtaining informed consent from the participants.

5.1.5 Data extraction

Data extraction was conducted using two pre-designed data extraction forms: a form for the entry of the online reports (<http://www.tfaforms.com/271050>) and another for the entry of CRED reports (<http://www.tfaforms.com/347693>). Both forms were piloted on a sample of studies and then modified to improve their ability to capture as many relevant details of the included studies as possible. The review depended mainly on the information available in the published versions of the eligible manuscript/report. However, where possible I attempted to contact the authors of the eligible reports when contact information was available from the published report or from internet search engines to fill in an online form (<http://www.tfaforms.com/315475>).

5.1.6 Assessment of risk of bias in included studies

Two potential reporting biases may have accompanied this systematic review: publication bias and access bias. In terms of publication bias, the included studies were likely to have been intended to meet humanitarian needs and were not usually prepared for academic purposes. Thus, these data/biosample collection activities are often not reported in the standard format for reporting research studies. Accordingly, the surveying agencies might not follow the standard requirements for publication in peer-reviewed journals, including the requirement to mention having obtained ethical approval or informed consent from

participants. This bias was addressed by contacting the authors of the included studies where possible to cross-check whether the included study had received formal ethical approval and, if not, to explain the reasons for not having received approval.

Second, access bias could result from the availability of some of the eligible studies on subscription-based databases that required institutional affiliation that I did not have. This bias was addressed by searching in multiple sources, including hand searching. For example, only 68 studies were found in the online search, while the hand search in the CRED archive included 138 additional studies.

5.1.7 Phase Ib: Data collection form for authors of the reports retrieved in the systematic review

Following the first phase of the online systematic review, I emailed the authors of the eligible reports when their emails were available from the published report or from internet search engines. I asked them to fill in a data collection form (Appendix 11). I contacted them to cross-check the findings from the reports published online and to seek clarification regarding these findings. For example, if an eligible report did not mention that an ethical review was undergone, the author of that report was asked to confirm whether an ethical review was not originally sought or whether it was sought but was not mentioned in the published report. In the hypothetical case of a discrepancy between the review's findings and the author's input, then the author's answer would replace that of the review. For instance, if a report did not mention obtaining ethical approval, but the author mentioned that approval was obtained, I would correct the data collection from

“not mentioned” to “mentioned”. Additionally, the authors were given the chance to elaborate on their perceptions regarding the two main ethical issues included in the review (ethical approval and informed consent) in the data collection form.

The results and a partial discussion of the systematic review are presented separately in Chapter 7.

5.2 Phase II: Fieldwork

Given that the overall research question of the thesis focuses on *how* research involving humans undertaken during armed conflicts ought to be ethically guided, qualitative research methods seemed to be most relevant to answer it. The purpose of the fieldwork phase of the project was to describe the research ethics practices during the study period and how they could have been affected and perhaps explained by the conflict setting in Darfur. This description was gained from those involved in these practices as researchers or as research participants within a qualitative case study.

Qualitative case study methodology provides tools for researchers to study complex phenomena within their contexts. When the approach is used sensitively, it is a valuable method for health science research to develop theory, evaluate programs, and develop interventions.

Therefore, a qualitative case study method was chosen, as it “facilitates exploration of a phenomenon within its context using a variety of data sources, which allows for multiple facets of the phenomenon to be revealed and understood” (Baxter and Jack, 2008, p. 544). In addition, this project fulfilled all the

criteria that Baxter and Jack suggest, following Yin (Yin, 2009), as relevant when using a qualitative case study design. These criteria include:

“(a) the focus of the study is to answer “how” and “why” questions; (b) you cannot manipulate the behaviour of those involved in the study; (c) you want to cover contextual conditions because you believe they are relevant to the phenomenon under study; or (d) the boundaries are not clear between the phenomenon and context” (Baxter and Jack, 2008).

These criteria apply to this project, as it aimed to understand the role that the conflict context played in the research practices, and the boundaries between the conflict context and the research practices were not clear.

Yin (2009) has suggested two models for qualitative case studies: single case and multiple cases. The single case study is appropriate where it represents a critical or extreme or unique case, while multiple-case designs allow cross-case analysis and comparisons between diverse settings (Yin, 2009).

Yin has also suggested that the use of multiple data sources is a good strategy because it enhances data credibility. The data sources included in this phase targeted participants who represented the three main categories involved in research in Darfur during the relevant study period (Figure 5-1). These categories include: 1) the researchers, who were either independent researchers, or affiliated with a governmental entity, or affiliated to a national or international NGO, 2) the researched Darfuri communities including IDP and host communities (refugees were excluded because the project targeted Darfuri population in Sudan only), and 3) Sudanese authorities responsible for the governance of research and

humanitarian work in Sudan. Their number and profile will be discussed in detail in (subsection 8-3).

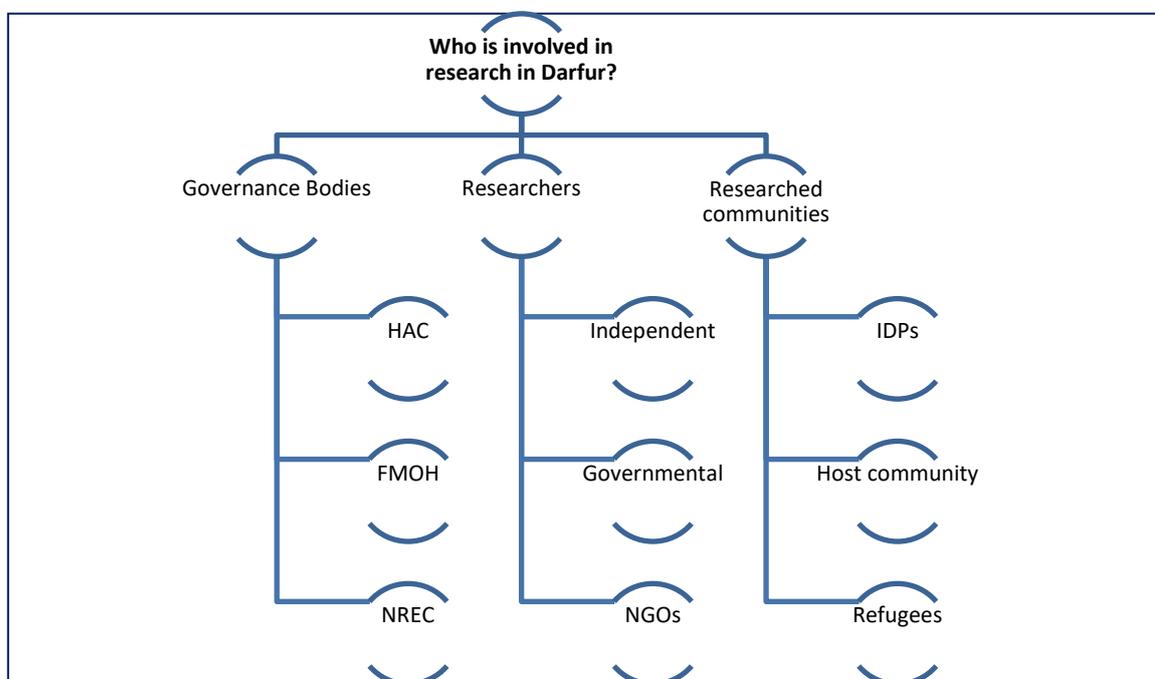


Figure 5-1 The main categories of stakeholders in the research activities in Darfur. HAC: Humanitarian Aid Commission; FMOH: Federal Ministry of Health; NREC: National Research Ethics Committee; NGOs: Non-governmental Organisations; IDPs: Internally Displaced Persons

5.2.1 Semi-structured interviews

Semi-structured interviews are typically organised around a set of predetermined open-ended questions, with other questions emerging from the dialogue between the interviewer and the interviewee to obtain richer descriptions of phenomena being studied. Other qualitative interviewing approaches include structured and unstructured interviews. These were excluded, as the structured interview aims at producing quantitative data, while the unstructured interview is

more relevant to observational anthropological studies (DiCicco-Bloom *et al.*, 2006).

Semi-structured individual face-to-face in-depth interviews were conducted with representatives of the INGOs, the Humanitarian Aid Commission (HAC), the department of research at the FMOH in Sudan, and the chairperson of the NREC. These individuals were selected for their roles in the preparation, coordination, or review of research or humanitarian activities within their respective institutions.

Given that there are more than 100 NGOs working in Darfur, I planned to select the INGOs that had undertaken the most research activities in Darfur during the study period as determined by the results of the systematic review described earlier. If an INGO refused to participate in the study, it was replaced with the INGO following it in terms of the extent of their research activity in Darfur, whilst maintaining the representativeness of the selected INGOs. For example, if the organisation that refused was a UN Specialised Agency, it was replaced by another UN Specialised Agency.

The interview questions (Appendices 1 and 2) were designed, following Patton, to be open-ended, neutral, sensitive, and clear to the interviewee (Patton, 1987). The plan was to conduct a sufficient number of semi-structured interviews to reach “theoretical saturation”. This is defined by Glaser and Strauss (1967) as the point at which “no additional data are being found whereby the (researcher) can develop properties of the category” and the “researcher becomes empirically confident that a category is saturated” (Glaser and Strauss, 1967, p. 65).

All the interviews took place in the interviewees' offices in Khartoum and were recorded using a digital audio recorder. Data are stored according to the University of Birmingham Code of Research Practice for a period of 10 years following the completion of the project (University of Birmingham, 2016). I conducted, transcribed and translated all the interviews.

Written field notes were also taken. These notes were used as an aid to make the later transcription of the audio records more complete. I have integrated many of these notes within the transcripts shared with my supervisors to help them assess the precision of the transcripts.

5.2.2 Focus group discussions (FGDs)

Focus group discussions are a form of structured, attentively moderated group interview that capitalises on (usually spoken) communication between research participants to generate data, instead of the researcher asking each person to respond to a question in turn. This method reveals the participants' conscious preferences, recalled experiences, and stated priorities (Kitzinger, 1995; Kuniavsky, 2003). Focus group discussions furthered the aim of this project by providing "an environment where people (ideally) feel comfortable revealing their thoughts and feelings and sharing their views of the issues and assumptions that lie at the core of an experience and to relate them to real-world situations" (Goodman, Kuniavsky and Moed, 2013). In relation to this project, these core experiences of the researchers and the individuals from the researched communities were integral to understanding the practice of research within the

context of conflict and highlighting their expectations of any future changes in this practice.

Focus group discussions were planned with two groups of participants. The first group included the NGO representatives who were responsible for the preparation and/or the undertaking of the research activities in Darfur, to explore their experiences with issues related to their research activities that they considered to have ethical implications. The second group included representatives of the Darfuri communities in which the research activities took place, who were mainly IDPs. “Community representativeness” refers only to demographic representativeness and not the representativeness of views, which could differ across Darfuri regions. The access I was granted was limited to certain areas in Khartoum, whose IDPs may not reflect the wider demographic variability in Darfur.

I initially aimed for one FGD for each of the two groups (the NGOs and the IDPs) in each of the three states of Darfur, for a total of six FGDs, with at least one of the researched-community FGDs devoted to women only. However, moving the study area from Darfur to Khartoum meant that all FGDs were held in Khartoum. The characteristics of the participants are reported in Section Five.

The FGDs were not designed to collect factual information about participants’ personal involvement in research, which could be significantly affected by recall bias (given the long period covered by the project). Rather, they were designed to encourage participants to share their perceptions about how research activities ought to be conducted, regardless of their previous participation in similar

research. Therefore, prior participation in research conducted in Darfur was not a prerequisite to participate in the IDPs' FGDs.

Given the complexity of the setting in which the data were collected; an initial period of extensive preparation with the relevant stakeholders was needed. In addition, the help of two female research assistants (RAs) was needed for the facilitation of the women's FGDs. The RAs were chosen based on having previous experience in conducting qualitative studies and having previously facilitated FGDs with women. Both RAs had experience of working on qualitative studies with the Darfuri population. The following section describes the facilitation of the FGDs.

5.2.3 Focus group discussions with internally displaced persons

The location of the FGDs with the IDPs had to be changed twice. Originally, the FGDs were planned to involve the Darfuri IDPs who had lived in a camp in Darfur, but the location was moved to the IDP camps in Khartoum. The revised plan was to conduct four FGDs in four main IDP camps in Khartoum, with at least one of these devoted to women only. This was further revised at the request of the NISS officers (see below), and I was only granted access to one specific geographical area in Khartoum.

The government of Sudan (GoS) does not officially acknowledge the presence of any IDP camps in Khartoum. Accordingly, the NGOs, whether national or international, were not active in these areas, despite the presence of IDPs. Therefore, the area that I was granted access to was not a camp in name or in structure. The people were living in brick houses that had been temporarily

abandoned by their owners, who were mostly living abroad. They were permitted to live in them temporarily until the owners returned, or until they could return to Darfur.

5.2.4 Obtaining security clearance to access IDP areas

Unlike in Darfur, where many organisations work regularly in the IDP camps and have been granted access to almost all of them, obtaining access to the Darfuri population in Khartoum was more complicated.

I had already secured ethical approval from the NREC in the preparatory visit to Khartoum prior to applying to the University's ethics committee. However, when I informed the NREC of the University's request to move the study site from Darfur to Khartoum, they asked that I apply for another ethical approval from the Khartoum State Ethics Committee (KSEC). The KSEC exempted me from a resubmission, stating that I did not need to repeat the same process that had already been completed by the national committee. Similarly, the initial approval of the federal HAC, which I had secured earlier, was revoked. I was then referred to the Khartoum State HAC (KSHAC), because the work had moved from Darfur to Khartoum. The KSHAC approved the technical aspects of the project. The project also needed approval from the NISS, which asked for some requirements to obtain security clearance. These requirements included my CV and the topic guides.¹⁸ After submitting the required documents, they asked me to come to the

¹⁸ The responsible NISS officer did not accept the topic guide for the FGD, stating that "there is no such thing as focus groups; we need questionnaire with clear choices". In response I sent the facilitator's guide that had some prompts and 'choices' to be used in the FGD, if needed.

NISS headquarters, for what was an hour-long interrogation-like meeting (Appendix 9) by the security officer responsible for foreign organisations.

5.2.5 Focus group discussions with NGO representatives

Originally, one FGD was planned to include six to eight NGO staff involved in the organisation and implementation of research activities involving the Darfuri population. The targeted NGO staff would be informed about this project by the head office of the NGO in Khartoum, which would also send them a copy of the information sheets, informed consent forms, and invitation letters. Those who agreed to participate in the FGD would have been asked to contact me directly via email.

This plan was adapted to accommodate an unexpected reluctance and refusal on the part of NGOs who had initially agreed to be interviewed in the preparatory visit and then changed their position in the data collection phase. I had to rely more on the FGDs to compensate for the smaller number of interviews. In Chapter Eight, I describe the profile of those who participated.

In contrast to the response to the invitation to be interviewed, the invitation to participate in FGDs was well received. A total of 34 NGO staff agreed to take part. I divided them into three FGDs, each consisting of 10-12 participants. I facilitated one group, while the two female RAs facilitated the other two. Participants were informed about the nature of this study and the FGD through the information sheet. They had an opportunity to ask questions. The FGD facilitators emphasised that the participants had to keep whatever information was shared in the FGD strictly confidential.

5.2.6 How do the empirical findings inform the philosophical analysis

To answer this question, I believe two points need to be clarified and briefly outlined. First, it must be justified why an empirical bioethics approach is needed to answer this project's research questions. Second, it must be explained how the empirical findings will inform the normative philosophical analysis.

As mentioned earlier, this project combines the collection and analysis of empirical data with philosophical normative analysis. This combination is the main component of empirical bioethics (Dunn *et al.*, 2012), which seeks, as Ives (2008) suggests, to develop “ways of contextualising philosophical moral theorising, and locating it within a discourse that draws on empirical data (generally qualitative) and moral theory” (Ives, 2008, p. 1).

The use of empirical bioethics fulfils the two main requirements for empirical bioethics suggested by Dunn *et al.* (2012), namely justification and practicality (Dunn *et al.*, 2012). Justification will be provided by discussing the philosophical arguments, whereas the empirical findings are used as evidence to argue for (or against) the practicality of the philosophical justifications. The overall vision is to provide a contextual integration for the normative arguments, without which it will not be possible to “ascertain whether interventions predicated on a particular argument [...] bring about the changes to practice that cohere with the account of the good in the requisite claim” (Dunn *et al.*, 2012, p. 468).

In practical terms, any planning for more comprehensive ethical guidance requires an understanding of the current practices as seen by those who practice

them. The empirical data help to “uncover the normative assumptions and values that lie behind practice and belief” (Ives, 2008) to inform the ethical reasoning. Policies developed without adequate consideration of the views of those affected by them and apart from the contextual realities within which they apply are less likely to be followed.

The use of an empirical bioethics project provides more components to be considered when approaching the normative research questions of this project, which include the established theories that have informed (and sometimes formed) mainstream ethical guidance in healthcare and research, along with a reflective interpretation of the communities within which these theories should apply.

Additionally, using an empirical project helps in achieving the four main goals suggested by Musschenga (2005) to introduce empirical research into practical ethics (Musschenga *et al.*, 2005, p. 469):

1. *Description and analysis of the actual conduct of a group with respect to a morally relevant issue;*

The systematic review provides a description of the current practice of ethical review and obtaining consent for studies conducted in Darfur. Later, the qualitative study provides further analysis of the findings of the systematic review.

2. *Identification of moral issues that escaped the attention of ethicists, but are relevant in a specific context;*

Though the moral issues raised in this project are not new, nor have they necessarily escaped the attention of ethicists, the empirical project should help in

gaining a better understanding of the participants' moral experiences. Audi (1998) suggests that moral experiences "might be a ladder to understanding moral principles, but not their epistemic or ontic foundation" (Audi, 1998, p. 364).

Moreover, the empirical findings are essential for developing an empirically informed argument. In this thesis, the empirical findings are qualitatively analyzed and categorized into themes that form the basis of the discussion, which may either support or counter the philosophical arguments upon which the conclusions of this project are based.

3. *Description and analysis of the cultural and institutional aspects of a context or practice – procedures, processes, nature of the relations between subjects, their beliefs, attitudes, and so on – relevant for evaluating the practicality of ethical guidelines and principles;*

The empirical project provides an in-depth description of the organizational and societal structures that could explain the participants' moral positions. Most of the discussion is based on the empirical findings, which would have been inaccessible without an empirical project.

4. *Description and analysis of the actual moral opinions and reasoning patterns of those involved in a practice.*

The empirical project aims to explore areas that would have been overlooked by a purely theoretical/philosophical study. It particularly aims to study how the community dynamics, along with the socio-political context, could affect the moral views of the participants (governance bodies, the NGOs, and the IDPs).

Based on my knowledge of empirical bioethics, I use an empirical bioethics approach in which the findings from both the systemic review and the fieldwork are integrated to provide a robust discussion of how the studies conducted in Darfur were and ought to be ethically guided. This integrated discussion is based on the discussion of the participants' views on how to define "research", the appropriateness of the mainstream international ethical guidelines to research conducted in Darfur, and finally the participants' views of how research ought to be ethically guided.

The use of the empirical findings to inform the philosophical analysis is guided by the methodological framework presented by Frith (2012), which consists of four elements: (Frith, 2012, pp. 201–204)

1- Setting out the circumstances;

The empirical findings, along with the relevant literature, are used to map the conceptual boundaries of this project, where the project's participants specify which humanitarian activities ought to be ethically guided and what characteristics such an ethical oversight should contain. This use of empirical findings will help in providing "a full description of a problem, area, dilemma, and the circumstances in which it is located", like "examining the social context of bioethical issues or problems".

2- Specifying theories and principles;

Every set of research ethics guidelines provides ethical principles that ought to be followed for research to be deemed ethical. However, these ethical principles

are usually mentioned in a general abstract form. The empirical findings are specifically used to reflect the participants' understandings and interpretations of these principles. Moreover, the empirical project is designed in such a way that participants are able to provide their own set of principles. This exploration is essential to ensure the translation of the ethical principles into workable, practical, and feasible rules, as many authors have concluded (van Delden and van Thiel, 1998; Musschenga, 1999; Ives *et al.*, 2008; Kon, 2009).

3- Using ethical theory as a tool of analysis; theory building;

Frith suggests that “theory can be used to approach the data and it can also arise from the data itself [...] theory interprets data and data interprets theory – and the two processes can occur in the same study” (Frith, 2012, p. 203). In this view, theory and practice are in a symbiotic relationship, rather than a linear one. In this project, this symbiotic relationship between the theory, represented by the research ethics guidelines, and the data, in the form of the participants' views, is framed to reach a set of coherent and viable moral views. These views are not based on the passive acceptance of the participants' views as being morally right only because they endorse them, nor do they follow the mainstream by using the guidelines as ‘ethico-meters’ or ‘moral scales’ on which the participants' beliefs and practices ought to be measured.

To achieve this coherence, I try to maintain a state of conceptual openness to three possibilities for each finding of the empirical project. Either the participants' views could be more consistent, coherent and grounded than the mainstream guidelines; or the mainstream view is sounder and more coherent

than those of the participants; or, finally, a new standard/principle is needed. The final option applies when the participants express their views about an ethical issue that is not mentioned or sufficiently addressed in the relevant literature. Here, I argue, it becomes the role of the researcher to elaborate on the participants' views and add the required normative components when needed to make the findings presentable and consistent with the overall presented arguments.

4- Making normative judgments:

The empirical findings are used to provide a “description of the problem [...] to produce a defensible (on the basis of reason and argument) solution or recommendation” (Frith, 2012, p. 204).

To achieve this, I use what I refer to as “mutual scepticism”, where neither the theory nor the practice is given any form of moral superiority or philosophical immunity. Both the guidelines and the participants' views, should they turn out to be different, will be exposed to the same level of scrutiny. What is required, as Hughes (2001) cited in Frith (2012) suggests, “is a careful justification of how the decision was reached” (Frith, 2012, p. 204). Eventually, the arguments that are accepted as the most sensible, morally speaking will be relied on to justify any call to make the necessary changes to operationalize and materialize these changes.

This approach aims to reduce the potential risk of subjectivity associated with this type of study and helps in achieving the aim of producing a coherent, philosophically robust, evidence-informed framework that is normatively sound, socially acceptable and practically feasible.

Overall, the two main components explored using empirical bioethics in this project, the theory and the community of practice, are presented and discussed as complementary rather than exclusive from each other. In effect, I try to maintain what Jennings and Dawson (2015) call “a critical distance from the given, to think reality otherwise” (Jennings and Dawson, 2015, p. 31). Coherence sought by using this approach is not a one-way (bottom-up or outside-in) route; it is rather a dynamic process through which and within which various elements are kept, removed, or added (De Vries and Van Leeuwen, 2010).

This empirical approach is reflected in the qualitative analysis through the systematic and consistent use of quotes to support the discussion of the empirical findings. I use a combination of the empirical findings and the philosophical analysis as the backbone for the development of the overall proposition of this project. In this way, the empirical findings do not only help in but are also essential for answering the normative questions of the project.

6 CHAPTER SIX: SAMPLING, STUDY PROCEDURE AND RECRUITMENT

6.1 Background

This chapter describes the phases of the thesis, the empirical project design and data collection methods and how the challenges faced in the study's fieldwork led to changes in the intended plan (Figure 6-1).

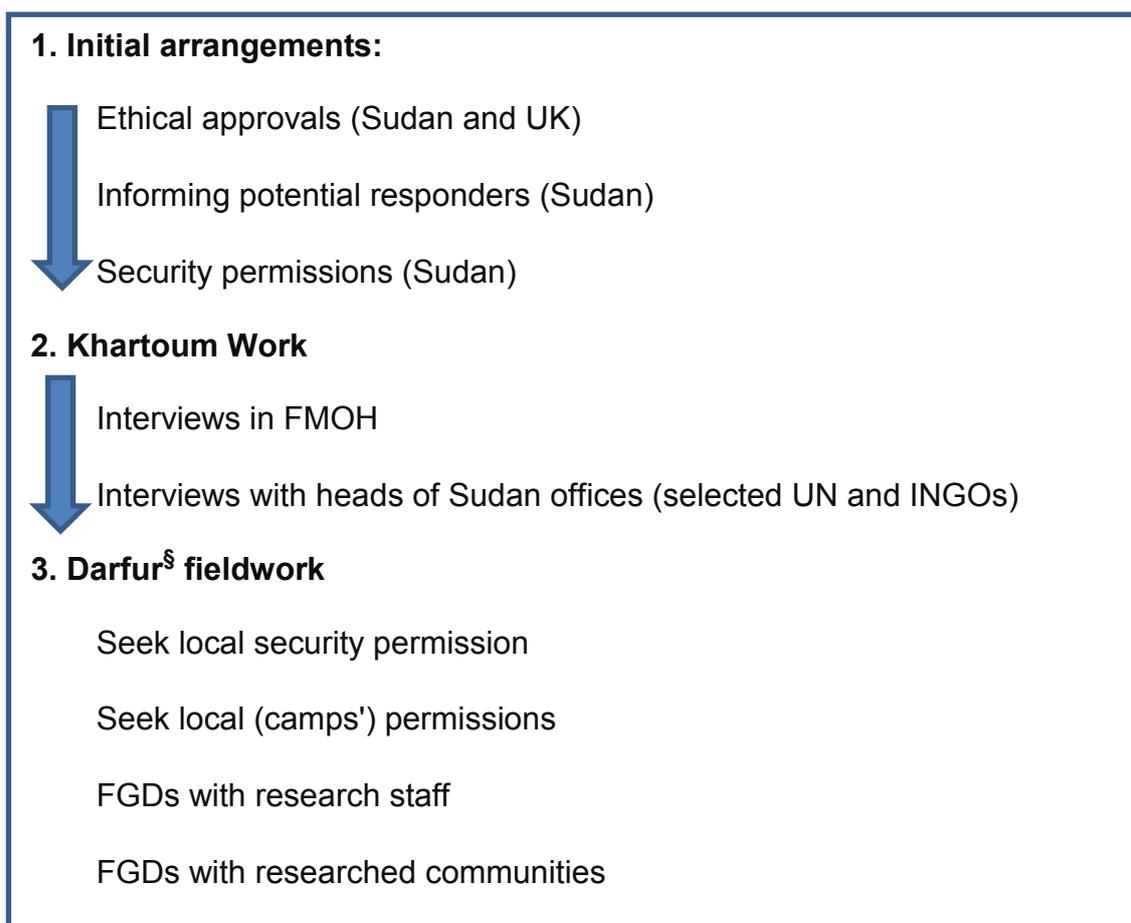


Figure 6-1: Planned flow of study procedures in fieldwork.

[§]This was changed later as requested by the University's ethics committee (subsection 5.2)

6.2 Sampling

To achieve the aim of gaining an in-depth qualitative understanding of the participants' views on the ethical issues related to research, a qualitative purposeful sampling technique was used (Coyne, 1997). Purposeful sampling is a

qualitative sampling strategy in which “the researcher actively selects the most productive sample to answer the research question [...] based on the researcher's practical knowledge of the research area, the available literature and evidence from the study itself” (Marshall, 1996, p. 522). These criteria were used to determine those sampled in the qualitative project through the following:

- 1) My previous experience in undertaking and supervising some research activities in the three states of Darfur, which made me aware of the humanitarian setup and whom I expected productive potential informants to be;

- 2) The available literature, along with the findings of the systematic review conducted in the first phase of the project; and

- 3) The data as they were being collected in the fieldwork; if, for example, one of the interviewees suggested including another useful resource person(s), or assigned other more experienced staff in his/her institution to be interviewed.

Purposeful sampling was used in this project because it helps in selecting what Patton describes as information-rich cases from which “one can learn a great deal about issues of central importance to the purpose of the research” (Patton, 1990, p. 196).

Along with purposeful sampling, I also used theoretical sampling, which Coyne defines as “the process of data collection whereby the researcher

simultaneously collects, codes and analyses the data in order to decide what data to collect next” (Coyne, 1997, p. 625).

Theoretical sampling serves the iterative process of qualitative study by making the samples theory-driven, i.e. building interpretative theories from the emerging data and selecting a new sample to examine and elaborate on this theory (Marshall, 1996). In this project, theoretical sampling was used to inform further data collection, which led to the recruitment of other participants from within the three specified categories of participants (i.e. the researchers, the researched, and the research authorities) who were not included in the purposeful sampling. For instance, during an interview with a representative of a governmental body, she mentioned a university whose staff and master’s students sought permission to conduct research with IDPs. I tried to approach the university’s master’s coordinator but she was not available at the time of the fieldwork.

It should be noted that this project did not use quantitative sampling for theoretical and practical reasons. Theoretically, though statistical representativeness can be helpful in social studies, it is not a primary requirement in order to understand social processes (Mays and Pope, 1995). The focus of this project is on ‘why’ and ‘how’ questions. These questions are answered by exploring beliefs and values, which are not normally distributed among members of the study population. Some participants are richer informants than others (Marshall, 1996), depending on a number of variables not uniformly distributed among the target population.

I should also acknowledge that the sampling was limited by the ethical and security approvals I received (subsection 11.2).

6.3 Recruitment and procedures

In terms of recruitment, participants can be divided into two categories, namely individuals and institutions. The individuals are those targeted for their individual identity. These included the independent authors (i.e. the researchers who were not affiliated with any governmental or non-governmental entity inside Sudan when conducting their research in Darfur) and the IDPs. The institutional representatives included those recruited for their affiliation to an institution, namely NGOs (both national and international), and the bodies responsible for the regulation of humanitarian and research activities in Sudan.

The recruitment strategies that I used in the different phases of the project can be also divided into two categories, namely direct and indirect contact (Table 6-1).

Table 6-1: Description of recruitment strategies used in this project and those targeted by each strategy

	Direct contact	Indirect contact
Description of strategy	Those for whom I could find contact information in the public domain and could thus contact directly without the need for prior permission	Those whose contact information was only available or who could only be contacted through another person(s)
Targeted participants	Independent authors	INGO staff
	Directors of the INGOs	Directors and staff of NNGOs
	Directors of the humanitarian and research regulatory bodies	Darfur community representatives (IDPs)

6.3.1 Direct contact

- **Independent authors**

Independent authors were identified from their names on the reports/manuscripts included in the systematic review. They were contacted by email using addresses available in these publications and asked to complete a data collection form, which was available online, as the authors were in various countries. If an author did not provide their contact information in the publication, the website of their affiliated institution was searched for an email address. I sent the authors the project's participant information sheet and an invitation to participate by email. Reminders were sent to those who did not respond within two weeks of the initial invitation.

This strategy did not seem to be very effective. Of the 120 authors who were emailed, only 15 responded, of whom 7 completed the data collection form. The other 8 explained that they had not completed the form either because they thought their work did not involve the collection of human data or samples (five respondents), or they considered their role as 'supervisory' or 'peripheral' (three respondents).

Despite this low response rate, this strategy led to an important addition to the project. One of the respondents suggested and facilitated my visit to the Centre for Research and Epidemiology of Disasters (CRED) in Brussels, where I could access hard copies of the reports on research conducted in Darfur that were not accessible online.

- **Governmental humanitarian and research regulatory bodies**

Humanitarian and research activities in Sudan are overseen by the HAC and the National Research Department at the FMOH, respectively.

The director of each institution was identified by visiting the respective department/body. After identifying the relevant individual, a participant information sheet and an invitation to participate were sent to his/her office. Both directors were given the option of nominating a member of staff to be interviewed rather than being interviewed themselves if they thought this was more appropriate.

- **Directors and heads of mission of the INGOs**

I targeted the UN Specialised Agencies and the NGOs that had undertaken the greatest volume of research, as identified in the systematic review. The director of each of the selected UN agencies or INGOs was identified through the agency's or INGO's website and then sent the participant information and an invitation to take part.

The success of this approach seemed to have depended on the ability to talk directly to one of the technical staff (i.e. not the administrative and the security staff). The UN agencies in Sudan have complicated security checks. No one can go beyond the reception desk unless there is a specific person waiting for him/her. I did not have personal contacts with many of these agencies. I therefore had to deliver the participant documents to the reception or the post office. Given the short time available for data collection, I had to (re)visit each of the agencies that did not respond within a week of the initial invitation, seeking an update every 7-10

days. It took an average of five visits to each UN agency to progress to an invitation. Out of the three high-security UN agencies, one refused to participate without giving reasons, and the other two did not respond.

Generally, apart from the exceptions mentioned above, this recruitment method was quite unsuccessful, and was certainly the least efficient, being ineffective when compared to the intensive labour required.

6.3.2 Indirect contact

6.3.3 NGO representatives

Given the slow pace of response and the few yet important refusals to participate, I had to rely more on the focus groups to compensate for the lack of participation in the interviews. This adaptation of the method was facilitated by the support of the health coordinator of the HAC. She facilitated the contact with the main NGOs that attend the monthly health cluster meeting. Afterwards, I sent these NGOs SMSs to introduce myself, explaining how I had obtained the number and why I had sent the message. Those who responded were given more information about the study and were offered participant information sheets to read. This process resulted in more than 30 staff of UN agencies, INGOS, or NNGOs agreeing to attend the FGDs. A date and time convenient to the majority of these participants were chosen and 34 participants were recruited from FMOH, HAC, INGOS, NNGOs, and UN agencies (see Chapter Eight).

The FGDs were conducted in workshop style, with the participants divided into three groups meeting simultaneously, each with one facilitator and co-

facilitator in a separate room in one of the FMOH training centres. The facilitators and co-facilitators were FMOH staff with experience in qualitative methods, whom I had trained using the discussion guide and informed about related issues, including gaining the participants' consent and respect for confidentiality.

6.3.4 Darfur community representatives

The recruitment of representatives of the Darfuri community required passing through several sets of gatekeepers. In addition to the official approvals (see 1.2.2 above), I had to obtain the approval of the 'community leader' to access the community and for help with identifying potential participants. He gave repeated hints that 'these people have needs' and if I wanted their collaboration, I would have to meet some of these. I was clear about this point with him and later with the IDPs, indicating that I was a researcher, not a humanitarian aid worker, and that I was not affiliated with any humanitarian agency. Perhaps the presence of the HAC representative, which was a condition for the security approval, raised their expectations. The accompanying HAC staff member reiterated my position. He offered to listen to their needs and promised to do his best to help them, regardless of their contribution to my study.

The community leader approached the heads of the households (all men), who agreed to receive more information about the project. I gave this information verbally, obtained their consent, and held two FGDs with those who agreed to participate. However, the involvement of women was resisted and initially refused on cultural grounds. Fortunately, this refusal was withdrawn when it was made clear that the women's groups would be facilitated solely by female RAs. The

female research assistants then approached the women, provided information and sought consent.

All the documents that I presented to the IDPs, the community leaders, and the Sudanese authorities were in simple Arabic, translated from the English versions that had received ethical approval. More detailed information was provided to the IDPs than to the interviewees, specifically in relation to the voluntary basis of participation, privacy and the confidentiality of the information that they shared in the FGD.

The information sheet and the consent form were read to the IDPs, and they were offered the choice of having them re-read to them by someone else of their choice. Every participant in the FGD was given the choice to either sign the informed consent form or to give witnessed verbal informed consent. Overall, the participants preferred not to sign and gave verbal consent.

The privacy of the participants in the FGDs was protected as much as possible. The IDP FGDs were held in the most isolated place in the neighbourhood that was feasibly accessible¹⁹, away from other residents and humanitarian, governmental or administrative staff. The participants, after consulting the community leader, expressed a preference for using one of the houses temporarily occupied by the IDPs. There was no clinic or school in the area where they lived, and I avoided holding the FGD in the community leader's house as this may have influenced the participants' ability to express their opinions freely.

¹⁹ 'Feasibly accessible' refers to a location within reach on foot, calculated based on the distance that an average resident would normally walk to get his/her water and food supply.

6.4 Structure and facilitation of interviews and focus group discussions

The structure of the interviews and the FGDs needed to balance two main considerations. On the one hand, I was aware that my previous experience in the area and my strong views could be potential sources of bias. This inclined me (and my research assistants, who helped in running some of the focus groups) to adopt a less active role as a facilitator when it came to the FGDs. On the other hand, given the focus of the project and the need to elicit explicit arguments and perceptions from the participants, a more structured, active mode of discussion was required. At times, I tended to challenge the interviewees and sought to actively clarify the arguments that were being used. For example, when I interviewed the representatives of the research bodies, I used the counter-arguments that researchers employ about the lack of capacity in the ethics committees in Sudan as probes for further clarifications during the interviews. This probing was made without dictating the content of those responses (Alderson, Farsides and Williams, 2002). Alderson and colleagues (2002) note that active facilitation is useful “to examine the logic and structures underlying common arguments and to reach the ‘deep structure of bioethics’” (Alderson, Farsides and Williams, 2002, p. 512).

6.4.1 The face-to-face semi-structured interviews with key informants

In the interviews, I followed the topic guide without needing to make significant modifications. The interview progressed as planned in a three-stage approach. First, I started with a standard warm-up by asking the interviewees about themselves, their positions and their duties. I then asked them whether

these duties involved the collection of personal data, including anthropometric measurements and/or biosamples. Subsequently, I asked them what kind of review preceded these activities, if any, and whether this included an ethical review. Additionally, I tried to obtain their insights on the main finding of the systematic review, namely the percentage of reports not mentioning obtaining ethical approval or consent, to explore with them the possible explanations for this findings.

6.4.2 The Focus Groups with representatives of IDPs and NGOs

The two topic guides for the FGDs with the NGOs and the IDPs were designed according to whether or not participants had direct experience in research in Darfur as organisers, data collectors, or participants. In either case, my assistants and I were less active in terms of interfering with the flow of the discussion. The NGOs staff had a great deal to share and their contributions to the discussion were generally well organised.

For the IDPs' FGDs, there was a pilot FGD with some colleagues from the FMOH who volunteered to play the role of IDPs. This was very helpful in identifying some communication problems I had. In the field, I was dressed in casual clothes, I sat with the participants on a mat on the floor, and, more importantly, I tried to make my facilitation as simple and neutral as possible.

6.5 Phase III: Normative phase (analysis and theory formation)

This phase consisted of qualitative data analysis, data interpretation and theory formation.

6.5.1 Transcription and translation

Initially, I transcribed all the recordings of the interviews and focus groups in the original language of the recording, which for the most part was a spoken Sudanese dialect of Arabic. After the initial transcription, I revised, edited, and then translated every transcription from spoken Arabic to traditional Arabic and then to English, unless the transcript was originally in English, which was the case with two interviews. I checked all the transcripts and then shared them with my PhD supervisors to assess the quality of the collected data along with any translation and readability issues.

I read through the translations a few times to familiarise myself with the data. I also listened repeatedly to the recordings of the interviews and the focus groups on a daily basis for about ten days to capture what might have been lost in translation.

Inevitably, in some sentences, the literal translation failed to capture the meaning and required broader interpretation. This is because the Sudanese dialect of Arabic uses a way of talking about the individual that may seem complicated to non-Sudanese, let alone non-Arabic, speakers. I give detailed examples in the Discussion, particularly about the use of the first and third person to talk about the same person. Therefore, to avoid confusion caused by the mixed use of first/third person forms, I had to translate the spoken sentence into a grammatical form of English.

Also, in the Sudanese dialect, like other spoken Arabic dialects, sentences are not short. We tend to use many words to express an idea. I tried to divide the long sentences into shorter and more comprehensible sentences using only punctuation marks and keeping the same spoken words when possible.

In the verbatim transcript, some sentences were not complete, and incomplete sentences were clearly labelled through the addition of (incomplete sentence) whenever needed. I tended not to interrupt the interviewee to ask them to complete these sentences, unless the interviewee had stopped completely.

Some interviewees used incomplete terms that are commonly used and understood in Sudan, like “the criminal” to refer to the International Criminal Court (ICC) for the crimes in Darfur. I have tried to explain these using footnotes to the transcripts, but I might have missed some. These were reviewed and checked with the help of my supervisors.

For the FGDs, the task of translating verbatim was even more difficult for two reasons. First, as would be expected in a group discussion, voices were often overlapping and the participants frequently interrupted one another. Second, unlike the interviews, the participants exclusively used the spoken Sudanese dialect, sometimes using local Darfuri terms that I could not interpret without the help of colleagues from the region. This language, as it is spoken, is not readily translatable into English. Ideally, I should have had a Sudanese colleague with good knowledge of both the Darfuri dialect and English to back-translate my translations from English into Sudanese Arabic to cross-check. This was not possible within the time and setting in which I worked. Therefore, I should

acknowledge that what I ended up with was a readable translated version of the traditional Arabic versions of the verbatim text, rather than a word-for-word verbatim written record. I acknowledge this as a potential source of bias in the Discussion.

6.5.2 Analysis

Westbrook (1994) suggests that the purpose of qualitative data analysis is to understand rather than to predict, so the analysis influences the gradual formation of the theory that provides an explanation of the phenomenon being studied (Westbrook, 1994). The qualitative analyst must take the data and find what is meaningful to the purpose of the study so that the results can be used (Krueger and Casey, 2015).

Miller and Crabtree (1992) propose four styles of qualitative analysis: quasi-statistical, template, editing, and immersion/crystallisation (Miller and Crabtree, 1992). I was inclined to use the editing analysis style, because it requires the analyst to act as an interpreter who identifies discrete units of texts and organises them into categories. This categorisation is done through qualitative content analysis using inductive reasoning, “by which themes and categories emerge from the data through the researcher’s careful examination and constant comparison” (Zhang and Wildemuth, 2009, p. 2).

The aim of the qualitative analysis in this project is to formulate a provisional theoretical framework within which the research practices that were undertaken in Darfur during the study period can be explained. Therefore, the analysis was

based on a coding process (see below) that focused on the normative aspects that I considered relevant to the project's normative research question, delineated as "What ethical standards ought to guide research that involves humans undertaken in such situations of armed conflict?"

This phase of the project also included the production of an empirically driven provisional ethical framework that proposes ethical principles that ought to guide the conduct of health research involving humans in a conflict context and how to apply them in practice. The development of the framework drew upon the analysis of the outcomes of the interviews and the FGDs in order to include as many of the issues raised by the interviewees and the FGD participants as possible. Overall, the framework's development was guided by the methodological framework presented by Frith (2012), as described earlier (subsection 5.2.6).

6.5.3 Coding

I carried out coding as a method of organising and managing meaningful segments of the data (Coffey, Holbrook and Atkinson, 1996) and as the first step in developing theoretical categories (Atkinson and Flint, 2001).

I used Atkinson and colleagues' (2001) suggested approach. In this approach, researchers interact with data, not just their subjects, when coding, and begin with coding by letting the codes arise from the data rather than applying pre-existing concepts to the data (Atkinson and Flint, 2001). Thus, I avoid Miles and Huberman's (1994) suggestion of planning a set of codes beforehand (Miles and Huberman, 1994). This was one of the measures I took to avoid potential bias in

the analysis (see Section V. Reflexivity). Thus, my analytical approach was a bottom-up, inductive approach that did not prescribe any a priori categories, assumptions, or theories. Rather, I tried to capture what the participants wanted to say, or more precisely my interpretation of what they wanted to say.

Computer-assisted qualitative data analysis software (CAQDAS) helps to assist with the conceptualization and visualisation of data, codes, and their linking and consolidation (Weitzman, 2000; Ritchie *et al.*, 2013). The software I used was NVivo qualitative data analysis software; QSR International Pty Ltd. Version 10, 2014.

I limited the use of CAQDAS to two main functions: 1) facilitating the standardisation of codes to enable their grouping and comparison, and 2) using advanced features of the software to search for keywords that I could have missed by reading the transcripts line-by-line. These steps were not meant to be the analysis itself; rather, they facilitated the analysis.

6.5.4 Re-coding and theme development

In the re-coding and theme-developing phases, I manually mapped the codes/labels to develop initial thoughts about the themes that were covered by the interviewees and the participants in the FGDs. I did this by gathering and categorising the codes and then linking them by establishing relations between them. These relations included whether the codes supported, contradicted, or depended on each other. While doing this, I rephrased and revised some labels/codes and merged others.

The transcripts were approached analytically using two methods. First, I tried to map the data in relation to the project's research questions. This step was essential to estimate the extent to which the data addressed the research questions of this project and to identify any gaps in the collected data.

Second, I re-organised the data into three datasets based on the participants' categories, namely:

- a. The interviews with the representatives of the governmental bodies, namely the HAC, the FMOH-RD, and the NREC;
- b. The interviews and the focus groups with the NGO representatives; and
- c. The focus groups with the male and female IDPs

In this categorisation, I had an initial expectation that the three different groups of participants may have expressed their opinions from completely different angles. I was wrong. I found that the more familiar I became with the data, the more I could see how the issues they raised were similar and complementary rather than different.

6.5.5 Interpretation

The interpretation of data seems inevitable in qualitative analysis, especially when it comes to perceptions about ethical issues. Both the IDPs and the professional staff in this project expressed their views in general terms and not as articulated, explicit ethical arguments. Thus, the analysis often required

interpreting their reasoning (Scully, Banks and Shakespeare, 2006). In addition, the way in which Sudanese people structure their sentences meant that interpretation was needed to make the data presentable to those who are unfamiliar with the Arabic language.

I used an inductive approach to interpretation, aiming at developing concepts and constructs from the data to portray a broader cultural meaning (Spiggle, 1994). This was consistent with the inductive approach I used for the whole qualitative analysis in the project.

As I am aware of the potential bias that could result from the interpretation of data, I have applied some steps for data validation and trustworthiness, as described in the following section.

6.5.6 Validation and trustworthiness

I tried to achieve validation and trustworthiness in this project by following a systematic approach suggested in the literature on qualitative research.

This approach includes the use of a variety of data sources as part of this project (see subsection 5.2). I also tried to achieve credibility by choosing a wide range of participants with various experiences and incorporating the main components of the research cycle in Darfur, including almost equal representation of women and men (Patton, 1987; Adler, Adler and Adler, 1994). I also tried to consider and test alternative classification systems, themes, and explanations during data analysis (Patton, 1999). For instance, in the systematic review, I resisted the temptation to generate clear-cut conclusions based on the

quantitative findings only, even when I had some evidence in the reports that supported these conclusions. Instead, I preferred to devise with a set of possibilities that I later presented to my interviewees to allow them to decide which of these possibilities was more reflective of their perceptions.

I also tried to achieve triangulation following Patton's (1999) recommendation of "combining multiple observers, theories, methods, and data sources" (Patton, 1999, p. 1193). Indeed, not all of these measures were achievable within my project. Nevertheless, there was a variety of data collection methods, participant profiles, and data sources. Moreover, the transcripts were sent to the supervisors of the project (after translation) immediately after each interview or FGD. They also checked the analysis regularly and independently. There were regular meetings to discuss and work through possible disagreements, and in a few instances they suggested different approaches to the analysis.

Because of the inductive and interpretive nature of the analysis, which relied in part on my perception of what the participants had wanted to say, I decided to prepare an online presentation of my initial findings for some of my project participants. These included the representatives of the humanitarian and research governance bodies and representatives of the national and international NGOs who took part in my study. In this presentation, I shared with them my analysis and obtained their feedback. Given the security restrictions and language limitations, I could not invite the IDP representatives to this presentation, as it was mostly in English. I asked for feedback regarding whether my analysis: 1) reflected their

points of view fairly, 2) missed any point they considered significant, and/or 3) emphasised a point that they thought unimportant or irrelevant.

Finally, where needed, I added reflexive comments to the texts to disclose important personal reflections and background to keep the reader aware of “the effect of the researcher, at every step of the research process” (Malterud, 2001, p. 484).

7 CHAPTER SEVEN: SYSTEMATIC REVIEW OF HEALTH-RELATED STUDIES INVOLVING HUMANS IN DARFUR (2004–2012)

7.1 Background

In the introduction, I outlined the socio-political context of the armed conflict in Darfur, the international humanitarian response to it, and the research activities that accompanied that humanitarian response.

This project studies the ethical considerations related to these research activities in Darfur (2004–2012) in two ways. First, through a systematic review to study how these ethical issues were reported in the publications resulting from the studies conducted in Darfur. Second, through an in-depth qualitative empirical project to study how the relevant stakeholders perceived and managed these ethical issues. The empirical project was described in the previous chapters.

In this chapter, I present the methodology and the results of the systematic review, followed by a brief discussion to explain its findings. These possibilities, along with the other findings, were used as starting points to formulate the discussion guides for the interviews and the focus groups that were done in a later phase of this project. The full discussion of the results of the systematic review is incorporated into the discussion of the findings of the whole project in Chapter Nine.

7.2 Rationale for the systematic review

Despite the availability of some literature discussing the ethical issues related to the conduct of research during conflicts (as detailed in Chapter 2), there remains a knowledge gap in this area. This gap is mainly related to, or perhaps resulting from, the lack of empirical studies adopting an ethical perspective on

current research activities conducted during conflicts. Additionally, there is a lack of knowledge about the research management system in Darfur where ethical issues are anticipated and dealt with. It is unclear whether such a system exists. The systematic review was thus needed to give an initial indication of how the ethical issues related to the studies conducted in Darfur were presented in the resulting reports.

7.3 Methods of the systematic review

The methods used for this systematic review have been described in detail in Chapter 5.

7.4 Results of the systematic review

The online search resulted in the inclusion of 68 reports or manuscripts out of the 2,034 studies that were retrieved. The CRED search included 138 eligible reports out of the 243 reports available in the archive under the entry of 'Darfur'. Figure 7-1 summarises the numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, for the online and the CRED search, respectively. Notably, all eligible reports were in either in Arabic or English, and no report was excluded based on the language of publication.

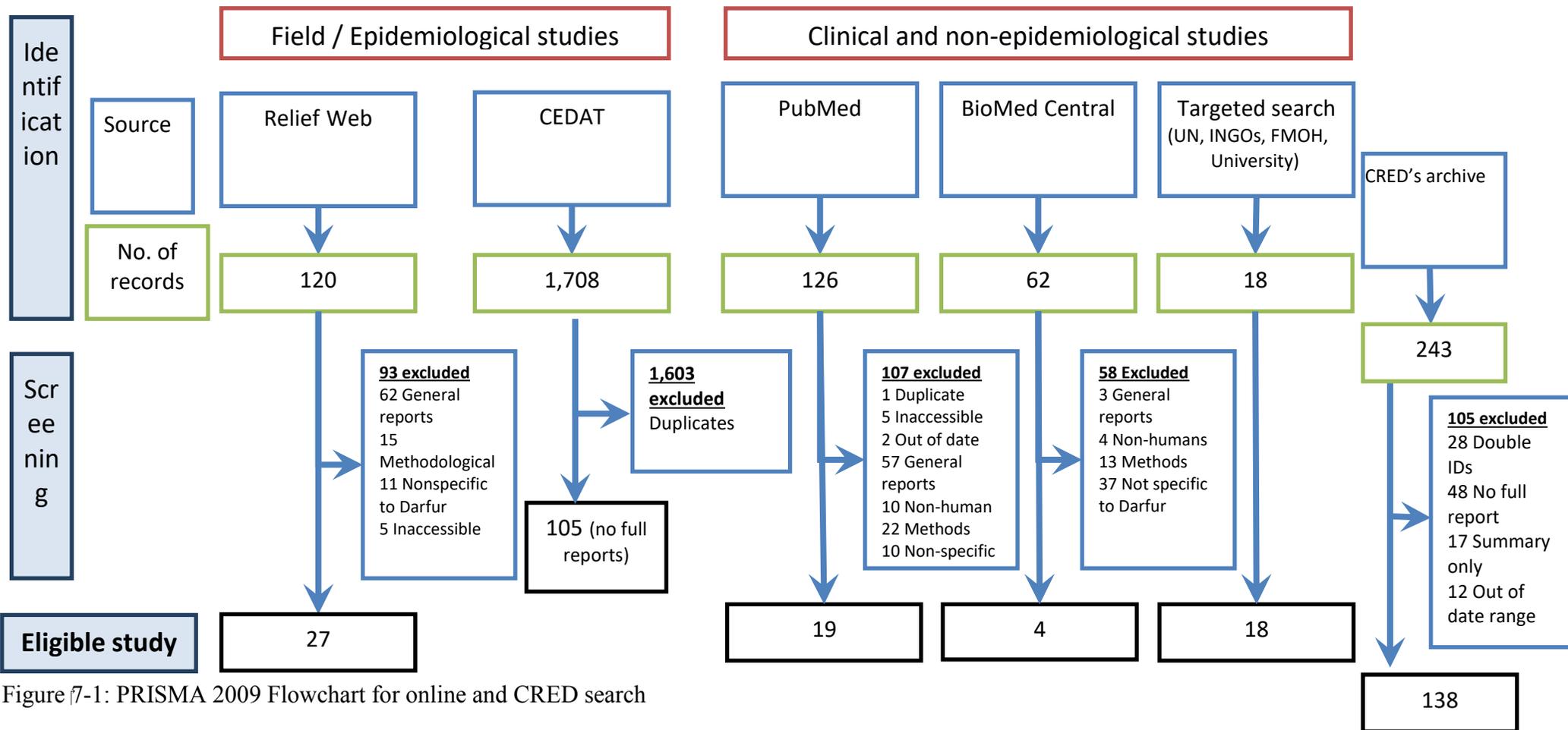


Figure 7-1: PRISMA 2009 Flowchart for online and CRED search

7.4.1 Overview of the eligible studies

The online and the hand search resulted in the inclusion of 68 and 138 studies, respectively. The monthly distribution shows that an average of three studies were published per month (range 1-5), with a slight variation in the annual distribution between the online and hand searches (Figure 7-2). Although both searches showed that most of the studies were published in 2004 and 2005 (38 and 39 respectively), the CRED search had another peak in 2010 (26 studies). Table 7-1 summarises the main characteristics of the studies that were included from both the online and CRED searches.

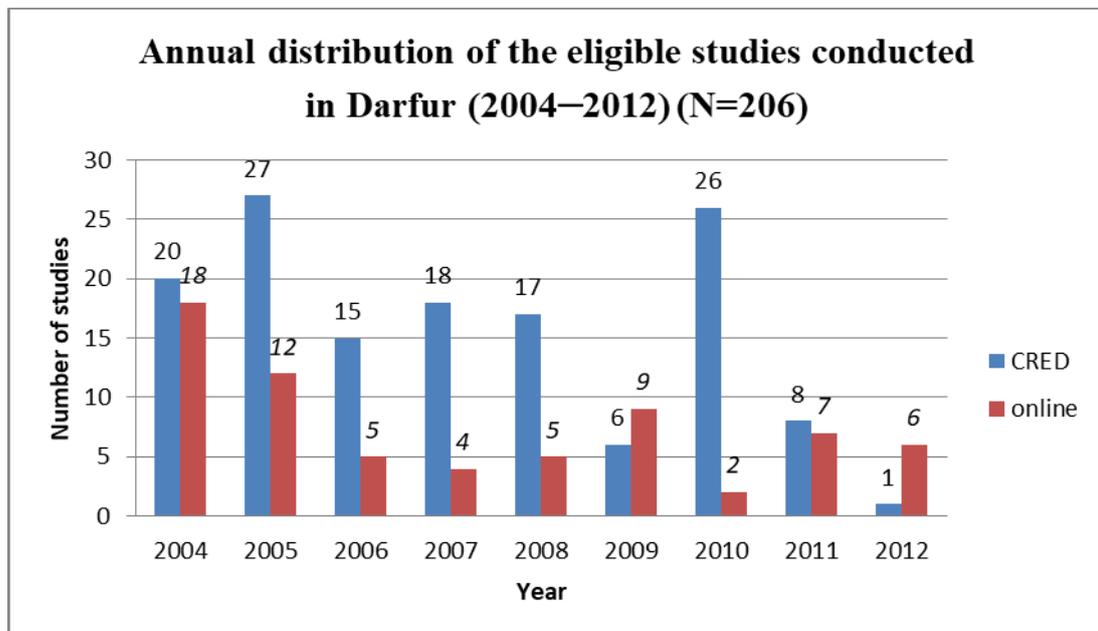


Figure 7-2: Annual distribution of the studies conducted in Darfur (2004–2012) (N=206)

Table 7-1: Main characteristics of the included studies

	Characteristics of the included studies	CRED (N=138) (%)	Online (N=68) (%)
Study theme	Children's illnesses (including diarrhoea/ Acute Respiratory Illness)	48 (34.8)	11 (16.2)
	Clinical conditions (including AIDS, malaria, genetic diseases)	4 (2.9)	16 (23.5)
	Immunisation	119 (86.2)	10 (14.7)
	Mental health issues	0 (0.0)	8 (11.8)
	Methodological, organisational issues	0 (0.0)	2 (2.9)
	Morbidity	91 (65.9)	12 (17.6)
	Mortality	124 (89.9)	18 (26.5)
	Nutrition and food security	130 (94.2)	28 (41.2)
	Other	34 (24.6)	24 (35.3)
	Violence and gender based violence (GBV), including rape	0 (0.0)	14 (20.6)
	Water, Sanitation, Hygiene (WASH)	37 (26.8)	8 (11.8)
	Women/Maternal/Reproductive Health	2 (1.4)	46 (67.6)
Type of the main surveying agencies	UN agency	27 (19.6)	28 (41.2)
	Independent researchers	0 (0.0)	27(39.7)
	INGO	119 (86.2)	23 (33.8)
	Governmental body	46 (33.3)	14 (20.6)
	International (bilateral) agency	9 (6.5)	3 (4.4)
	NNGO	2 (1.4)	2 (2.9)
Data collection methods and	Questionnaires	135 (97.8)	50 (73.5)
	- Interviews (including verbal autopsy)		

	Characteristics of the included studies	CRED (N=138) (%)	Online (N=68) (%)
tools	FGDs	10 (7.2)	23 (33.8)
	Anthropometric measures	128 (92.8)	11 (16.2)
	Blood/serum sample	2 (1.4)	11 (16.2)
	Review of medical records	11 (8.0)	10 (14.7)
	Review of non-medical reports	116 (84.1)	8 (11.8)
	Direct observations (including observing oedema)	106 (76.8)	7 (10.3)
	Others	7 (5.1)	4 (5.9)
	Urine/stool sample	0 (0.0)	3 (4.4)
	Other body sample	0 (0.0)	1 (1.5)
Sampling techniques	(Multi-stage) cluster sampling	137 (99.3)	36 (52.9)
	Convenience/targeted (Non-random)		27 (39.7)
	Not applicable		2 (2.9)
	Not mentioned		2 (2.9)
	Other	1 (0.7%)	1 (1.5)
	Semi-random sampling		1 (1.5)
	Systematic/random sampling		6 (8.8)

All the mortality household surveys retrieved online (18; 26.5%) and from CRED (124; 89.9%) examined more than one epidemiological indicator, such as morbidity or food security. Therefore, the percentages of different themes sum up to more than 100%.

7.4.2 Type of data collected and data collection methods in the included studies

In both the online and CRED searches, the most commonly used data collection tools were questionnaires (135; 97.8% and 50; 73.5% respectively). However, in CRED studies, the use of anthropometric measures (128; 92.8%) such as height and weight and the review of non-medical reports such as vaccination cards (116; 84.1%) were mentioned more frequently than in the online studies (23; 33.8% and 11; 16.2%, respectively). The use of anthropometric measures is common in nutritional surveys, and review of vaccination cards helps in minimising recall bias and in validating the answers of the carer in surveys involving children.

The mention of the use of FGDs was higher in the online studies (23, 33.8%) than in CRED studies (10; 7.2%). Similarly, taking biosamples (mainly blood (whole or serum) (11; 16.2%) and urine/stool (3; 4.4%)) was mentioned more in the online studies (15; 22.1%) than in the CRED studies (2; 1.4%) (Table 7-1).

The most commonly used population sampling technique in both the online and the CRED studies was two-stage cluster population-proportional sampling (36; 52.9%, and 137; 99.3%, respectively).

7.4.3 Target population and locations of the included studies

Both the online and the CRED searches revealed that the IDPs, usually within their camps, were the main target populations (39; 57.4%, and 106; 76.8%, respectively), followed by the affected host communities (31; 45.6%, and 76; 55.1%, respectively). The Darfur states were almost evenly targeted by the included studies (Figure 7-3). However, the online search revealed that the study

areas in six studies (8.8%) also included neighbouring Chad where thousands of Darfuri refugees are present, and one (1.5%) randomized control trial (RCT) was conducted in Egypt.

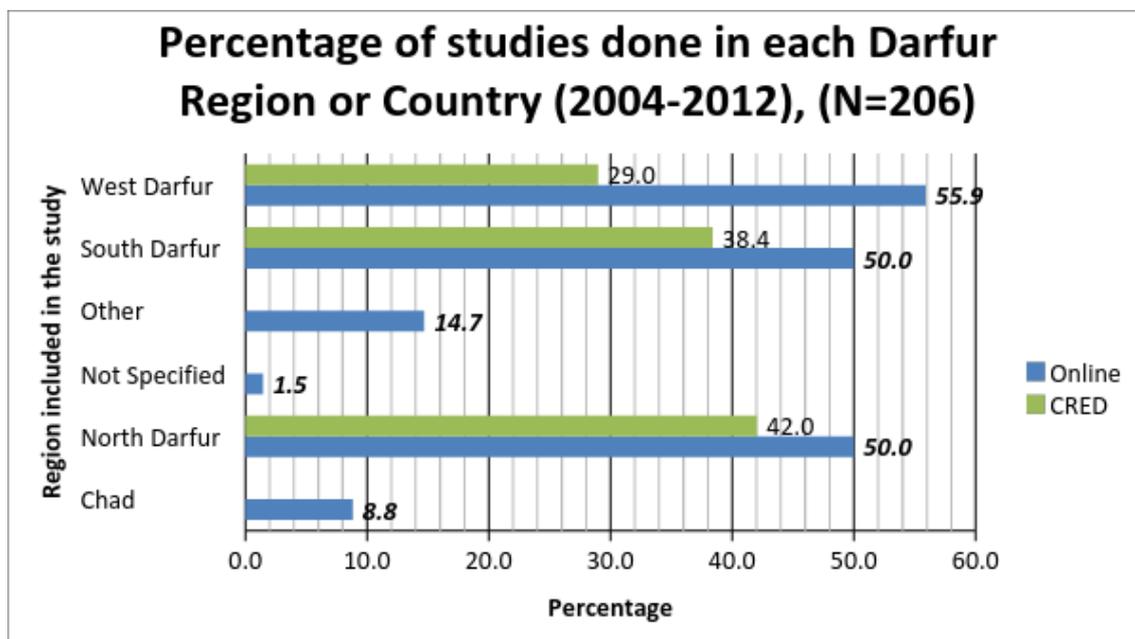


Figure 7-3: Areas where the included studies took place (2004-2012)

The studies included in the review mostly targeted more than one type of population in more than one state of Darfur; hence the percentages sum up to more than 100%.

7.4.4 Mention of ethical review

None of the reviewed CRED studies mention seeking or obtaining ethical review or approval. The online search revealed that nine studies (13.2%) mentioned that they had obtained ethical approval. Of these, three studies were approved by a university ethics committee, three were approved by the surveying INGO's ethics committee, and only one study was reviewed by the Sudanese NREC. Eight of these nine studies (89%) were retrieved from peer-reviewed

journals, while one study was retrieved from the website of the federal ministry of health in Sudan (Table 7-2 and Figure 7-4).

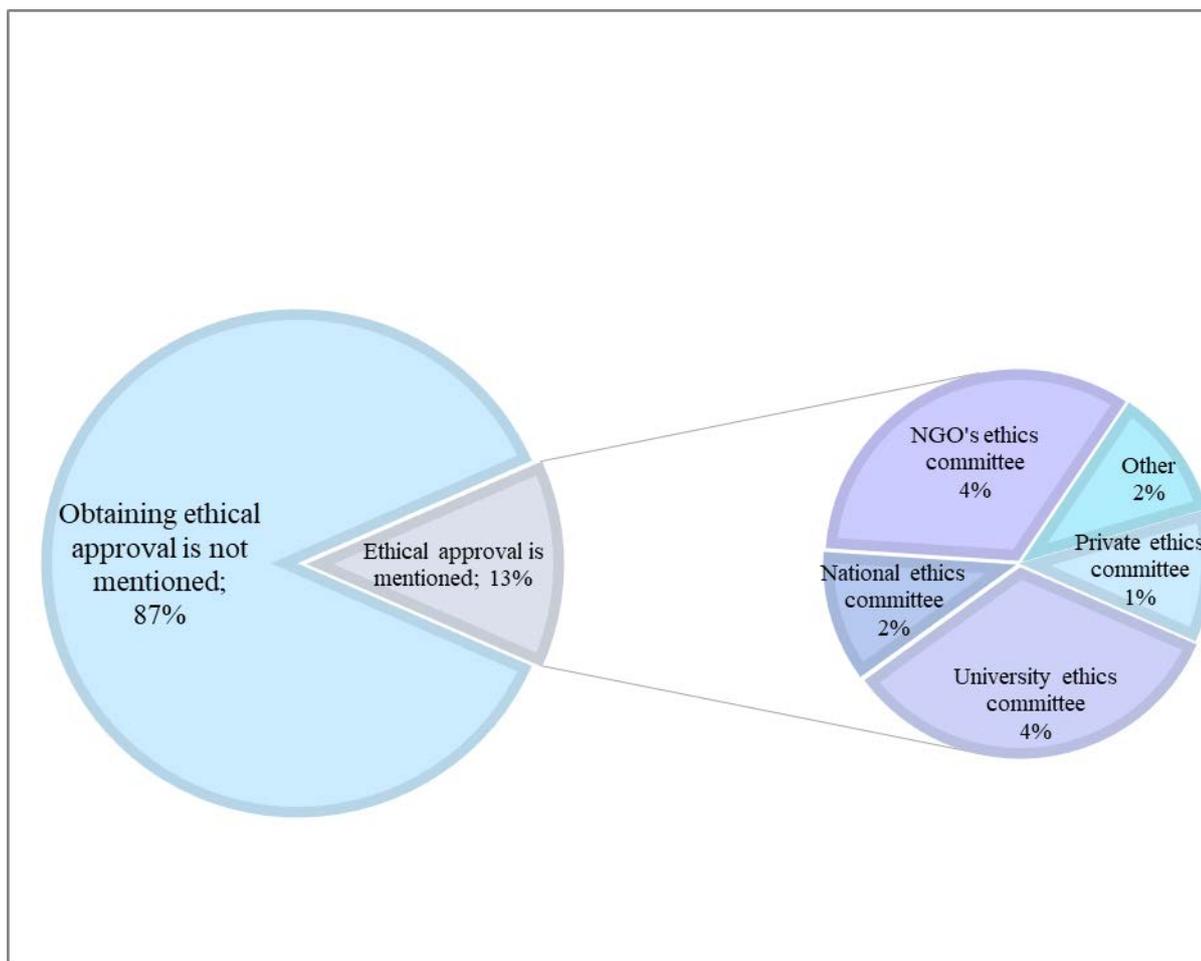


Figure 7-4: Sources of ethical approval of the studies included in the systematic review

Table 7-2-A: Characteristics of the studies that mentioned obtaining ethical approval

	Study A	Study B	Study C	Study D	Study E
Type	Article	Article	Report	Article	Article
Who conducted it?	Independent authors	INGO UN Agency Government	Governmental	Independent authors	Independent authors
Type of study/article	Non-randomized Non-epidemiological research	Non-randomized Non-epidemiological research	Household (Multi-Indicator) Survey Other	Non-randomized Non-epidemiological research	Household (Multi-Indicator) Survey

	Study A	Study B	Study C	Study D	Study E
Retrieved from	Peer-reviewed journal	Peer-reviewed journal	FMOH website	Peer-reviewed journal	Peer-reviewed journal
Themes and indicators	- Women/maternal health - Mental health issues - Violence (GBV/rape)	- Clinical/medical conditions	- Child health/rights - Malaria - Women/maternal health	- Human rights - Violence (GBV/rape)	- Violence (GBV/rape)
Type of data collected	- Primary identifiable data - Primary non-identifiable data	- Primary identifiable data - Primary non-identifiable data	- Primary non-identifiable data	- Secondary identifiable data - Secondary non-identifiable data	- Primary identifiable data - Primary and secondary non-identifiable data
Were human specimens collected?	No	Yes	Yes	No	No
Data/biosamples collected	- Questionnaires - Interviews	- Questionnaires - Urine/stool samples	- Questionnaires - Interviews - Blood/serum samples	- Review of medical records	- Review of nonmedical reports - Questionnaires - Interviews
Study area and population	- Affected community area	- General community	- General community	- NGO/desk review	- Refugee camp
Darfur Region(s) included in the study	- West Darfur - North Darfur - South Darfur	- South Darfur	- West Darfur - North Darfur - South Darfur - Other Sudanese States	- South Darfur	- Chad
Sampling technique	- Convenience/targeted (non-random)	- Semi-random sampling	- (Two-stage) cluster sampling	- Other: retrospective review and analysis of medical records of victims of torture	- (Two-stage) cluster sampling
Source of ethical approval	- Academic ethics committee	- Other	- National ethics committee	- NGO's ethics committee - Academic ethics committee	- Private ethics committee

	Study A	Study B	Study C	Study D	Study E
Name of the ethics committee	-AUW ethics committee	-The study was approved by SMOH, followed by the local health authority.	-NREC	-The MSF Ethical Review Board	-American Bar Foundation's institutional review board
Participant consent obtained?	Yes	Yes	Yes	Not stated	Yes
How was it obtained?	Written	Verbal	Written		Verbal
<p>Study A: Exposures to war-related traumatic events and post-traumatic stress disorder symptoms among displaced Darfuri female university students (Badri, Crutzen and Van den Borne, 2012)</p> <p>Study B: High prevalence of urinary schistosomiasis in two communities in SD: implication for interventions (Deribe <i>et al.</i>, 2011)</p> <p>Study C: Malaria Indicator Survey Northern States of Sudan – October-November 2009 (Elfatih <i>et al.</i>, 2010)</p> <p>Study D: Medical evidence of human rights violations against non-Arabic-speaking civilians in Darfur: a cross-sectional study (Tsai <i>et al.</i>, 2012)</p> <p>Study E: Racial Targeting of Sexual Violence in Darfur (Hagan, Rymond-Richmond and Palloni, 2009)</p>					

Table 7-3-B: Characteristics of the studies that mentioned obtaining ethical approval

	Study F	Study G	Study H	Study I
Type	Article	Article	Article	Article
Who conducted it?	- INGO - Independent authors	- INGO - Independent authors	- Independent authors	- Independent authors
Type of study/article	- Non-randomized Non-epidemiological research	- Mortality survey - Nutrition/food assessment	- Household (multi-indicator) survey	- Household (multi-indicator) survey
Retrieved from	- Peer-reviewed journal - INGO website	- Peer-reviewed journal	- Peer-reviewed journal	- Peer-reviewed journal
Themes and indicators	- Mental health issues	- Mortality - Nutrition and food security - Violence (GBV/rape)	- Other (poverty)	- Human rights - Women/maternal health - Mental health issues - Reproductive health
Type of data collected	- Primary identifiable data - Primary non-identifiable data	- Primary identifiable data - Primary non-identifiable data	- Primary identifiable data - Primary and secondary non-identifiable data	- Primary identifiable data - Primary non-identifiable data

	Study F	Study G	Study H	Study I
Were human specimens collected?	No	No	No	No
Data/ biosamples collected	- Review of medical records - Questionnaires	- Questionnaires - Interviews - Anthropometric measures	- Questionnaires - Interviews - FGDs	- Questionnaire - Interviews
Study area and population	- Health facility	- IDP camps - Affected community area	- IDP camp - Affected community area - NGO/desk review - General community	- IDP camp
Darfur region(s) included in the study	- West Darfur	- South Darfur	- West Darfur	- South Darfur
Sampling technique	- Convenience/targeted (non-random)	- (Two-stage) cluster sampling	- (Two-stage) cluster sampling	- Systematic/random sampling
Source of ethical approval	- NGO's ethics committee	- NGO's ethics committee	- Academic ethics committee	- Private ethics committee
Name of the ethics committee	- The MSF Ethical Review Board	- MSF and Epicentre	- University College London	- The Western Institutional Review Board
Participant consent obtained?	Yes	Yes	Not Stated	Yes
How was it obtained?	Verbal	Verbal	Verbal	Verbal

Study F: Mental health treatment outcomes in a humanitarian emergency: a pilot model for the integration of mental health into primary care in Habila, Darfur (Souza, Yasuda and Cristofani, 2009)

Study G: Mortality and Malnutrition Among Populations Living in South Darfur, Sudan Results of 3 Surveys, September 2004 (Grandesso *et al.*, 2005)

Study H: Child Poverty in an Emergency and Conflict Context: A Multidimensional Profile and an Identification of the Poorest Children in Western Darfur (Trani and Cannings, 2013)

Study I: Basic Health, Women's Health, and Mental Health Among Internally Displaced Persons in Nyala Province, South Darfur, Sudan (Kim, Torbay and Lawry, 2007)

7.4.5 Mention of informed consent

The studies that did not mention obtaining consent were 121 (58.7%) and 39 (18.9%) in number in the CRED and online searches, respectively; while the studies that mentioned obtaining informed consent from their participants in the online search numbered 29 (42.6%) and in the CRED search 17 (12.3%) .

Approximately one-third of the studies that mentioned obtaining informed consent (N=29) were found by the online search (9; 31%). Informed consent was mostly obtained verbally in the results of both the online and CRED searches (18; 26.5%, and 13; 9.4%, respectively).

7.4.6 Communication with authors

Following the online search, 60 authors' emails were retrievable from either the published reports or the internet. An email was sent to each author to introduce this review and to invite them to fill in an online form (Appendix 11). Only eight authors filled in the form. None of the answers provided led to any modifications or corrections in the results of the online review. The CRED search did not result in any contact details additional to those found online.

7.5 Discussion of the systematic review

7.5.1 General overview of the findings

The dominance of household multi-indicator surveys that focus on mortality, morbidity and nutrition seems relevant to the need for planning and assessing humanitarian interventions in Darfur. Most of the studies targeted IDPs and the

host communities and to a lesser extent the refugees. This could be explained on a methodological basis, given that PPS, which is used in these surveys, focuses on larger groups, and the IDPs and host communities are larger than the refugee groups.

The studies included in this review were mostly conducted between 2004 and 2007, which is concomitant with the influx of INGOs into the region. This is similar to the findings of Degomme's work, which also showed an average of five surveys per month between 2003 and 2008, reaching as high as 11 surveys in a single month (Degomme and Guha-Sapir, 2010). CEDAT reports more than 800 mortality and nutrition surveys conducted in Darfur between 2003 and 2012 (CEDAT, 2013). CEDAT also reports that in 2005 alone, more than 150 nutritional surveys and 50 mortality surveys were undertaken in Darfur. This could be attributed to the international attention given to the crisis in Darfur. The 2010 peak in the CRED reports could be a reporting peak rather than a true peak. The CRED's archive depends completely on the voluntary sharing of reports. CRED officials mentioned that INGOs might share the reports of the previous few years all at once. Practically, this means that a higher proportion of the reports of an NGO at any given point in time may reflect the timing of commitments to sharing their reports, rather than their being the most active organisation during that time.

As would be expected, most of the surveys were done by humanitarian agencies. For example, two-thirds of the included studies from the online search (51; 75%) and most of the CRED studies (119; 86.2%) were conducted by UN agencies and/or other INGOs. It is also understandable that the proportion of

INGO reports is higher in the CRED search than in the online search, because the CRED's archive depends almost entirely on the INGOs' contribution.

The contribution of NNGOs both in the online search (2; 2.9%) and in the CRED search (2; 1.4%) is too low to be explained by the general difficulty in accessing the reports of the included studies. This could reasonably be explained by the NNGOs' limited research undertakings, which could in turn be an area that needs further research. It might reasonably be expected that there would be a greater contribution from the NNGOs, which are supposed to be working in these conflict-affected areas and should have done assessments like those of the INGOs. Given that the results reflect a significantly smaller contribution of NNGOs in the studies, it is important to study the reasons for this to work on improving this contribution.

The online studies that were published in peer-reviewed journals (26, 34%) were also concerned with the humanitarian impact of the conflict, as well as other specific conditions like hepatitis, malaria, and HIV/AIDS (Boccia *et al.*, 2006; Guthmann *et al.*, 2006; Yousif, Mansour and Ateem, 2009) and genetics (Nicand *et al.*, 2005). Unsurprisingly, as RCTs require stability and logistics that were not available in Darfur, there was little RCT activity, with only one retrievable RCT conducted on Darfur refugees in Cairo (Meffert and Marmar, 2009). Moreover, RCTs are unlikely to be methodologically useful to answer the kinds of research questions raised in conflict settings.

7.5.2 Sampling, type of data collected and data collection methods

Multi-stage cluster population-proportional sampling (MSPPS) is considered the standard sampling technique for household surveys (Bostoen *et al.*, 2007; Checchi *et al.*, 2007; Galway *et al.*, 2012) and is usually employed by the UN and INGOs to ensure that they have a sample as representative as possible of the whole population. The difficulty that this method encounters in conflict situations is the inaccessibility of some clusters due to insecurity (Hussein, 2006; Olivia Lomoro *et al.*, 2007), which also explains the use of convenience or targeted sampling as an alternative.

MSPPS was the sampling method used most in CRED surveys (135; 97.8%) and online (50; 73.5%).

The use of FGDs was mentioned more in the online studies (23, 33.8%) than in the CRED studies (10; 7.2%). Similarly, taking biosamples (mainly blood (whole or serum) (11; 16.2%), and urine/stool (3; 4.4%)) was mentioned more in the online studies (15; 22.1%) than in the CRED studies (2; 1.4%) (Table 7-2). These differences probably reflect the nature of the studies and the target publication site. The collection of biosamples is usually used in studies that involve clinical aspects and not purely epidemiological studies. The CRED reports were all on epidemiological studies.

The most commonly used data collection tools in both the online and CRED searches were questionnaires and interviews (including verbal autopsy), which are the most methodologically relevant tools given the aims of the retrieved studies.

As most of the included reports were household studies that looked for epidemiological indicators (e.g. mortality) within a given recall period, questionnaires are the best tool to collect large amounts of data in a relatively short time. Focus group discussions were used in the studies that aimed at objectives beyond the calculation of a given epidemiological rate, such as mental health issues (Rasmussen *et al.*, 2010) and vulnerability to sexual assault (Deribe *et al.*, 2011).

The use of anthropometric measures, including measurements of the height and weight of children under five years old, was mentioned in most of the studies retrieved from the CRED search (128; 92.8%). About one-fifth of the studies retrieved from the online search (15; 22.1%) stated that they collected biological body samples. Moreover, in three of the retrieved studies, the biosamples were sent to European laboratories, and nothing is mentioned about whether the patients consented to this exportation or the further use of their samples.

7.5.3 Mention of ethical review

As none of the CRED studies mentioned their ethical approval status, the following focuses only on the studies retrieved from the online search. Most of these studies (59; 86.6%) did not mention whether they had obtained ethical approval and none of the studies found in the CRED did. This does not necessarily mean they did not seek ethical review or that they were not ethically approved. There are a number of reasons why a study's ethical review status would not be mentioned. These possibilities are discussed below and form the basis of the hypotheses that were studied later in the project. Though one of the

aims of contacting the authors of the retrieved reports was to explore why the studies' ethical review statuses were not mentioned; the limited feedback received from the authors cannot be used as the basis for a generalizable conclusion.

7.5.4 Possibilities to explain the lack of mention of obtaining ethical approval

7.5.4.1 Possibility one: These studies were held to be exempt from ethical review

This possibility is supported by a statement that was found in one of the studies included in this review. The Crude Mortality Survey that was led by the WHO and jointly conducted by other UN agencies and the GoS states that “WHO guidelines do not require ethical review for retrospective surveys during humanitarian emergencies ...” (World Health Organization and Federal Ministry of Health, 2005a, p. 7 of 7).

This statement clearly outlines that WHO surveys during emergencies do not require ethical approval, yet the justification for this exemption from ethical review can be questioned. One of the authors who completed the online form mentioned that ethical approval was not sought because

“[E]mergency survey[s] [...] done for primarily operational programming reasons – no time to seek review; WHO guidelines suggested that emergency surveys not involving the collection of biosamples could be exempt from IRB review” (*Participant 1*).

However, it is not possible to draw a firm conclusion from a statement mentioned in one study or by one participant. Other reasons for exemption from

ethical review were set by the MSF ethics committee for the MSF REB for retrospective analysis of previously collected clinical data (subject to various protections) (MSF Ethics Review Board, 2013b). This exemption is unlikely to have been applied in the studies included in this systematic review, whose main inclusion criterion was the prospective collection of personal data and/or biosamples.

7.5.4.2 Possibility two: Mentioning ethical review was not required

Most of the studies retrieved from the online search (39; 57.4%) and almost all of those retrieved from the CRED search (128; 92.7%) were conducted by humanitarian aid agencies. Given the difficulties faced by these agencies during conflicts, their focus is on sharing the findings of their surveys. Perhaps it is less relevant to share details about gaining ethical approval or seeking participants' consent. However, even if this is true regarding the studies published in disaster-specific databases, where mentioning ethical review or consent is not a requirement for publishing a study report, it should not apply to the one-third of studies (26, 34%) that were published in peer-reviewed journals. In the latter, "authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible [ethics review] committees" (International Committee of Medical Journal Editors, 2013). The discrepancy between the 34% of studies that were published in peer-reviewed journals and the 13.2% that mentioned being ethically reviewed could be interpreted in three ways. It could either suggest that studies were published in peer-reviewed journals without stating their ethical approval status, or the published study did not require ethical approval as judged by the editors of the relevant journal. Lastly, it is possible that

the submission process required a statement but that this statement was not then published.

7.5.4.3 Possibility three: Ethical review was considered as if granted

This possibility assumes that the studies done by the organisation were assumed to have been ethically approved, and so the researchers did not have to mention this approval in their published reports. This possibility could be supported by other findings in the present study. For example, the only studies that were ethically approved by an NGO committee were those reviewed and approved by the MSF ethics committee. However, MSF has criteria for exempting some types of (retrospective) research from ethical review (MSF Ethics Review Board, 2013a). Thus, those who were exempted from ethical review would not mention obtaining ethical approval, and only those who required ethical approval would mention it. This variation in the initial requirement for ethical approval could explain why some of the MSF studies reported their ethical review while others did not.

7.5.4.4 Possibility four: Pre-approved proposals

This is an alternative approach to ethical review that is based on ethically reviewing and approving ready-made generic study protocols of emergency research when the research needs to be conducted in an urgent and timely manner, i.e. where it cannot wait for a full ethical review. This approach has been suggested by a WHO Technical Group (2009) for research to be conducted during pandemics (Group, 2009) and has been adopted by the MSF ethics committee (MSF Ethics Review Board, 2013a). In the context of this systematic review, this could mean that one or more of the included studies was viewed as 'emergency

research' that was part of wider research whose protocol had previously received ethical approval. There is no finding in this review to support this possibility.

7.5.4.5 Possibility five: The ethical review was not part of the template used

At least for the studies retrieved from the CRED search, the patterns and formatting used for reporting were very similar, as though they used a common template. These similarities applied to the methodologies and the reporting of the results. For example, multi-stage cluster sampling was used by almost all of the CRED studies reviewed (137; 99.3%) and more than half of those found online (36; 52.9%). Moreover, many of the reports used exactly the same wording to describe the sampling procedure.

This possibility can also be supported by the finding that the studies conducted by one INGO mentioned 'Ethical Considerations' using exactly the same words and structured under exactly the same bullet numbering (Relief International, State Ministry of Health and UNICEF, 2011; State Ministry of Health, Relief International and UNICEF, 2011). This is particularly significant if other INGOs also use a template. Theoretically, changing the template that such organisations use to report their studies may change the extent of inclusion of ethical considerations in future studies. For example, if a template included a section on 'informed consent' or 'ethical approval', then those using it would be likely to include more details about these aspects.

7.5.5 Mention of consent

In the online search, more studies mentioned that they obtained consent (29; 43%) than mentioned that they had been ethically approved (19; 13.2%). More

studies in the online search than in the CRED search (17; 12.3%) mentioned obtaining consent. The former finding could be partially explained by the fact that most of the included studies were household-based studies which used similar methodologies that were described in detail and made available to humanitarian aid workers to use (Rose *et al.*, 2006; World Relief and State Ministry of Health, 2010). These methodologies are described in common guides used by the researchers in these agencies. These guides usually mention a section on 'informed consent' under the 'methodology' section, so those who use these templates consider obtaining consent a part of the methodology. This assumption could be supported by the finding that some commonly used template guides mention obtaining consent from participants without mentioning other issues related to ethical review (Rose *et al.*, 2006; Humanitarian Accountability Partnership, 2010). Therefore, those who follow these guides would only mention what these guides contain, which is consent and not ethical approval.

As might be expected, most participants' consent was obtained verbally (18; 27%), which is more feasible than obtaining written consent, given the culture of Darfur where people do not like to or cannot sign papers.

The finding that consent was mentioned in more of the online studies than the CRED studies has two possible explanations. First, there is more variation in the studies found in the online search, which included publications in peer-reviewed journals in addition to epidemiological field reports. It is more likely to find consent mentioned in an article published in a peer-reviewed journal than in household surveys that are mainly shared for their epidemiological findings.

Second, most of the CRED studies were produced by a relatively limited number of organisations whose main interest is the field-related details, namely the results and survey methods. In contrast, the online studies included studies done for non-humanitarian purposes by non-humanitarian researchers who may follow different reporting formats. Also, the NGOs might have used template guides of survey methodologies that did not include or did not emphasise the mention of consent. For example, consent is built into the first part of the standard survey template and is considered a routine that it is not considered worth mentioning.

7.5.6 Characteristics of the studies that mentioned being ethically approved

The nine studies that mentioned receiving ethical approval do not have much in common with one another and reflect the general trend of the other studies, with the exception that eight of them were published in peer-reviewed journals (Grandesso *et al.*, 2005; Kim, Torbay and Lawry, 2007; Souza, Yasuda and Cristofani, 2009; Elfatih *et al.*, 2010; Hagan, Brooks and Haugh, 2010; Deribe *et al.*, 2011; Badri, Crutzen and Van den Borne, 2012; Tsai *et al.*, 2012; Trani and Cannings, 2013). However, there are three points worth noting.

First, MSF's procedure for the ethical review of its field surveys (ERB) is the only INGO ethics-related oversight mechanism mentioned in the studies found in this review. Other NGOs might have their own ethics committees and procedures, but they were not mentioned in the included studies.

Secondly, it appears that only two studies were ethically approved in Sudan. One was reviewed by a Sudanese university's ethics committee (Badri, Crutzen

and Van den Borne, 2012), while the other was the only study that was reviewed and approved by the NREC (Elfatih *et al.*, 2010). Both committees are in Khartoum, not Darfur. Sudanese national guidelines require all studies that involve humans that are “linked to external bodies and that take place in more than one state (Interstate)” (National Ministry of Health, 2008, p. 23) to be reviewed by the NREC. This single study fulfils this condition, but most of the other studies were also done in more than one state and should have been submitted to the national committee, if the national guidelines had been followed.

The findings on the mention of consent and ethical review were key elements of the interviews and the discussions with the representatives of the NGOs and the governance bodies.

7.6 Limitations of the systematic review

The findings of this systematic review are subject to three limitations. Firstly, the conclusions of this review are based on the data reported in the reports/manuscripts of the included studies, which may not be accurate. A satisfactory level of precision could not be confidently attained, even after searching offline resources and communicating with the authors and the surveying institutions, given the limited feedback received from the authors. This limitation was addressed later in the project through semi-structured interviews with relevant stakeholders. Secondly, the status of ethical approval and informed consent were not always required to be included in the published versions of the study reports. The publication requirements vary depending on the policy of the surveying agency or the publisher, so comparing various types of reports may not be

consistent. Lastly, an important limitation lies in the fact that the reports included in this study were significantly lower in number compared to what is known about the amount of research undertaken in Darfur during the relevant period. As mentioned earlier, CEDAT estimates that more than 800 surveys were undertaken in Darfur between 2004 and 2012 (CEDAT, 2013).

IV. SECTION FOUR: RESULTS, DISCUSSION, AND CONCLUSION

8 CHAPTER EIGHT: RESULTS OF THE EMPIRICAL PROJECT

8.1 Introduction

8.1.1 General overview of the results

The previous chapter reported on the systematic review that addressed one of the thesis's empirical questions: what were the ethical issues encountered and reported on during research involving humans undertaken in Darfur during the study period? The systematic review concluded with a few possibilities that could explain its two main findings, namely the percentage of studies that reporting undergoing ethical review and obtaining informed consent. These findings, along with the relevant literature, were used to formulate the topic guides for the interviews and the focus group discussions in the empirical project that followed.

This section presents the findings of the empirical project, which aimed to address two of the thesis' research questions: 1) what ethical standards and procedures were used to provide guidance and oversight for research undertaken in Darfur during the study period?; and 2) what ethical standards ought to guide research involving humans undertaken in such situations of armed conflict? The latter question is related to the question of why these ethical standards were chosen.

Figures 8-1 and 8-2 provide an overview of the themes and how they are related to each other in two different yet complementary ways. Figure 8-1 maps the main themes under the respective project's research questions to assess whether these questions were adequately answered. Figure 8-2 represents a normative categorisation of the findings, which was essential to set the stage for the philosophical analysis presented in the Discussion.

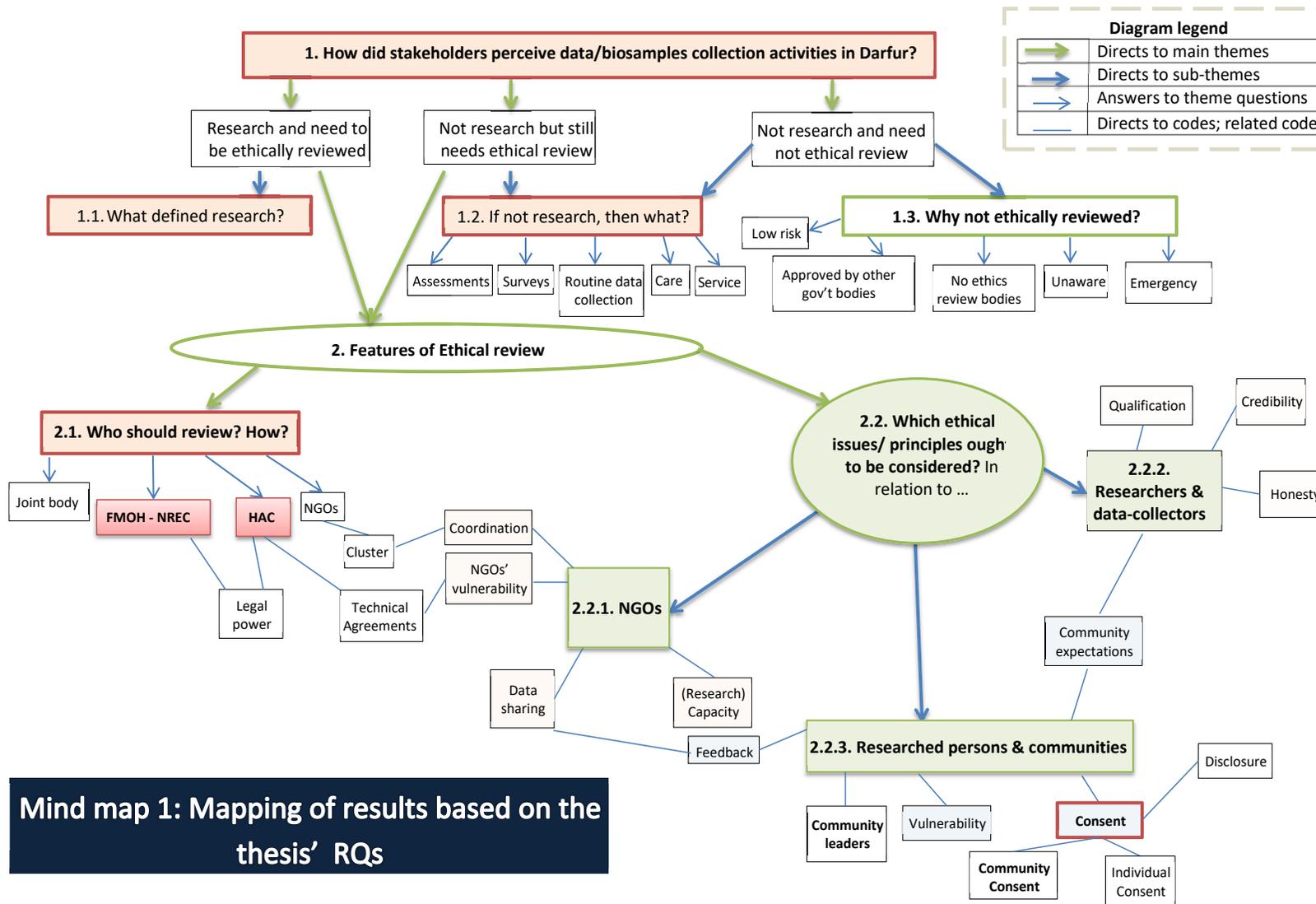


Figure 8-1 Conceptual mapping of results based on the thesis' research questions

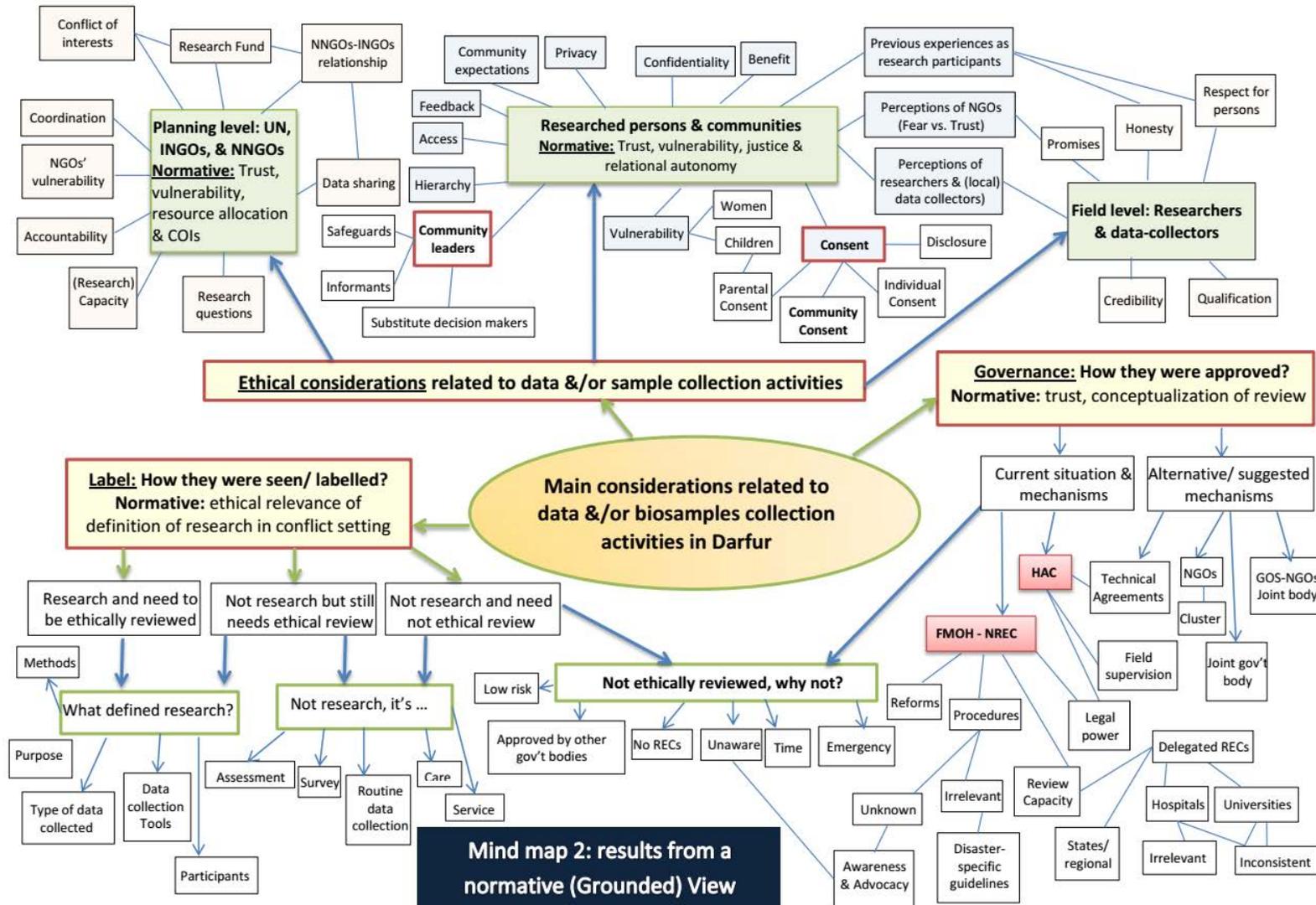


Figure 8-2 Thematic normative (grounded) mapping of results

The section begins with introductory notes on the methods used to report the findings, followed by the participants' profiles. It then presents the participants' views around five main themes: 1) the defining features of "research"; 2) "governance" for both humanitarian interventions and research; 3) the current status of ethical governance of humanitarian research and their suggestions on how to improve it; 4) the relationships among the various stakeholders and how these relationships affected the conduct of "research"; and 5) the meaning and practice of "informed consent" and the role of community leaders in the decision-making process.

The participants' views are outlined, compared, and then summarised, using quote(s) to illustrate the main views on each theme.

8.1.2 Introductory notes

This section provides some information necessary to understanding the results and the quotes used to support them. Any reference made to "state" or "states" refers to one or more of the 18 Sudanese states. Regarding the quotes, I tried to avoid changing the original directly translated wording of the quotes unless needed, as explained in the methods section. Edited parts of the quotations are represented by '...' in the quote, for example for necessary grammatical corrections (e.g. replacing "this studies" with 'these studies'). If quotation marks "..." are used outside of the quotes, then they are meant to indicate emphasis or that a term is not being used with its usual meaning (e.g. "research"). Within the quotations, segments contained within round brackets clarify meaning. For example, when a participant talked about a data-collector and a participant in the

same sentence, then used the 3rd person “he”, I have indicated who was meant in the sentence. The segments contained between square brackets are completions of missing words, like when a participant used the word “commission”, I have added [Humanitarian Aid] before it to explain which commission s/he was referring to. If material from the quoted sentence was omitted, it has been replaced by [...]. I deemed these edits necessary, otherwise the structure of the sentences and the use of some words may be confusing.

Each quote is followed by the speaker’s ID (see Table 8-1) which contains letters to denote the category to which this participant belonged (e.g. female internally displaced persons (IDPs) were denoted as ‘IDP-W’) followed by a number, which is the number of the focus group (1 - 3) in which s/he participated, then a forward slash to identify him/her within the group. For example, participant ID “FGD-NGOs2/6” refers to participant number 6 in the second FGD that involved the representatives of the NGOs.

For the quotes from humanitarian governance bodies (HGBs) and research governance bodies (RGBs), I chose not to name the governance bodies to which the interviewees belonged to help to maintain confidentiality. There are also a few personal notes that I have added to elaborate on a fact that was briefly mentioned by the participants. To avoid confusion, participants’ words are consistently provided as quotes; any additional information from my personal experience is inserted as a footnote.

Finally, given that the FGDs included representatives of various categories (e.g. UN, INGOs, and NNGOs), the views of the non-governmental staff participants in

the FGDs are categorically referred to as “organisation” or “organisational”. In the Discussion, I differentiate between the views of each category when needed to highlight differences in these views, where they exist.

8.2 Participants’ profiles

The categories of participants are explained in the Methods section (subsection 5.2). Table 8-1 summarises the targeted number of interviews or FGDs with each category of participants and what was actually done. It also shows the duration of participation for each category and indicates the ID given to the participants.

Table 8-1: Categories and numbers of responding participants

Category of participants	No. of invitees	Invited for	Responded	Participated			Average duration (in minutes) ²⁰	ID
				Tot.	M	F		
1- Independent researchers (involved as complementary part of the systematic review)	121	Online data collection forms	15	8	6	2		IR; each participant is denoted IR1 – IR7
2- The directors/heads of Sudanese offices of relevant UN Specialised Agencies and the Red	6	Interviews	3	1	1	0	40 min	UN
	5	FGDs	2	2	1	1	96 min	FGD-NGOs

²⁰ This is calculated as the average between the shortest and the longest interview/FGD durations in minutes.

Category of participants	No. of invitees	Invited for	Responded	Participated			Average duration (in minutes) ²⁰	ID
				Tot.	M	F		
Cross/Crescent								
3- The directors/heads of missions of the included INGOs	6	Interviews	3	1	1	0	46 min	INGO
	10	FGDs	8	8	4	4	96 min	FGD-NGOs
4- The directors of NNGOs	20	FGDs	20	19	13	6		FGD-NGOs
5- Governmental humanitarian and research governance bodies (HGBs and RGBs, respectively)	3	Interviews	3	3 ²¹	2	1	49 min	HGB, RGB

²¹ 1 HGB, and 2 RGB

Category of participants	No. of invitees	Invited for	Responded	Participated			Average duration (in minutes) ²⁰	ID
				Tot.	M	F		
6- Relevant FMOH departments	6	FGDs	4	4	1	3	96 min	FGD-NGOs
7- IDPs	13 men	FGDs	12	12	12	0	41.5 min	IDP-M
	12 women	FGDs	12	12	0	12	23.5 min	IDP-W
Total				70	41	29	662 (actual recorded minutes)	

In total, there were 70 participants: 5 interviewees, 34 participants in the NGO focus groups, and 12 male IDPs and 12 female IDPs in the IDP FGDs. The following subsections present further details on the representation of specific categories.

8.3 Response to the invitations to participate

8.3.1 The UN agencies' response

As stated in the Introduction, many of the main UN agencies are working in Darfur, in addition to more than 100 (mostly international) NGOs, and are organised in clusters. Most of these UN agencies are the cluster leads. For example, the WHO is the lead of the health cluster, the WFP is the lead of the humanitarian aid and food security cluster, and so on. Moreover, the systematic review (Chapter Seven) showed that the UN agencies conducted 19.6% and 41.2% of all the eligible studies from the CRED and the online searches, respectively. Therefore, their insights were significant to this project.

The UN agencies' response to the invitations, as the above table suggests, was variable. Out of six invited UN agencies, only two responded. One accepted and the director nominated one of the staff to be interviewed on his behalf. The other refused without citing any reasons. In other agencies, the responsible person was either "in a meeting", "in a training workshop", or "in the field", i.e. outside Khartoum. Later, one of the UN agencies nominated two of its staff to attend the FGDs. In total, one representative of one UN agency was interviewed, and representatives of other two UN agencies participated in the FGDs.

The absence of two key UN agencies (which either did not respond or refused to participate) is a limitation (acknowledged and discussed in subsection 9.4.1).

8.3.2 The INGOs' and the Red Cross/Crescent's response

The INGOs' position was not significantly different from that of the UN agencies. Out of six INGOs invited for interviews, only two responded. One accepted and nominated a staff member to be interviewed, but "not as a representative of the organisation". Another relayed the organisation's refusal to participate in an unofficial phone call, where the caller apologised, citing the sensitivity of my study and the problems they already had with the government at that time. The invitation to attend the FGDs was better received. Eight participants representing 7 INGOs attended the FGDs. The difference between the generally hesitant responses to the interview invitations and the more positive responses to the FGD invitations is by itself a finding worth reporting and discussing.

Neither of the Red Cross/Crescent missions in Sudan participated. One of them apologised in two ways. The official statement was that "they do not conduct any research activities"; they "only conduct [a] few focus groups when needed". I explained to them that these sorts of activities are included in my working definition of "research". This prompted an informal apology like the one I received from the UN agency that refused. For the other mission, the answer I received in my follow-up visits to their office was that "my invitation is on the Secretary's General desk and he will respond to it when he returns from his travels". He did not respond, at least not in the three-month fieldwork period during which I was in Khartoum.

8.3.3 The NNGOs' response

Though I initially thought NNGOs would be the most difficult to reach because most of them lack websites, offices and physical addresses, their response to my invitation was almost 100% acceptance to participate in the FGDs (19/20). It should be noted, however, that not all the participating NNGOs were working *in* Darfur at the time of the group discussion, as the main criterion for invitation was having previous experience in studying conflict-affected populations.

Summary points

- There was some reluctance from the non-Sudanese, non-governmental humanitarian sector to participate in the empirical project, citing different reasons, some of which were conveyed to me 'off-the-record'.
- Eventually, all the targeted sectors (GoS, NGOs, and UN) were represented either in interviews, in the FGDs, or in both, despite the absence of a few key organisations.

8.4 The meaning of “research”, what ought to be reviewed, and the capacity to conduct it

The working definition of “research” in this project was outlined earlier, specifically referring to the collection of health-related data/biosamples from humans, not for the sole purpose of their clinical care, and excluding any other type of research (e.g. purely sociological or anthropological studies). This definition was initially used as a guide to formulate the topic guides for the interviews and FGDs. Later, I also used it to clarify what I meant by “research” when recruiting the participants. However, the participants were left to express their own perceptions and offer alternative definitions of “research”.

The participants were drawn from the humanitarian sector, the governance bodies, and the population of IDPs. I present the participants’ views on what among the humanitarian activities they considered “research”. I then present the other terms used by the participants to describe these activities. The chapter ends with the participants’ views of research-associated risks and the “qualities of the researchers” in humanitarian contexts.

8.4.1 What constitutes “research”?

In seeking to establish ethical guidance for health research during conflicts, it is useful to first consider notions of how the concept of ‘research’ is constructed, using the perceptions of participants.

The participants suggested five main features of “research” activities in the humanitarian contexts, which are: 1) involvement of human participants, 2) data collection methods and tools, 3) purpose of the activity, 4) the type of data

collected, and 5) the activity's associated risks. Generally, those representing the governance bodies tended to broaden the scope of what they considered as research, while those representing the NGOs tended to narrow it. I now go through each feature, explaining how it was used by the participants to describe research, with respective supportive quotes.

8.4.1.1 Human involvement as a defining feature of “research”

Representatives of the RGBs maintained that “human involvement” *per se* was an indicator to consider the data/biosample collection activity as “research” and linked the label “research” to the need for ethical review. Though the need for ethical oversight was not challenged by other participants, including those who refused to call their activities “research”, there was some variation in opinions on how to conduct this review. It is worth noting that some participants' arguments against “ethical review” were against the current mechanisms of ethical oversight as represented by the NREC and not about refusing ethical oversight in principle.

“[T]he reference definition for research or health research is the same as the definition in the World Health Organisation, which includes any of the types of [research], whether epidemiological, and socio-behavioural, basic, and clinical, and socioeconomic... what matters [is] that all of them have human subject involvement” (RGB-1).

8.4.1.2 Methodology and data collection tools as defining features of “research”

The participants who used the activity's methodology and tools as defining features of “research” usually did so to support two views. The first was to argue that the data/biosample collection activities they conduct follow “standardised methods” or use “standardised questionnaires”, implying that they were reviewed

and approved before use. Thus, there was no need to have them re-reviewed for every study.

The second was to link “research” to particular types of methodologies, designs, and contexts or to a set of data collection tools. These mostly applied to clinical research done by scientists or academicians. Thus, to these participants, the lack of these elements would render these activities “not research”. There was also the typical assumption that “research” refers to clinical research, implying that only clinical research can be described as “scientific” research.

“[...] ethical considerations [are] regarding [...] the introduction of experimental study, to introduce new medications, drugs, and the selection of the sample²². But what I am talking about here (in humanitarian settings) is [to] provide a rapid assessment. This is what we are doing in ‘our organisation’s’ mission” (INGO-1).

“No, I don’t call it research of course. I cannot call this research [...] because by the nature of the conflict you cannot perform the studies in their scientific, precise way [...]” (FGD-NGOs3/8).

8.4.1.3 Defining “research” by its purpose and outcomes

This feature was arguably the most complicated concept to report for a number of reasons. Different stakeholders had expected different outcomes from the conducted studies. Examples of these expectations included the mere acquisition of data for planning and advocacy; service to the studied communities; a general benefit beyond the studied areas; obtaining an academic degree; and even the expectation to produce ‘positive’ data to reflect improvement in the humanitarian situation. For most of the participants, if the activity was initiated with

²² It was not clear if the participant was referring to a biological sample or a sample of a study population.

one of these outcomes in mind, they considered it is as “research”. Contrarily, at least for the IDPs, if the activity ‘failed’ to achieve an outcome; it is not proper research.

The idea of focusing on the ‘purpose’ of the activities was used both by those arguing for ethically reviewing these activities and those arguing against it.²³ The following two quotes reflect both views, respectively.

“That’s research definitely [...], they are making use of the data. [...] So I believe it is research and once being research, not necessarily to be clinical, even the one conducted at the community level should have ethical clearance” (RGB-2)

“It (i.e. survey or assessment) is done to support, or to get information, which can guide ‘...’ immediate response. So usually it is rapid initial assessment, followed immediately by a rapid response. So, it is not a theory we need to validate [...]” (INGO-1).

Another difficulty in reporting this feature arose from the humanitarian representatives consistently blurring the limits between what constitutes humanitarian “research” and the humanitarian services they provide. This was one of the areas this project tries to explore, as the initial assumption that there is a clear difference between “research” and “service” turned out to be difficult to sustain. Sometimes, it was difficult to distinguish between whether the participants were talking about providing services or about conducting research. Although all the questions and guiding points used in the discussion were based on “research”, the participants consistently referred to examples from the services they provide,

²³ Refer to my introductory note that what they refused was submitting their studies to NREC, not refuting the ethical review in principle.

whether these services were accompanied by “research” or not. In the discussion, I consider whether this distinction is possible and/or helpful.

From the IDPs’ side, they had an expectation that the studies conducted by any “charitable association” in their areas ought to have a positive outcome either for them or for other communities.

“Field visits (the studies) have consequences. After the field visit, the next step is the most important – action. Because of what happened from the first step to assess (the humanitarian situation); after evaluation [is finished] should come to the implementation” (IDP-M2/4).

The link between “research” and “academia” seemed persistent across the various categories of participants. The following quote from a “confused” participant in an NGO FGD is an example.

“I feel slightly lost (confused). Are we talking about scientific research? [like] Doctorate, masters and that carried out by the individual and then presented for ethical approval? [...], or are we talking about the research to be used in the field of the development or the emergency or health and so on? I think we are talking about the second type” (FGD-NGOs2/4).

For female IDPs, “research is a far thing” that only benefits the researchers and is not relevant to them if it does not include the provision of service.

“Research is for you (talking to the research assistant) to benefit from; we (the IDPs) do not take advantage of them (the studies). Let the information (results) with you [...] they do not return something to us [...]” (IDP-W1/1).

There was a particularly interesting finding linked to the service-based view of “research”. Most of the IDPs maintained a view that the conduct of studies in their communities was a sign of care. Thus, they repeatedly expressed gratitude to

researchers who came to their areas. Some asked for research to be conducted more frequently.

“I see it as a sign of care. As long as there are interested entities, even if once a year, [someone] takes the information and investigates your affairs²⁴. I consider it a ‘beautiful’ step and these studies should be, if it were not monthly, supposed to be at least every two or three months, to investigate the conditions of the people” (IDP-M2/6).

It is important to note here that the IDPs I was granted access to were an under-researched group, given their peculiar position as unofficial IDPs outside the usual NGOs’ working focus in Darfur-based camps.

8.4.1.4 Taxonomy of “research”

Participants representing the humanitarian sector used different terms to describe their data/biosample collection activities in humanitarian settings. The commonly used terms were “surveys”, “studies”, “projects” and “rapid assessments”. These terms were often used interchangeably. Thus, it was not clear, from what they said at least, what the differences among them were, except for a few participants who tried to distinguish “surveys” from “research”.

“The national organisations, [...] they conduct surveys, not research. There is a difference between survey and research. The study or the research is the big thing. The survey is part of the research” (FGD-NGOs3/3).

Other participants tried to provide characteristics for the label they used to describe these activities, like “initial”, “rapid”, or “nation-wide”. Generally, the participants used these terms without clear justification or explanation. In the humanitarian literature, however, this distinction did not seem to be clear either. In

²⁴ He used a Sudanese term that is usually used when a family member comes and checks the conditions of his/her relatives to see if they need help.

the Discussion, I argue for the irrelevance of the label given to these activities and that the ethical relevance lies with what they comprise, not what they are called.

8.4.2 What ought to be reviewed? Research-associated risks (and trust)

For the representatives of the HGBs and RGBs, almost all the humanitarian activity that involves “collecting information” should be reviewed. They tried to justify the need to review such activities by emphasising these activities’ potential risks to the country and to the participants.

The participants’ perceptions of risks associated with data collection activities in humanitarian settings were one of the main findings that brought up the emerging theme of “trust”. It is worth noting that these risks were not mentioned as a defining feature of “research”, but rather justify why a prior review of intended data collection activities is needed. In addition to the types of risks usually cited in the mainstream research ethics guidelines, such as physical risks, psychological risks, and social risks, the representatives of the governance bodies and the IDPs emphasised “political risks”.

8.4.2.1 Political risks

Some participants from the governmental side and some IDPs emphasised this political risk and frequently used sceptical expressions such as “hidden agendas” and “other purposes” as possible motivations for the conduct of such studies.

Political sensitivity was also used to justify why the review and approval of the surveys in Darfur were mainly done by the HGBs, along with security and

intelligence services, and not RGBs. The emphasis of this review was on what could have political implications, without reference to the ethical implications of these activities.

“For Darfur, it has its own situation [...]. Things seem political because they are [politically] ‘linked’, especially the surveys [...] We need to guard our things because no matter what, any organisation whatever has – and this is my own opinion – its own hidden agenda whatever it is” (RGB-1).

Likewise, an HGB representative explained the special procedures to approve humanitarian studies.

“[...] we have specific authority within which there are the specialised entities, by which we mean the Security, the Intelligence, and so on and so forth. Because I do not want to say that any work of a foreign organisation has [bad/hidden] dimensions. This is not in our minds and we do not begin by considering that he (NGO staff) has a hidden agenda or something like that [...] but we take precautions” (HGB-1).

The interviewee’s denial of a lack of trust somehow shows how deep the lack of trust was. Trust is the main moral lenses through which the findings of this project will be discussed.

On the other hand, some IDPs pointed out the political risks in the questions they were asked, especially from the INGOs, not knowing if these questions were “real or political”. Thus, most of them agreed that researchers should come to them through the community leaders because they (the IDPs) cannot know “what is in ‘the researcher’s’ conscience”, which is a Sudanese expression of doubt about someone.

8.4.2.2 (Direct) Risk to participants

Apart from the political risk, there was general agreement among various participants that humanitarian studies were associated with the potential of direct risk, given the vulnerability of the target groups. An example they mentioned was the risk related to the collection of blood samples. The IDPs preferred these samples to be collected in a health centre rather than in their households. Among other possible risks, I specifically asked about two risks, which I anticipated at the start of the project to be important to the IDPs. However, both seemed to be trivial to the IDPs I interviewed. These two risks were the assumed 'retraumatization' resulting from being asked about their war memories, and the risk of having the completed questionnaires containing the IDPs' detailed information falling into the hands of armed militia.

RA²⁵1 *Well, if we assume that they (the researchers) collected information including your names and addresses, do you think that such information may cause you any concern or a threat, for example, if they fall in the hands of an armed militia?*

IDP-W1/3 *We give our names directly. We have no objection.*

IDP-W1/2 *(Interrupting) There is not any danger.*

IDP-W1/1 *Let them know them (our names). We have no problem. We are clear.*

IDP-W1/5 *And what will they do to us? Even if those papers fell into their hands, so what?*

IDP-W1/3 *They will not be able to reach us.*

IDP-W1/5 *Even if they reached us, what will happen? Let the facts reach.*

²⁵ Research Assistant (RA)

It is worth noting here that among the limitations of the empirical study was that the IDPs I was granted access to did not mirror the typical structure of the IDPs in Darfur, who may have different views in terms of sources of concern.

Other participants referred to examples of direct, though non-physical, risks, like participants' lack of privacy due to the physical structures of their households.

“the Southerners²⁶ [who] are residing in Rawakib²⁷ with no privacy and anyone can see inside, [...] I instruct them (the data collectors), to seek permission, and to seek authorization before entering Al-Rakubah if there was a door, I knock on it and if there is not, I clap my hands” (FGD-NGOs3/3).

Another example of a potential lack of privacy was some male IDPs' emphasis on being present when their wives were being questioned or their children were being weighed. Contrarily, the female IDPs preferred not to have any male from the household with them while being interviewed.

“[The presence of] my husband is not a problem, but if it was my brother, Can I talk to him²⁸? Best not to be my brother or my husband or my son. However, if the discussions are public, even if there are men, I don't mind. However, the private (women's) things should be defined (discussed) with us by girls, only as women on our own” (IDP-W1/5).

8.4.2.3 Risk to data collectors and researchers

The third and final type of risk to be covered in this chapter is the risk to the data collectors in the field. Though I expected this to be a significant risk for the representatives of the NGOs, this was not held to be so by those interviewed. This

²⁶ Southern Sudanese refugees who fled the conflict in South Sudan to Sudan (see Introduction (1.1.4.))

²⁷ This is the plural of Rakubah, usually a temporary hut-like shelter made of straw, and covered by plastic sheets, or other primitive materials

²⁸ It could be interpreted as “how can I speak to you freely with him around?”

does not necessarily mean that risks to data collectors do not exist or are not a problem elsewhere. Many of those representing the NGOs were not actively working in Darfur at the time of the discussions. Additionally, the representatives of the humanitarian sector see this kind of risk as associated with the nature of the conflict setting and not as exclusive to research, and thus no activity can be categorized as “research” only because it carries such risk.

I have previously acknowledged that an incident that put one of the teams of data collectors at risk was a motivation that brought me to this project (Section V. Reflexivity). I expected that other NGO representatives would have had similar experiences. To my surprise, there were only a few examples and hints about this type of risk, which were shared as details in a story rather than as issues by themselves.

“If we want to reach for ‘one community’ we have to pass through the other community; [...] the society in which we are passing through may feel that its needs are not being met [...], so there becomes a type of grievance and exposes the safety of our workers passing by them to risk. This happened to us and there were precedents where some of our employees were shot and there were injuries, and since then we have learned that if we crossed a region, we have to study their needs” (FGD-NGOs2/1).

8.4.3 Capacity to conduct research

One complementary aspect that helps in understanding the participants’ views on research is their views on the capacity to conduct it. There were three points of agreement regarding the humanitarian research capacity: the reduced

research capacity of the NNGOs, the need for training of the data collectors, and the importance of having reliable and credible information from the field studies.

The NNGO representatives showed dissatisfaction with the quality of the research conducted in Sudan and linked this to the lack of support and national funding and the lack of proper qualifications for researchers and data collectors.

“It is very rare to find ‘national organisations’ conducting a study. [...] dependent on foreign organisations or working with foreign organisations in their research. [...] I can assure you that more than 90% of the governmental agencies that undertake research in the areas of the displaced [persons] have received [foreign] grant support and not governmental support. This means that if they did not find [foreign] support; they will not conduct research” (FGD-NGOs3/3).

Some of the representatives of the NNGOs shared experiences of how poorly qualified data collectors ruin studies.

“I know there are people (data collectors) sit under the shadow of a tree and fill the whole questionnaire from that shade, and nobody with them without seeing a single person; and brings you the questionnaire back” (FGD-NGOs1/5).

Similarly, many of the NGO representatives expressed their views on the attributes that the researchers and the data collectors should have. For example, some participants likened the researcher to a “prophet”, which is not commonly used in casual Sudanese conversations outside the religious context, except to refer to a perfect person who does not or should not make mistakes²⁹.

“I want to summarise the shape (the qualifications) of the researcher. The researcher must be role model for all the beautiful qualities of the human person, almost a Prophet. The ideal is what makes you acceptable in the community in

²⁹ This could liken to the use of term of ‘angels of mercy’ given to doctors and nurses

which the research is taking place. If you were not sincere, honest, decent, patient, and these beautiful qualities, you should have them to do your research.” (FGD-NGOs2/7).

Finally, the NGOs’ representatives shared some ideas to improve the national capacity to conduct research, mostly relating to the importance of training data collectors, supported by other regulatory measures. Some participants suggested training data collectors on ethical issues along with the technical³⁰ aspects of research, as well as close field supervision. However, a few participants suggested more binding measures, like making the data collectors sign a pledge of good conduct.

“Training is not enough. They need to sign [a pledge] that they will write the accurate thing. They should not make up information that is not true. They have to sign an agreement that they are [...] responsible for any information, a pledge” (FGD-NGOs1/5).

Summary points

- The participants used five main elements/features to describe “research”: its participants, data collection methods and tools, purpose, type of data collected, and associated risks.
- Most of these features were not unique to research and so it was not possible, using these features alone, to clearly demarcate research from non-research activities conducted in a humanitarian setting.

³⁰ The term ‘technical’ is the term commonly used to refer to the scientific and preparatory aspects of research, hence, the name the Technical Review Committee, whose role is to review the scientific aspects of research while the ethical aspects are revised by the ethics committee.

- There was general agreement on the limited national capacity to conduct research in Sudan, especially in humanitarian settings.

In the next subsection, I present the participants' views on how research ought to be ethically overseen, guided, and regulated.

8.5 The official narrative

Despite the lack of agreement on how to label the data/biosample collection activities undertaken in the conflict setting of Darfur, there was more agreement on the need for ethical oversight of these activities. In the Introduction (Chapter One), I presented an overview of the humanitarian- and research-regulating structures in Sudan, the HGBs and RGBs, respectively. In this chapter, I present the participants' views on these mechanisms and structures and their relevance to the humanitarian work in Darfur. The focus, though, is on the views from the official bodies responsible for the governance of humanitarian and research activities in Sudan, hence the title "the official narrative". This narrative will later be compared to that of the representatives of the humanitarian agencies and the IDPs, referred to as the "field narrative".

First, this subsection presents how the concept of 'governance' for both humanitarian and research activities was perceived and applied. I then complement the findings reported in the previous chapter by relating how the participants defined "research" to their views on whether these activities ought to have ethical oversight. Later, I present the main reasons I could find for not submitting these activities for ethical review. In the last part of the chapter, I describe the mechanisms suggested by the participants for the ethical oversight of "research" conducted in the humanitarian context of Darfur.

8.5.1 Governance of research and humanitarian activities

The concept of 'governance' was described differently in terms of what it comprises, its mechanisms, and its role in guiding/controlling research and

humanitarian activities. In this subsection, I present the findings on the participants' views on each of these elements. I should start, though, with two important notes. First, as previously detailed in the Introduction (subsection 1.2.10), there is a clear discrepancy in the procedures and legal powers of the research governance and humanitarian governance bodies, in favour of the latter.

Second, for humanitarian governance, there are three levels of oversight by three entities. First, there is the governmental humanitarian governance authority, represented by the HAC. Second, there is self-governance at the level of the non-governmental body, whether NGO or UN agency. Lastly, there is governance at the community level. By contrast, research governance seems to have only one central level, represented by the NREC, which compared to HAC lacks any local or field presence. Only the first two levels of humanitarian governance are presented in this subsection, while the role of community constructions of governance is outlined in sections 8.8 and 8.9.

The participants expressed their views on governance within two frameworks: governing bodies (or structures) and guiding documents, as explained below.

8.5.2 Governance as bodies and structures

The structures of the RGBs and HGBs in Sudan were detailed and compared in the Introduction (section 1.2.10). In this chapter, I focus only on the HGB and RGB representatives' strong positions on the governance roles of their bodies. They frequently gave detailed descriptions of their structures that "govern" and

“guard”. This section summarises these structures as described by the interviewees, starting with those of the RGBs and followed by those of the HGBs.

8.5.3 Research governance bodies (RGBs)

The most commonly mentioned research governance body was the National Health Research Council (NHRC), which is composed of two main committees (technical and ethical) and a secretariat, which is the Research Department at the Federal Ministry of Health. These structures have gone through many reforms since their establishment in 1996 (Table 1-4), where the NHRC and its committees, along with the Research Department, have been established, re-established, de-structured, and restructured under different names in 1998, 2000, 2004, 2005, 2008, and 2012. There are still on-going reforms. In the Discussion, I highlight possible reasons for and effects of these transitions on the conduct of studies in conflict-affected regions.

Almost all the categories of participants considered the NREC and the Research Department at the FMOH as credible reference points that should have a leading role in the ethical review of the studies in Darfur.

“[A] research coming from outside into this country [...] ought to ‘come’ through the national ethics committee, and the national ethics committee has to review it, and has to have an idea about it, and has to have eventually endorsed it or otherwise” (RGB-2).

Participants’ views varied as to whether the NREC should perform this role independently, delegate it to other local/national bodies, or work as partners with other stakeholders. These views are highlighted later (section 9.3)

“[I]t is the role of the Research Department to work on including the ethical review in the technical agreement³¹ to stay reassured that the results of studies will feed into the ministry and this strengthens the position of the ministry [of health]” (FGD-NGOs2/11).

Nevertheless, the current ethical review capacity in Sudan was viewed with some concern and possible solutions to address these concerns were raised. The concerns focused on the ability of the NREC, at least within its current working mechanisms, to provide an appropriate ethical review of the studies conducted in Darfur.

The main suggestion to overcome the NREC’s centrally functioning review model was to delegate the ethical review authority to local committees, whether in the hospitals, universities, or states. In fact, this delegation had already been agreed to due to the NREC’s workload. Three ministerial decrees in 2007 and later the Public Health Act in 2008 granted this delegation of review authority (see Appendices 4-6). Accordingly, the Research Department started to establish standards for research units in a few then-federal hospitals; however, the de-federalization of these hospitals disconnected them from the FMOH. The status of the hospital-based research units was not known even by the RGB representatives.

At the state level, the initial idea was to have a research ethics committee in every state. This was described as “imaginary” by an RGB representative. The suggested alternative was sectoral or regional committees, where Sudan is divided into geographical sectors/regions, each of which has a review committee.

³¹ The technical agreement is a prerequisite for any NGO that wants to work in Sudan, signed by the NGO and the GOS, represented by HAC.

“I think that if we managed to do the sectorial [Committees.], given that we cannot say that [...] any state should have an IRB. Because [by so doing], we will be imaginary and not all the states have [studies] done in them” (RGB-1).

Currently, the status of these committees in terms of their existence and functioning was reported to be unknown by the RGB representatives. Moreover, the local capacity to review research proposals outside Khartoum was viewed with doubt by some participants.

“If you are talking till now about only 15 committees developed so far, and it is unknown whether [...] functioning or not functioning [...] They were not accredited” (RGB-1).

Moreover, it was noted that there are no RECs in Darfur; review by a committee was thought to be needed for the ethical oversight of humanitarian studies.

“At the moment, they (RECs) are not there (in Darfur). But we must have it in the foreseeable future. I am talking about regional or state ethics committees, which still need further training. [...] and that’s not only for Darfur but also other states within the country” (RGB-2).

The NGO representatives raised similar concerns about the research review capacity in the states and whether these committees, if present, were aware of the national (federal) regulations.

In summary, there was general agreement that RGBs’ roles in the governance of health research in conflict settings were not known; that there was no RGB representation in Darfur; and that the main suggestion to improve the RGBs’ role in governance was to decentralise the ethical review process.

8.5.4 Humanitarian Governance Bodies (HGBs)

This section discusses the participants' views on the HGBs. One of the themes that emerged repeatedly was the relationship between the HGBs and other entities. The representatives of the HGBs noted three main roles for HGBs: “safeguards of national sovereignty”; “partners” in humanitarian activities, including humanitarian research and the publications resulting from them; and, finally, as reviewers of such research. The latter role is explored further in section 9.3.5.

First, the role of the HGBs as “guardians” was held to be achieved through the Technical Agreements (TAs), which are the agreements signed by any NGO, whether national or international, and the HGBs. No non-governmental entity is entitled to work in Sudan without signing a TA. The HGBs' role as guardian was mentioned in relation to national sovereignty and to guarding the participants' rights.

“At the end of the day, this is our Sudan. We are Sudanese staff and we are concerned with this country. Let the lead in the survey itself, or in its structure, be the people themselves, and [to be] led by the concerned ministry. It is she (the ministry) that should lead the work, and guide the work” (HGB-1).

Second, the HGBs' role as “partners in research” was expressed in two forms of partnership: technical and procedural. The HGBs have staff affiliated to the ministries relevant to the different types of humanitarian intervention, such as the ministries of health, education, agriculture, and so on. The technical form of partnership was reported to rely on the obligatory involvement of the corresponding staff in the intended project. For example, health surveys in Darfur

need to be reviewed and approved by the relevant department in the MOH, educational surveys need to be reviewed and approved by the ministry of education, and so on. The procedural form was described at the federal and the state levels, respectively.

“[If] you want to do a survey in Darfur, [...] you want to, for example, take a plane, [...]. Then certain procedures need to be followed here (in Khartoum). The permit you need for travel with a plane from here to there as a survey team is done with me here. [...] You, as an organisation, must come to me” (HGB-1).

“If the study has scientific aspects we send them (the researchers) to the State ministry of health, for example, to revise it, then it (the proposal) is sent to the people of the Security (the National Intelligence and Security Service) and police and after their approval, we will be with them³² [in the field]” (FGD-NGOs3/3).

It was clear that the HGBs’ involvement in the studies in Darfur, compared to the RGBs’, is more direct and is mandatory for the NGOs as part of the TAs that authorise them to work.

This involvement was not only procedural, but also included technical and methodological aspects of the surveys.

“And sometimes we move further in the arrangement and coordination [...], whether in the form of the questionnaire or the methodology used in the survey. We got to the point [...] that we refused an approach used in the implementation of the survey named MIRA if it passed you, Multi-integrated Rapid Assessment [...] as ‘HGB’ and as a government and as a country. We rejected this approach completely” (HGB-1).

³² It is not uncommon to have some survey teams accompanied (or observed) by army, or intelligence officers.

Lastly, the HGBs' role in approving the reports of the humanitarian research was emphasised. The representatives of the governance bodies expressed concerns about how NGOs could use the data obtained from the surveys they conducted in Darfur. Some of these concerns were covered in section 8.5.2.

“The survey findings can be possibly used for any purpose. Now I have opened my country, and let you into hot (conflict-affected) places and you collected information, but [regarding] the employment of this information - here we should [have a] pause, including their (i.e. survey’s findings) containment” (HGB-1).

A frequently cited example was the use of Darfur studies by the International Criminal Court (ICC) as evidence of war crimes claimed to be committed by the president of the republic.

“You know that humanitarian affairs and humanitarian affairs’ gate had dragged us to the ‘Criminal’³³... it is information after all... information, studies and research, ‘and the like’ from which the people extracted information and documented it. They raised these reports to the United Nations and so on” (HGB-1).

The HGBs' role in approving the humanitarian studies' reports for publication was described in terms of the partnership between the HGBs and the humanitarian agencies.

“Yes, I am the government. I am the country. I contribute to it in full participation and the findings to be with me. All the process happens through a real partnership... so what I consider a survey, I have in mind in what happened during previous practices [...] for example, there was in the report of a survey that

³³ A short reference commonly used in the Sudan to the International Criminal Court (ICC) on Darfur crimes, which warranted an arrest order for the Sudanese president Omar Al-Bashir in relation to the claims on his role in the atrocities in Darfur.

'halted the country to one man'³⁴. We [...] were briefed and it was reviewed, and the findings of the survey were announced in a very different shape" (HGB-1).

8.5.5 Governance as laws, regulations, and guidelines

The second governance-related theme that emerged from the HGB and RGB representatives was the presence of a regulatory framework that gives their bodies' specific authorities. The representatives made frequent references to the laws and other guiding and procedural documents which were outlined in the Introduction (sections 3.1 and 3.2). As a reminder, the HGBs' regulatory and legislative powers exceed those of the RGBs.

For RGB representatives, mentioning the ethical review of research in the Public Health Act without any reference to punitive actions against those who break the law was not sufficient. They expressed concerns about the lack of power of the research ethics committees, including the NREC.

"And the problem is that the research ethics committees are not very much empowered, even the national one. Because, if they were empowered, they could stop that research. And, nobody would embark on any research without informing them and ask for their ethical clearance" (RGB-2).

In addition to the law, another emerging theme was the interpretation of governance as the presence of regulatory documents, namely the guidelines and the application forms associated with them.

"Because we at the federal level running after governance and we don't want

³⁴ The original expression as said was 'made the country stand on one foot', which is used in Sudan to indicate a serious situation in which unusual measures are needed.

to restrict the things. No, we are just regulating but the regulation comes through what? Through the guidelines and the documents we publish” (RGB-1).

8.5.5.1 Humanitarian-specific guidelines and procedures

Most of the participants who were asked whether the current (national) research ethics guidelines were suitable for Darfur agreed on the need for conflict-specific guidelines. It should be noted here that except for the RGB representatives, no one was aware of the presence of the national guidelines or the NREC.

The way in which the participants expressed how these guidelines should address the situation in Darfur varied, even among the RGB representatives.

“I think that the ethical guidelines that we have now can be general [guide], but for Darfur [...] we need guidelines for any survey or studies within the emergency situation or disaster situation or whatever. I think so; especially that it is during emergencies and during disasters that the ethical [issues] become more” (RGB-1).

“[The national guidelines] have to be for the whole country and the situation in Darfur we believe and we hope to be a temporary one [...] but we could be either objective or selective in applying some of them and we could make the SOPs³⁵ for how to apply them in Darfur” (RGB-2).

Currently, there seemed to be no conflict-specific ethical review mechanism or procedure in place. However, many participants from both the HGBs and the NGOs believed that ethical considerations were already considered by the current mechanisms that applied. By “current mechanisms”, they were referring to the procedures of preparing humanitarian and other nation-wide surveys. The NGO

³⁵ Standard Operating Procedures

participants described the preparations for their surveys, which seemed to be meticulous and to proceed through different levels of technical committees. Occasionally, international experts were recruited for the sole purpose of participating in these preparations.

The HGB representatives described additional levels of review, namely that done by the police and the NISS in these preparations. They justified this involvement by the need to protect against possible “ethical violations of the studies”.

“We have a higher committee from which there is a sub-committee evolved; that is concerned with exactly what you say (ethics). It is a technical committee headed by the minister concerned with the humanitarian affairs. From this Technical Committee stem more specialised technical committees in the management of work in Darfur [...] with the concerned authorities, and when I say the concerned authorities and the regular security forces, I mean the intelligence (NISS), I mean the police, in terms of protecting from ethical violations and even physical protection. All of those (ethical considerations) are well considered and included in all the working mechanisms” (HGB-1).

In contrast, the RGB representatives did not seem to have any operational authority over or meaningful involvement in the humanitarian studies.

Summary points

- The RGBs have undergone several reforms for the last two decades.
- The RGBs have no role in the governance of health research in humanitarian settings, and there are no RGBs in Darfur.

- The main suggestion to improve the RGBs' role in the governance of research in conflict settings was to decentralise the ethical review process.
- Contrarily, the HGB bodies are directly and powerfully involved in the governance of all humanitarian activities, including studies conducted in any humanitarian setting.
- The procedures, guidelines, and agreements that regulate humanitarian activities and studies do not explicitly mention or tackle the ethical issues in these studies.

8.6 Ethical oversight of humanitarian research: views on the current practice

In section 8.5, the participants' concepts of "research" in the humanitarian context were highlighted. In section 8.6, the views on the governance of humanitarian activities, including "research", were outlined. They were generally focused on the presence of governance bodies and regulating documents. This section considers the possible link between the views on "research" and governance that could improve our understanding of the status of the ethical review of research conducted in Darfur. This section also addresses one of the empirical research questions: What ethical standards and procedures were used to provide guidance and oversight for research undertaken in Darfur during the study period?

8.6.1 The need for ethical oversight

No participant challenged the idea of having ethical oversight of health research in humanitarian contexts. However, they had varying views about what counts as "research" and if all humanitarian activities count as research. Participants used various justifications for the need for ethical oversight, the most prominent being the vulnerability of those affected by conflicts, the risks associated with these studies, the possible sensitivity of the questions in such studies, that it was mandated by the law or guidelines, and finally as a requirement of the NGO's policies.

"We must consider the risks, whether health or social or even the future [risks] for the vulnerable groups, especially for the two categories of women and children" (FGD-NGOs 2/8).

"We try to follow the ethical standards even without knowing that there is

something called the Committee on Ethical Standards³⁶ - [we have] Self-controls.” (FGD-NGOs 3/3).

This agreement was across almost all the participants, even those who did not consider their data/biosample collection activities as “research”.

INGO-1 In ‘our organisation’, there is such research ‘but’ not in Sudan mission. In other projects, there ‘are’ studies, following ‘these’ ethical guidelines and so and so. But for the rapid initial assessment, it is more related to provide a rapid response – emergency.

GH So, you do not consider what you do as research. Am I right?

INGO-1 No. Not research.

GH So, in terms of your work, what you consider as research that needs to be ethically reviewed? What would define... (interrupted by the interviewee)

INGO-1 Actually, it is ethically reviewed. [...] I think this form (questionnaire) used to assess the situation of people in need is usually discussed from the ethical point of view at a higher level.

In summary, the need for an ethical review of humanitarian studies was a point of agreement among participants. This theoretical agreement on the need for ethical review does not match the relatively low percentage of mentions of ethical review as reported in the systematic review. In the remainder of this section, I summarise how the participants justified not submitting their studies for ethical review.

8.6.2 Reasons for not submitting activities including data/biosample collection for ethical review

The findings of the systematic review were presented to the participants (mainly during the interviews) as raw data for them to comment on. The

³⁶ The participant was referring to NREC

possibilities that were suggested at the end of the systematic review were also used to probe or enrich the discussion about the systematic review's findings. I now compare the initial possibilities I proposed with those shared by the participants in the empirical study.

Some participants, especially from the humanitarian agencies, avoided calling these activities "research", as in the above quote. It is worth noting that, contrary to my expectations, the label of the activity did not seem to be the main reason for not submitting it for ethical review. Instead, the participants described other reasons, which are summarised below with an illustrative quote for each.

(a) Studies were considered low-risk:

Unlike the representatives of the governance bodies, most of the NGO representatives considered the humanitarian studies to be of low risk and therefore exempt from ethical review.

"[...] where there is no harm and [researchers] do not take biological samples or [undertaking] low-risk research. This can be [an] exception from ethical [review]" (FGD-NGOs2/1).

(b) The ethical standards were followed without formal review

Representatives of some NNGOs and INGOs argued that the absence of formal ethical review does not mean the absence of ethical standards. They gave examples of their procedures and organisational values and emphasised that the absence of ethical review did not render their work unethical.

"We try to follow the ethical standards even without knowing that there is something called the Committee on Ethical Standards - [we have] Self-controls" (FGD-NGOs3/3).

(c) Lack of awareness about and advocacy for ethical review

The lack of awareness about the presence of the NREC and the national research ethics guidelines was stated by almost all the participants as a possible cause for not submitting their work for ethical review, even those representing the RGBs.

“It is possible [...] that they are genuinely not knowing (about NREC) it is possibly [one of our] shortcomings. We did not advocate” (RGB-1).

“Actually, I didn’t hear about this committee or guidelines but people were talking generally about ethics and taking the consent of the people, but I didn’t hear any mention of this committee or these guidelines, honestly speaking” (UN-1).

(d) Time-related justifications: Emergency, urgency and time lag

Time-related justifications were used in two contrasting ways by the NGOs and the RGBs, to which I refer to as the urgency argument and the urgency counter-argument.

The NGO’ representatives frequently used words like “emergency”, “rapid”, “urgency” and their derivatives and synonyms to describe their activities. Rapid response is thus needed and the ethical-review-related procedures take a long time.

“Any camp for us means emergency” (FGD-NGOs3/1).

“Generally, in Sudan, we have ‘tortoisied’ (i.e. very slow) procedures realistically. The period of two months to get the ratification to work in the Darfur region is long to the extent that what I want to study may have changed” (FGD-NGOs1/7).

In contrast, representatives of governance bodies argued against this by suggesting that the situation in Darfur is no longer an emergency.

“The survey does not take place unless the situation has become a bit stable and there are no people dying, so the souls are preserved [...] in a stage [in which] I have already saved the lives. [...] I think that the ethical review will not disrupt humanitarian aid at all and will not lead that we lose our lives” (HGB-1).

Representatives of another UN agency argued along the same lines as the governance bodies, emphasising that the time for ethical review would be shorter than the time for technical and logistic preparations.

“Ethical [review] committee³⁷ cannot take a long time; not like the technical work. I think this (ethical review) can go parallel with that. Usually, I don’t agree with collecting this information ‘...’ in a hurry at the expense of having people’s consent or having these ethical considerations and because unless you have this consent, I think all that you have done is unethical. [...] I don’t agree with this [urgency] argument” (UN-1).

(e) Approved by other (governmental) bodies

Some NGO representatives referred to the close collaboration between their organisations and the partner ministries as implicit approval that could replace NREC approval.

They argued that this alternative approval was valid based on three main points. First, governmental bodies reviewed the data collection tools they used, and if these bodies approved the project, why was there a need to submit them to another governmental body? Second, there were governmental departments working alongside the organisations in the field. Some of these departments were within the FMOH, where the RGBs were located. If these ‘neighbour’ departments were not aware of the research governance procedures and did not follow them, then it would be unfair to expect the organisations to be aware of them or follow

³⁷ The participant was referring to the NREC

them. Lastly, they thought the ethical issues had already been considered and safeguarded by this close governmental monitoring.

“All the parties go together: the [Humanitarian Aid] Commission, WFP, the concerned ministries, the governmental counterparts, OCHA, they form Joint Assessment Missions. When ‘these are’ established, this means the tacit approval of the governmental agencies and means the tacit consent of the people who we want to do the assessment for. There is approval from all the sides to help these people” (FGD-NGOs1/4).

“There are close governmental involvement and joint work with the humanitarian actors; could we consider such involvement as approval – ethical approval? We are working at a higher level. This includes OCHA from the part of United Nations and the [Humanitarian Aid] Commission from the government’s side and ‘the ministries’. Is this participation an ethical approval? Or must there be bodies concerned with the ethical approval?” (FGD-NGOs1/4)

(f) Pre-approval of the tools used

Many participants indicated that the data collection tools (e.g. questionnaires) are standardised, and to them, this means they have already been reviewed and approved elsewhere.

“It (the survey) used standardised [data collection] tool, already considered these ethical issues and it is used [...] by other NGO’s missions, so there is [...] no ethical issue raised during our assessments because these [ethical] issues [...] considered already in the form, everything is considered [...]” (INGO-1).

(g) NGOs’ reluctance to submit their studies for ethical review

The RGB representatives implied that the NGOs systematically did not seek ethical approval out of reluctance or unwillingness to do so. The following quote exemplifies this ‘reluctance’ view, as well as a counter-argument to the ‘urgency’ argument suggesting that the NGOs cannot complain of delays in a process in which they did not even participate.

“If they (the NGOs) have the intention to submit it (the study), they would ‘have submitted’ it and then the ‘ethical committees’ look into it, even if they fail to pass it because of time; they may have an excuse, but the problem is that it is a vindication, which they are putting for a procedure which they didn’t initiate. [...] They could have asked that “let’s have an ethical clearance” and then wait for it if it’s too long; then they will have the excuse that “we’ve asked for it, [but we got] no reply, [so] we started”. But they don’t, and my belief is that they do not even consider doing that.” (RGB-2).

8.6.3 Alternative review models

“[...]in fact, it is meaningless for someone in Darfur to bring it to here in the federal [committee]. This is not practical” (RGB-1).

The need for changes in the current research review system to suit the needs of the humanitarian setting was undisputed, even by the RGB representatives. In this section, I briefly describe the main mechanisms that the participants suggested to achieve this.

Although most of the participants agreed that the NREC should have a key role in providing the guidance for ethical review, many of them expressed varying degrees of doubt about its suitability for Darfur studies. The participants justified their concerns by its centrality, the lack of NGO representation, and the use of a review mechanism that some participants considered irrelevant to their work. To them, the nature of the work in Darfur and the humanitarian context in general needed more flexibility in terms of time and procedures that according to them may not be achieved within the current standard ethical review mechanisms.

“I think the situation in Darfur is a very special one, and you cannot go through all the procedures which we do nationally here where things are at ease, and I feel that a special way of dealing with the research there [...] is possible and it should be looked into [...]” (RGB-2).

Thus, the participants suggested a few supplementary mechanisms that would support the current research governance mechanisms. Before outlining these mechanisms, it is worth noting that the participants did not offer them as definitive or as mutually exclusive. On some occasions, the same participants suggested more than one method to be implemented simultaneously. Additionally, many of these mechanisms were raised as impulsive suggestions, rather than rationalised recommendations within the course of an interview or an FGD. This explains why some of the suggested mechanisms may seem immature, overlapping, or inconsistent. In the Discussion and the Framework sections, I try to interpret these suggestions to form more comprehensive and actionable recommendations.

Despite the variety of the mechanisms the participants suggested, they agreed on some general features of these mechanisms. They held that mechanisms should be:

- a) Inclusive, i.e. have a balanced representation of both ethical and humanitarian expertise;
- b) Compliant with the national research ethics guidelines, yet not necessarily following their procedures; and
- c) Operationally-oriented, i.e. consistent with the special conditions of humanitarian work.

Finally, the role of community structures, like the community committee, the people's committees, and the local authorities, was integral to almost all the suggested mechanisms. Table 8-2 summarises the suggested alternative ethical review mechanisms.

Table 0-1 The suggested alternative ethical review mechanisms

Suggested mechanism	Main features and participants' views	Illustrative quote
1. Modified NREC procedures	Accelerated review process through a 'pre-approval approach', which is to have set of data collection tools reviewed and approved by NREC during the preparatory phase of the surveys, so the NGOs can use them directly in the field later.	<i>"Because there is something called 'E-prep', or emergency preparedness. So, in case of emergency, to have agreed tool, [...] to agree on the tool [that] will be used. [...] This could be for each emergency response to have agreed [-upon] tool or agreed methodology considering the ethical issue before the response, and to discuss this regularly" (INGO-1).</i>
2. Primary review (scanning) committee	An ad-hoc body that is affiliated with the Research Department that can offer an accelerated review or an exemption from review based on some form of 'triaging' of the studies based on their	<i>"In 2010 or 2011, a committee was formed, we can call it primary review committee and put its guidelines and SOPs (Standard Operating Procedures) so that it actually makes the sorting of the [proposals]."</i> <i>"They evaluate, "Does this need [to be seen by the</i>

Suggested mechanism	Main features and participants' views	Illustrative quote
	associated risks.	<i>ethics committee]?” (RGB-1)</i>
3. Sectoral/Regional ethics committees	Establish ethics committees in the different geographical regions (sectors) of Sudan and delegate them to do the review after building their capacity.	<i>“So, we can delegate the function of the national ethics committee to a regional ethics committee there, [...] And there, there are enough people who could look into the protocol, and if there is a problem they could ask [NREC]” (RGB-2).</i>
4. Review by HGBs	Integrate the ethical review along with the technical review to be part of the TAs already in place between the HGBs and the organisations	<i>“[...] for any survey we want to do, we share its methodology and the questionnaire with HAC [...]. HAC revises the questions and if they feel that in them any breach of the privacy of individuals [...]; it (HAC) asks us to either withdraw or alter them in any way. This is one of the ways that ensure not to breach</i>

Suggested mechanism	Main features and participants' views	Illustrative quote
		<i>the privacy of individuals or to be aware that there are ethical controls” (FGD-NGOs2/2).</i>
	Establish a ‘department for research’ within the HGBs to review humanitarian studies.	<i>“I suggest the establishment of a department for research in the [Humanitarian Aid] Commission [...] Moreover if there is an organisation that needs to conduct a research in each area, it gets this approval from this department” (FGD-NGOs2/5).</i>
5. Joint review body	To establish a review mechanism that includes the relevant governmental and humanitarian stakeholders. Generally, there were three suggested forms. The first was to keep the current review	<i>“So, I think there is a need for having an independent stand-alone [...] ethical committee with clear guidelines that are updated and considering all the issues, for example as I said, context-specific, gender issues, and user-friendliness I think there is a</i>

Suggested mechanism	Main features and participants' views	Illustrative quote
	<p>mechanism but to make it more inclusive by having representatives of the organisations in the research committees.</p> <p>The second was to have a “standalone ethics committee”, which is independent of the current research governance mechanism.</p> <p>The third was to have a joint governmental review mechanism, whether among the different departments of the FMOH or between</p>	<p><i>need to have certain committees” (UN-1).</i></p> <p><i>“HAC is not represented in the [Authority and (NREC) committee [...] HAC should be part of it (the committee); it is the [humanitarian] coordination body. It is the one that has the say. If I want to conduct research, I need the technical and the coordinating bodies. It should be part” (FGD-NGOs1/5).</i></p>

Suggested mechanism	Main features and participants' views	Illustrative quote
	the FMOH and the HGBs.	
6. Review by the NGOs	<p>To involve NGOs in the ethical review of humanitarian studies. There were two different views: First as supportive to the NREC, either by providing guidance in case the NGOs have specific guidelines, or as representatives of the community in the review committees.</p> <p>Second, through some sort of organisational in-house independent review, e.g. some indicated that their</p>	<p><i>“I believe that it should be the people in Sudan, the concerned people in Sudan, or the national ethics committee who considers it. I would agree that MSF and others all have their ethical guidelines [...]. But still, they are not working in their own country. They are working in a different country. And the ethics bodies or review bodies in that country should be involved” (RGB-1).</i></p>

Suggested mechanism	Main features and participants' views	Illustrative quote
	practice was ethically guided by their self-imposed organisational ethical standards.	
7. Review within 'cluster'	Integrate the ethical review within the clusters (see Introduction, section 1.2.6) by including members of the ethics committee in the cluster structure and meetings.	<p><i>"The National ethics committee [...] is completely absent in the cluster. It is not represented. It should be a part of the cluster" (FGD-NGOs1/2).</i></p> <p><i>"If all things [become] under the cluster, it means that the national mechanism³⁸ will appear in everything, e.g. assessments [...]" (FGD-NGOs1/4).</i></p>
8. Review by universities	Some participants suggested a	<i>"[...] The universities there (in the states) could act</i>

³⁸ Referring to the National Research Ethics Committee

Suggested mechanism	Main features and participants' views	Illustrative quote
and research institutes	partnership with the universities and the research institutes in the states, who could be tasked with conducting the ethical review of humanitarian studies in their states.	<i>as ethics committee for that particular project, and they probably 'know better'. [...] They know what is feasible and what is not feasible, and they could advise, along with that they could approve it on behalf of the national ethics committee" (RGB-2).</i>

Summary points

- All the participants agreed on the need for ethical oversight of health research in conflict settings.
- The views of those representing the humanitarian agencies offered some justifications for the lack of a formal ethical review of most of the studies conducted in Darfur. These justifications included that they were not aware of the RGBs, the studies were low-risk, the ethical standards were already followed without a formal review, and the humanitarian needs were urgent.
- The participants suggested a few alternative ethical review models to enhance or replace the current research ethics governance system.

8.7 The field narrative

In the Results so far, I have presented how the participants perceived the concept of “research” in humanitarian settings. I have also presented the participants’ views on the governance mechanisms that I described as the “official narrative”. In this section, I will highlight the complexity of the relationships among the different stakeholders with and within the conflict-affected communities. These relationships include those of the humanitarian agencies with their governmental counterparts and the communities they serve. The complexity of relationships in the field is described as the “field narrative”, in contrast to the official narrative described above.

To dissect this complexity, three types of relationships are identified. These are 1) inter-governmental relationships, 2) NGOs-GoS relationships, and 3) NGOs-GoS-community relationships. This subsection focuses on the first two types of relationships, while the interaction with the community is described in the next section.

8.7.1 The inter-governmental relationships and coordination

Participants representing both governmental and non-governmental institutions agreed that there is a lack of inter-governmental coordination when it comes to the ethical review of humanitarian studies. As explained earlier, the HGBs have the operational and legal powers to control the humanitarian activities, including humanitarian studies, while the RGBs are remarkably absent.

The humanitarian agencies were only required by law to work with the HGBs and the governmental ministries relevant to their work. The representatives of both research and humanitarian governance bodies, along with the NGOs’

representatives, agreed that the governance mechanisms are unrelated and neither of them is fully aware of how the other mechanism works.

“[...] in terms of ethics and review [we have] no relationship with them (HGBs). They're supposed to be represented in the [Research] Council, but things are not clear yet” (RGB-1).

This lack of mutual awareness seemed to cause confusion about the roles of the governance bodies when it comes to ethical review.

“There is an overlap that affects the clarity of who reports to whom. For example, we are now working with the Federal and the State Ministry of Health on the one hand and HAC on the other hand. The [Humanitarian Aid] Commission has control over the humanitarian aspects. Is the ethical policy³⁹ comes out from HAC? Or does it come from the technical expertise of the concerned (governmental) parties?” (FGD-NGOs1/4)

These questions about the source of ethical guidance from the governmental side were repeatedly asked by many representatives of the humanitarian sector. The representatives of the governance bodies did not have clear answers, given the complexity of the relationships and lack of clear demarcation of each party's role in the humanitarian setting.

8.7.2 Organisations' relationships

The humanitarian agencies work within a mesh of relationships among themselves and between them and other governmental counterparts. Some of these relationships were voluntary, but most of them were not and were governed by a series of necessary requirements. For example, the NGOs must be registered with the HGBs before conducting any activity and must seek permission for their travel and other activities, including the execution of studies.

³⁹ The participant was referring to the ethical standards and guidelines for research.

“Regarding the form of the relationship I am the responsible authority. I registered [the NGOs] and I am the observer, and I am the one to evaluate, and I am who determines the existence or termination of the existence of the voluntary entity or voluntary organisation... OK?” (HGB-1)

These authorities included the involvement of the police and the NISS in the approval procedures, as mentioned in earlier chapters. However, it is worth noting that the governmental policies towards the humanitarian agencies witnessed an important shift in 2009 when the so-called “fast-track policy” was suspended. This meant, practically, that many of the previously granted exemptions and facilities were revoked. The NGO representatives’ views of this shift were not as negative as might be expected. Some of them described this shift as an expected move from “response” to “control”.

“When the war began in 2003, the country was not well-suited for any kind of rapid humanitarian response and there was a state of general chaos and this continued until 2009, so this is why in 2003 and 2004 the number of the surveys was big [...] definitely the response in the first stage differs from the control in the second stage” (FGD-NGOs1/7).

On the other hand, the voluntary relationships could be exemplified by the relations between the various governmental departments that are part of the GoS and the relation between the INGOs and the NNGOs. The latter relationship is partly driven by the INGOs’ need to delegate some of their activities to the NNGOs.

Most of the participants perceived their institutional relationships with other stakeholders as part of the job, despite some complaints about delays, the lack of coordination, and the lack of awareness about some procedures. Nevertheless, there are many imbalances in these relationships in terms of power and resources among the different partners. In the following subsections, I highlight some

examples of the effects of these imbalances in the inter-governmental, inter-organisational, and governmental-organisational relationships on the conduct of humanitarian studies.

8.7.3 Institutional vulnerability (NGOs and GoS bodies)

The representatives of both the governmental and the humanitarian agencies perceived their institutions as sometimes in an involuntary, imbalanced, and inter-dependent relationship with other stakeholders. These features led to a perception of what I refer to as “institutional vulnerability”, by which I mean the inability of an institution to fully and independently protect its best interests due to a lack of material resources or legal powers that must be provided by another institution. Table 8-3 briefly highlights the sources and ethically relevant implications of this vulnerability.

Table 8-3: Main sources and examples of institutional vulnerability

Who?	Needs who?	For what?	Source of vulnerability	Example
HGBs	International organisations	<ul style="list-style-type: none"> • Provision of services not affordable or possible by the GoS alone • Reduction of the pressure of the international community on the GoS 	<ul style="list-style-type: none"> • Lack of national resources to fill the INGOs' roles efficiently • International pressure to facilitate the NGOs' work 	<ul style="list-style-type: none"> • The reports of studies conducted by the INGOs were used as evidence by the ICC for the alleged war crimes committed in Darfur
INGOs ⁴⁰	Humanitarian governance body	<ul style="list-style-type: none"> • Registration and obtaining travel permissions 	<ul style="list-style-type: none"> • The HGBs can (and previously did) revoke the NGOs' permissions • Confiscate property • Legal actions against 	<ul style="list-style-type: none"> • 13 INGOs were expelled from the country in 2008 • The ICRC was banned for three months in 2015 • UNAMID has currently been asked to end its

⁴⁰ The Sudanese NGOs are called 'national' organizations, while the non-Sudanese organizations are not called international; they are called 'foreign' organizations. The word 'foreign' in the Sudanese politics and media is usually used as a discriminatory label to make people cautious of something.

Who?	Needs who?	For what?	Source of vulnerability	Example
			their staff	mission and leave the country
NNGOs	International organisations and Humanitarian governance bodies	<ul style="list-style-type: none"> • Resources, funds, and technical support • Registration and security permissions 	<ul style="list-style-type: none"> • Lack of technical knowledge and resources to run their activities independently 	<ul style="list-style-type: none"> • Almost no humanitarian activity, whether service or research, is conducted by an NNGO without INGO support

Who?	Needs who?	For what?	Source of vulnerability	Example
Governmental departments (other than HAC)	International organisations	<ul style="list-style-type: none"> Resources, funds, and technical support 	<ul style="list-style-type: none"> Heavy reliance on partnerships with the intentional organisations⁴¹ Some areas in conflict-affected areas are not accessible to GoS staff alone 	<ul style="list-style-type: none"> All national and pan-Darfuri surveys in Darfur are mostly supported by the UN and other INGOs

⁴¹ This includes providing essential services, like education and health in conflict-affected areas, paying salaries and training for some GOS staff, and providing equipment and vehicles

8.7.4 Examples of ethical implications of the current institutional relationships

The largely imbalanced relationships among the different stakeholders could have many ethically relevant implications. However, the focus here is on three notable concepts that were frequently mentioned along with the institutional relationships, which are partnerships, data sharing, and funding.

First, “partnership” implies a continuous voluntary relationship between two or more equivalent parties who mutually benefit each other. This did not seem to be the case here. There were some examples that reflected the idea that “partnership” was merely used as a polite description of imbalanced relationships. For example, there was mention of a so-called “mandatory partnership”, which was introduced to fill the gap in capacity between international and national NGOs.

“The mandatory partnership means it is a must, in the technical agreement, to clarify the national partner organisation for each foreign organisation because of the disparities between the capacities and capabilities, and so on. You know the differences between the foreign organisation and the national organisation; thus, some sort of partnership became mandatory.”

The HGBs’ representatives justified this form of partnership by guaranteeing sustainability should the foreign organisation leave. Some NGO representatives were concerned about the bureaucracies associated with such mandatory partnerships between them and the HGBs.

“Because ‘if I mention’ the true objectives they will not give me [permission],

I may introduce other goals so I can get the approval, let us be clear, and this was why [some] organisations were expelled because they presented goals (to obtain approval), and then worked on other goals” (FGD-NGOs1/7).

Second, one of the contested issues related to studies in Darfur is the sharing of the data resulting from them. The sharing of results, commonly referred to as “data” in the quotes, was described in three ways: as a requirement to increase humanitarian aid efficiency, as an example of governmental control, and in relation to an ethical commitment to share them with the IDPs.

“Sharing studies is important because if you did a study in an area and then came another organisation this will make it easy for it.” “[...] rather than losing more funds in research that will lead them to the same outcomes, [...] and not to duplicate the work or reinvent the wheel, if the information is already available” (FGD-NGOs2/2).

Representatives of various organisations shared ideas about the need for and means of sharing data with the humanitarian sector and the community, including a suggestion to gather them in an “information bank”.

“The WFP makes the reports within the reach of its working organisations whether CBOs⁴² or national organisations working there, and then give them an outline of the result. They then share the outline of the findings [with the community]” (FGD-NGOs1/4).

Some NGOs’ representatives expressed frustration about some governmental departments’ tendency to ignore the survey data shared with them.

⁴² Community-Based Organizations

However, the most contentious aspect related to the sharing of the results of humanitarian surveys was the role of the HGBs in deciding what is to be published and how.

“Even when you finish the study, make your interpretation of the results, and you make your report, you must share it with ‘HGB’, and ‘HGB’ doesn’t give you the permission to share it (the report) with others unless it approves it and found nothing that would harm the sovereignty of the state or the targeted communities. After that, you are given the ‘OK’ to share your study.” FGD-NGOs2/2

Finally, sharing the results with the surveyed communities was generally seen by many as a duty that can be fulfilled by informing the community leaders.

“I consider the sharing or the dissemination of the results by the surveying agency an ethical commitment. [...] They (the community members) have the right to know the results [...] and this is a moral duty that we do not commit to too much” (FGD-NGOs2/3).

Some IDPs considered a study whose results were not shared with them as a “failed study”:

“If I did not know the results, then this is a failed study. If you know the result you can also improve your situation” (IDP-M2/6).

Some female IDPs were more specific about what should be shared with them, for example blood tests, and what is less important, like questionnaires. The significance of the results of their blood tests to them was the same whether the blood was collected for a study or for clinical care. This was another incident where service and “research” could not be distinguished.

“The questionnaire is not necessary [to know its result] because it does not make a difference. What makes the difference are the things that affect me directly

[...]” (IDP-W1/3).

“As long as it took from me [a biosample for] tests, I must know what is the result of my tests? Isn’t it? If you find that I have a disease, I want to know what the disease I have is” (IDP-W1/5).

Summary points

- The governmental and non-governmental entities are related to each other through imbalanced, inter-independent and complex relationships
- The imbalances in their relationships lead to a state of vulnerability for some institutions, both governmental and non-governmental, which was most reflected in the three areas of partnership, data sharing, and necessary support.

8.8 Consent and the role of community leaders and wider community structures

In this final subsection, I present the participants’ perceptions of consent and its application in the field. I should start, though, by acknowledging that the participants’ views on this issue were unexpectedly complex in terms of what they considered consent to be and how it was sought and given. This complexity could be attributed to three main causes, which I state here briefly and analyse thoroughly in the Discussion. First, my initial approach to consent was based on the mainstream individualistic approach to informed consent, as outlined in the mainstream research ethics guidelines. Second, though I was aware of the social structures in Sudan, these structures in the humanitarian context were more

complex than what I had encountered in my previous experience in Darfur. My previous roles in some epidemiological studies in Darfur did not require extensive engagement with the official authorities or the communities that were studied. Lastly, there was the difficulty attributed to the difficulty of distinguishing between humanitarian services and humanitarian studies. For most of the participants in the field (NGO staff and IDPs), they were the same. No studies were conducted without some relation to an anticipated, planned, or implemented service.

With this in mind, this chapter is divided into two main themes: 1) an overview of the community structures in the conflict-affected communities, with a focus on the community leaders and their roles in humanitarian research-related decisions; and 2) the views on informed consent and a description of how it was given by the humanitarian studies' participants.

8.8.1 Community leaders, community structures, and their roles in research within their communities

Generally, the community leaders' roles in relation to research conducted within their communities were categorised safeguards, informants, and substitute decision-makers. These roles were neither isolated from nor exclusive to each other and were not solely research related, i.e. the community leaders practised these roles for humanitarian service, research and other community-related affairs.

One finding is worth noting at the beginning. The frequently used term "community leaders" does not only refer to persons; it can also refer to structures

delegated by the affected communities to act on their behalf in certain roles. Figure 8-3 below outlines the structures within which the organisations functioned and the community decisions were made. No passage to a layer is possible without passing through the layer before it. The thick-lined circle is that of the community. The importance of community leaders in any humanitarian work, including studies, was among the points of unanimous agreement among the participants representing the humanitarian agencies and the IDPs. They agreed that meeting the community leaders should be the first step in preparing or implementing any activity in the targeted community. Thus, on many occasions, the community leaders were described as “doors”, “keys”, and “gates” to the community.

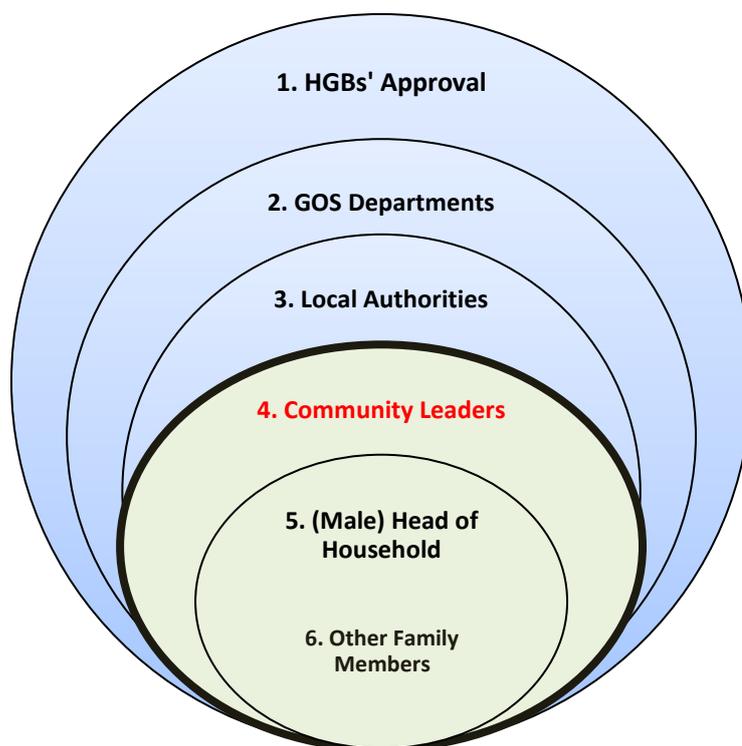


Figure 8-3: Concentric representations of layers (structures) within and surrounding the communities

“The community is entered through the doors and not the windows, through the identification of the community leaders and those who have a social, cultural, or political activity in the area” (FGD-NGOs3/2),

“[Community leaders are] the keys to the camp, if you have not convinced the Sultan⁴³ you will not reach the people [...] even [if you] sometimes feel that the Sultan is not trustworthy, but still you need to convince him so he can convince these people”. (FGD-NGOs3/3)

The importance of dealing with the community leaders was described as the “art of entering the community” that is required by researchers to facilitate their work.

“What if I don’t give them (community leaders) their respect they can obstruct your work. [...] Explain to them and then they introduce us to the community, there is the art of entering the community” (FGD-NGOs2/5).

“For them, the Sultans are the higher authorities, they obey them” (FGD-NGOs3/3).

This obedience was not absolute and nor as monocratic as it seems. The views of the IDPs highlighted how the community leaders usually acted within a wider community-situated decision-making process. They usually acted in consultation with community committees and other relevant local authorities. In addition, as Figure 8-3 above shows, the community leaders are not the final layer; even within the household, there is another hierarchy of decision-making.

One key element is whether the community leaders’ acceptance was an alternative to individual informed consent and/or applied some sort of pressure on the members of the community to accept what their leaders accepted. There was

⁴³ The title of the community leader in the southern Sudanese tribes.

general agreement that the community leaders' acceptance was not an alternative to individual consent and was not a source of pressure. Individual approval should still be sought and if a participant refused, his/her decision would be respected. The leaders were seen more as mediators than substitute decision-makers.

"I always instruct my group [of data collectors], "if you feel anyone is not accepting, stop immediately"; we withdraw immediately with respect to him and his opinion" (FGD-NGOs3/3).

From the IDPs' side, they explained how their community-situated decision-making processes worked and the role of the community leaders in these processes.

"We have our village council and I have this son (pointing to a young man sitting next to him), if there is anything, he brings it, so we do it. This is the person to be asked, he is the chief of the Village Council. Anything comes to him first then to us" (IDP-M1/3).

Generally, the IDPs did not consider that the presence of someone from the leader's side in the research team could affect their decision to accept or refuse to participate in a study.

"It (i.e. the presence of someone from the camp's leader) doesn't affect my decision whether to answer [the survey's questions] or not, if I want to answer I will, and if I don't I won't. They don't have any obligation to you" (IDP-M1/2).

Moreover, the female IDPs noted a similar structure in relation to the role of men within their households. They generally agreed that men should accept first before they decide.

"Men's approval [...] first. [...] comes from men and the 'community leader' first.

After the men agree and then we agree” (IDP-W2/s).

The IDPs also emphasised that they would always follow the community leader in his opinion. They frequently gave the example of why they accepted to participate in this project because they knew its objectives, and more importantly (to them) because I came to them through the leader of their community.

“We (the female IDPs) do not have any objection. You came with ‘the community leader’, so any opinion he gives, we agree with him” (IDP-W1/6).

8.8.2 “Informed consent”: Concept and practice

In this section, I report the main views of the participants about “informed consent” and share some examples of how it was obtained from the participants in humanitarian studies.

To begin with, the participants described consent using synonyms like “acceptance”, “approval”, or “consult”. Moreover, they did not only use it in the usual meaning pertinent to the individual research participant, but also for the approval of the local authorities and community leaders. In this section, some of the terms and descriptions of “informed consent” used by the participants are provided. Subsequently, I present a more elaborate differentiation between the types of consent, with a focus on the concept and practice of “community consent”.

Most of the participants agreed that seeking the consent of the participants in humanitarian studies is an ethical (or even legal) duty that should be fulfilled as a

sign of respect for the participant's dignity. However, there was variation in what was seen to constitute consent and which ethical values it served.

"I think that anyone that you need to involve in a study, or take information from, you need to consult him at least as a matter of dignity, but we in Sudan if anyone comes and asks, nobody usually objects or asks, "why do you need to ask me?" If he (the participant) will accept anyway, it would be better to make it official" (FGD-NGOs1/10).

Consent was almost always described as verbal, with no reference to an information sheet or that consent should be written to be considered valid. The verbal form of consent was considered the default. The few who justified why consent was verbal and not written referred to the urgent need for action.

"Approval (consent) is taken verbally, why? Because the response is [to an] emergency" (FGD-NGOs1/4).

Most of the participants considered seeking consent a sign of respect for people's dignity. Consent was, however, frequently discussed as an operational requirement to be able to access the community and not only as an ethical requirement.

"We were forced to inform the people about the nature of our 'work' and [that] we came to help. Only then we were able to continue our work" (FGD-NGOs2/10).

Although most of the participants agreed on the importance of obtaining individual consent, the IDPs frequently described their decisions in relation to other 'parties'.

"When they (the staff of an organisation) first come, they go to the people (leaders) of neighbourhood [committee], in the beginning, then president of the

neighbourhood [committee] agrees, and then they have with them people (representatives) of the committees and then knock on the doors, this is what is happening” (IDP-W1/2).

The community-situated approach to consent was justified as an expression of respect for the existing cultural structures. It was also said to be necessary to overcome the possible cultural and linguistic barriers between the data collectors and the participants, so the participants could be informed by their peers if the researcher failed to convey the study’s objectives. Consent was not seen as all about respecting the principle of individual autonomy, but as involving respect for other principles like dignity and pluralism.

I think that anyone that you need to involve in a study, or take information from, you need to consult him at least as a matter of dignity” (FGD-NGOs1/10).

Given this non-individualistic, multi-tier format of consent, compared to the common view of individual consent dominant in research ethics, it was not surprising to find some participants describing obtaining such consent as a ‘big problem’.

“The consent in Sudan is a big problem; it is not like “this is my name. I agree”. No, there are many layers starting from the Wali (state mayor), then the minister [of health], then the Neighbourhood People's Community, then the community leaders” (FGD-NGOs2/1).

From the above, consent in conflict-related studies can be described as a multi-tier, multi-person, and multi-principle community-situated shared decision-making process in which the participants of these studies were verbally informed, individually and collectively, of the basics of the intended study, either directly by the data collectors or by the community leaders. I refer to this broad process as

obtaining “community consent”. Individually obtained consent represented the last step within this broad step-wise approach.

The concept of ‘community consent’ was expressed in different ways by the participants, who also described different ways to obtain it. However, there were common points of agreement regarding consent, as summarised in Table 8-4.

Table 08-4: Common concepts about community consent in humanitarian studies

Common characteristics of “community consent”	Illustrative quotes
1. Relevant authorities and community leaders should be involved first	<i>“You sit down to the community leaders and give them examples, “we want to conduct a survey about the food insecurity in the target area. The survey consists of this and that, and these are the questions. Do you agree to answer these questions?” (FGD-NGOs1/4)</i>
2. Wide participation of the community members	<i>“You find all the men and youth sitting under trees, so you talk to them publicly and you spend more than one or one and a half hour talking about this and [...] after that, you have a community consent that people ‘can’ understand” (UN-1)</i>
3. Participants were informed and their consent was sought individually (after the community consent)	<i>“Some people don’t want to participate. So individual consent is very important, in addition to the community consent” (UN-1)</i>
4. Both individual and community consent were complementary (not	<i>“Certainly, personal consent of the person should be taken (gained) before they (the data collectors) fill ‘the questionnaire’ with him (the</i>

Common characteristics of “community consent”	Illustrative quotes
exclusive) to each other	<i>participant) [...] You give him a summary orientation about the study, [then obtain] individual verbal consent, as well as consent for group discussion” (FGD-NGOs1/4)</i>
5. Consents were taken mostly verbally	<i>“We are not keen on making them write anything except in limited [number of] studies” (FGD-NGOs1/1)</i>
6. Participants’ consent to participate is assumed unless explicitly refused, which could be described as an informal ‘opt out’ system.	<i>“We enlighten (inform) them about the issue (the study) verbally. We do not wait for their comments (feedback) unless someone [explicitly] objects. You enlighten, they remain silent, and you keep quiet after that. Then, you start your work [...] on that” (FGD-NGOs1/1).</i>
7. Consent is important to gain trust and to manage the participants’ expectations	<i>“[Consent is] [...] to let them know that this is a research and what is going to be [...] and even not to raise the expectations of people that they are going to receive something after the results of this research” (INGO-1)</i>
8. ‘Selective disclosure’ was common practice, i.e. the information disclosed to the participants varied according to the researcher's judgment of the participant	<i>“This (the consent) depends on you and the family’s acceptance of you. There are those, to whom you explain, [and] there are those we do not explain to them. It is for you to decide what you say. Sometimes you feel that this person will not understand so [there is] no need [to explain]. It is left to the discretion of the researcher” (FGD-NGOs1/8)</i>

The IDPs' views on "informed consent" were not different from those of the other categories of participants. However, they gave a more detailed community-oriented account that went beyond simply detailing decision-making within their communities. This decision-making process resembles a quasi-parliamentary model, where some members, led by the community leaders, were tasked with discussing and deciding within organised structures on the others' behalf. This delegation, however, was not only for research-related decisions but also for representing the community regarding its general needs in other fora.

"They (the leaders) gather the people. There would be an announcement that one of the organisations will be coming to you and then [the people of the] villages gather to wait for the people of the organisation to come to them, and when they come, the people of the organisation explain to the people their perception and then share their views on the appropriate option" (IDP-M2/4).

Female IDPs added a gender-related account in relation to their status within the community-situated decision-making processes. Although men had to give their approval first, women could still express their views if they differed from the men's.

Finally, there was variation regarding the disclosure of research-related information to the participants to obtain their consent. In this section of the results, I summarise and compare the views of what the NGO representatives were willing to disclose to what the IDPs expected/wanted to be disclosed to them.

For the NGOs, there was agreement on the need to disclose some information to those targeted by their activities, whether the intended activity was a service or research. They justified this disclosure by appealing to the vulnerability of those

they targeted, which gave them have high expectations of the NGOs coming to collect information about their communities.

“You would consider the people there (in Darfur), vulnerable people for being [involved in] research. So, they may not even be informed (aware) that they (the researchers) are doing research” (RGB-2).

Many participants described different approaches to gaining community consent. One approach was particularly interesting. It could be referred to as “demonstrative disclosure”. Generally, participants give their consent following a verbal explanation of the relevant facts about the intended study. However, in demonstrative disclosure, the researchers move a step beyond the verbal explanation. They bring samples of the tools and materials that will be used and show them to the community leaders to reassure them and to avoid confusion or doubts among the community members when the study starts.

“Do not do something they did not know. For example, [tell them] “We will go and measure the weights and will give women pills. These are iron pills⁴⁴, which ‘are’ not something (harmful), which is not a problem, not [...] planning pills, and will not cause infertility for men [...] The children will ‘be given’ milk. We are sure that the milk is not [...] expired” and give them samples to see. To reassure the people is the concept of consent. This is the concept of consent in Sudan – very wide” (FGD-NGOs2/1).

The information that most of the NGO representatives agreed should be disclosed to the community members included: the identities of the researcher and the team, organisational affiliation, and the purpose of the study. They also emphasised the importance of dealing with unrealistic expectations of their studies.

⁴⁴ These were pills containing a combination of folic acid and iron distributed by the NGOs as a supplement for pregnant women to prevent anaemia.

“I come to them (IDPs) with a group [of data collectors], say five. I tell them who I am, who those with me are, what is the research entity we belong to, where we came from, what we want from you (the participant), [and] then seek permission before we start. He (the participant) has the right to know why we came” (FGD-NGOs3/3).

From the IDPs side, there was not much difference. Some IDPs wanted to be provided with the outcomes of the study (once available).

“[...] the researchers should give us information to see their program⁴⁵. Is it valid (suitable) to me as a citizen or invalid (not suitable)? After that, if valid for me ok I will ‘participate’, [...] then I give him (the data collector) information” (IDP-M1/5).

Similarly, female IDPs wanted to know the study’s goals, procedures, and the affiliations of the researchers conducting it.

“There is a goal, isn’t it? Certainly, they did not come in vain. I want to know this goal that you (the researcher) wanted to reach. You came to my house so I have to know why you came” (IDP-W1/6).

8.9 Minor themes

As I noted earlier, the previous sections have covered the main themes that were emphasised by the participants and which I considered helpful in answering the project’s research questions. Nevertheless, there were other themes raised by the participants that could have been discussed as well. I was however limited in terms of what to report by two factors. First, some themes complemented other themes and so were not discussed in the depth needed to make them reportable as major themes. Second, there was difficulty in exploring all the themes, given

⁴⁵ The word ‘program’ is used in the Sudanese dialect as a placeholder for any kind of activity, when the exact word is missing

the project's available resources and time. Thus, I outline them as 'minor themes', which could be seen as seeds for ideas for future research (Table 8-5). However, their description as minor should not be understood to mean that they are trivial or unimportant.

Table 8-5: Summary of minor themes with descriptions and illustrative quotes

Theme	Description	Illustrative quote
Respect for persons and cultures "can make it or break it"	Most of the participants emphasised the importance of the researchers' awareness of the communities involved in their studies.	<i>"Your knowledge of the customs and traditions of the community can make it or break it. For example, there are communities that men data collectors cannot ask them certain questions. [...] Communities in Sudan are different. Therefore, the customs and traditions should be respected"</i> (FGD-NGOs2/5).
Rationalisation of community expectations	Some of the representatives of the humanitarian organisations emphasised the challenge of the community's expectations of the humanitarian studies. An essential preparatory step was to 'rationalise' these expectations, i.e. to be clear about the limits of the expected direct benefit from the study, if any.	<i>Community expectations can be exemplified by this IDP's quote: "After that, the organisations collected [our] names and went out with them; they should [have] come [...] with things to the affected people. [...] There are organisations that can help with such things, and there are organisations that take the names and go"</i> (IDP-M2/1).
Cultural sensitivities, especially regarding the participation of	A few of the male IDPs were against the idea of male data collectors	<i>"The discretion (from surveys) is that we do not accept entrance to families</i>

Theme	Description	Illustrative quote
women	interviewing women in their households and preferred female data collectors ⁴⁶ . Moreover, some men suggested that they needed to be present even if the data collector were female.	<i>(women). This should be done indirectly, and must be done conservatively” (IDP-M2/1).</i>
Research participants’ vulnerability	Some of the project’s participants used a variety of physical and psychological features to refer to the vulnerability of the potential participants in humanitarian studies	<p>Examples of the criteria used to refer to the vulnerability of the conflict-affected population:</p> <p><i>“who are suffering from the war effect or endemic diseases, or outbreaks, or may be neglected” (INGO-1),</i></p> <p><i>“[...] uneducated, unemployed, and may join the other forces (militias)” (UN-1)</i></p> <p><i>“Since we went out [of our villages] and we do not have anything, no clothes, no bed, no pension, and we have children” (IDP-W2/6).</i></p>

Summary points

- Researchers in humanitarian settings have to go through layers of governmental and community structures before being able to contact the research participants directly.

⁴⁶ Personally, I had great difficulty in arranging the women’s FGDs, despite assurances that only female research assistants would facilitate them. The community leader mediated one-week ‘negotiations’ that ended up by my promising I will not be present in the venue where the FGDs were taking place, and they wanted to see the female research assistants before accepting letting them in.

- All the participants emphasised the community leaders' roles in decisions pertaining to their communities both operationally and ethically.
- Consent was almost always obtained verbally rather than in a written form and was reported never to be agreed upon between the individual participant and the individual researcher. Community consent was the most common form of consent.
- Various participants described shared common features of how consent was sought by the researchers and given by the participants in the humanitarian studies

V. REFLEXIVITY

Reflexivity is a critical self-reflective qualitative research strategy. It addresses the possible subjectivity resulting from the interaction of the researcher with the people and events they encountered in the field. Researchers should reflect continuously on how their own actions, values and perceptions impact upon the research setting and can affect data collection and analysis (Primeau, 2003; Ives, 2007; Gerrish and Lacey, 2010). Primeau emphasises that reflexivity “enhances the quality of research through its ability to extend our understanding of how our positions and interests as researchers affect all stages of the research process” (Primeau, 2003, p. 9).

I thought it important to include this section on reflexivity before the Discussion section to clarify the conceptual progress that led to the main themes to be discussed.

The idea behind this project originated in my experience as the survey manager of the Sudan Household Survey in one of Darfur’s states in 2006. One of my data collection teams whose members were young men and women aged between 19 and 24 years went to a randomly selected remote village where there was no mobile or landline coverage. The village was classified as a “2-vehicles go-area”, i.e. safe enough to be entered in a convoy of two vehicles. They called me from a landline from the nearest village once they had arrived and told me they had started the data collection. A few days later, the security situation changed, as it often does in Darfur. The village was attacked and I lost communication with the team for a week. The parents of the team members started to call me to ask about

their children. I had no answer to give them, except for the rumours that this part of the state had been attacked by a group of militants, which the parents already knew. To cut a long story short, they survived the attack and managed to return physically safe with the completed questionnaires, having been helped by some locals. I gave those who chose to continue a few days off to recover from this traumatic experience. Some of them were too traumatised to continue and preferred to leave.

One year later, I went to Canada to study for a Master's degree in bioethics, which was a completely new field to me. In almost every course in the Master's, an endless list of questions arose for me about the rights of the participants in conflict-related studies, the rights of the data collectors, and other issues like the privacy and confidentiality of the data collected during armed conflicts. I continued to wonder what would have happened if the completed questionnaires had fallen into the hands of the fighting militias in that tribal conflict. These questionnaires had the names, ages, addresses, and other detailed information about more than 100 families. I believed that would have been catastrophic.

I have strong beliefs about human freedom and deliberative democracy as a political model, which aligned well with my introduction to autonomy and informed consent whilst studying for my Master's.

These beliefs and difficult times in the field made me start this project with very strong opinions about the importance of consent and the rights of participants to know about the unique possible risks of their involvement in a humanitarian study. During the course of the project, however, my supervisors managed to help

me to make a distinction between my personal beliefs and my role as a researcher. Gradually, I became aware of the dangers of such personal views, if not adequately managed, for the credibility of my work and the outcomes of this project. This fine-tuning shifted me from an activist mindset to a researcher's one.

Before the fieldwork, I acknowledged these initial perspectives and kept them in mind throughout, particularly when I started to work on the topic guides. I tried to minimise the effect my beliefs might have had on the way I formulated and asked the questions, facilitated the discussions, and reported and analysed the data. By always intervening as little as possible with the participants' expressions of their opinions, ensuring my analysis was derived from the data and by having a series of close checks on my works, as explained earlier in the thesis, I have strived to ensure that my interpretations of the data do not only reflect my own prior inclinations. In fact, I have changed most of my initial perspectives in the course of this project.

9 CHAPTER NINE: DISCUSSION

9.1 Introduction

In the previous chapter, I presented the participants' views about which of the humanitarian activities under study in this project, hereafter referred to as "humanitarian research activities"⁴⁷, ought to be ethically overseen, and how such ethical oversight should be conducted. These views were reported under four main themes: 1) the meaning of "research" and which humanitarian activities ought to be ethically reviewed, 2) the mechanisms of governance in place (the official narrative), 3) the current practice of humanitarian activities (the field narrative), and 4) consent and the roles of community leaders.

In this chapter, I start by explaining how the empirical findings informed the philosophical analysis and then discuss two possible narratives according to which these findings could be interpreted. This is done to answer three key questions:

- 1- What justifies submitting "research" (as defined in this project) for ethical review?
- 2- Who should be involved in the ethical oversight of humanitarian research activities? and
- 3- How should this ethical oversight be provided?

The discussion of the first question relates to the concept of "research" as commonly characterised by research ethics guidelines and what justifies subjecting "research" to more stringent ethical oversight, compared to other similar activities. I apply these justifications to humanitarian research.

⁴⁷ I use this term cautiously to indicate any research activity (as characterized earlier in the thesis) conducted in a humanitarian context.

Second, the discussion of the second and third questions relates to the theme of “research” governance. The overall argument is that the mainstream research governance model is not appropriate for the ethical oversight of the humanitarian activities under consideration, because it lacks the two conditions of moral representativeness and operational practicality. To represent this lack of moral representativeness, I use the example of the consent of human subjects to participate in “research” as a core ethical requirement in all the research ethics guidelines. I contrast the mainstream individualistic autonomy-based approach to consent with a relational autonomy, trust-based ethical approach. This contrast is achieved through a systematic critical analysis and contrast of both the participants’ views and the relevant literature, especially that on consent and trust. The approach is outlined in detail in the Methods section (subsection 5.2.6).

Finally, I conclude that to bridge these moral and operational gaps, the governance systems for the humanitarian activities under consideration ought to acknowledge the community values and complement the community’s structures.

To this end, the discussion is focused on how the empirical findings and conclusions support the kinds of changes to disaster research ethics suggested by the relevant literature. The aim is to provide a robust normative justification for why we should accept the culturally specific values identified in the empirical research (i.e. a trust-based system) over the theoretically driven imported values.

Two pieces of literature receive particular consideration in the framing of this discussion. The first is Zwi et al. (2006), who suggest “a more interactive relationship between the key stakeholders involved with research in conflict-

affected settings [...] based on incremental changes to guidelines or slight modifications to methods” (Zwi *et al.*, 2006, pp. 266–269). The second is Mackenzie *et al.* (2007), which highlights some of the “challenges involved in applying the central normative principles governing the ethics review process [...] to the context of refugee research” (Mackenzie, McDowell and Pittaway, 2007b). Both articles focus on the following aspects in relation to research undertaken in refugee settings: power, autonomy and agency; consent and community representation; confidentiality; reciprocity, risk, and benefit; trust and mistrust; harms, risks and benefits; and the role of local bodies in the ethical oversight of research (Zwi *et al.*, 2006; Mackenzie, McDowell and Pittaway, 2007b). In this chapter, these aspects are discussed in alignment with the themes presented in the Results, along with examples of how these ideas might be implemented in the Sudanese context and what a trust-based research governance model might look like.

The choice of these two studies is based on the similarity between their approaches and conclusions and the findings of this project. In a way, these findings can be interpreted as empirical evidence for the kind of challenges they highlight and the changes they call for. Nevertheless, it should be emphasised that the use of these two pieces is meant to be a method of framing the discussion rather than a repetition of what is mentioned in the two articles. Therefore, the discussion does not give equal weight to each of the principles mentioned in the two studies and sometimes endorse different views. To illustrate, the stepwise consent suggested by Zwi *et al.* (2006) matches the finding that community consent is the main form of consent, yet I use the empirical findings to elaborate

on the discussion of the complexities within which the process of obtaining takes place. In contrast, the authors suggest iterative ethical approval and the use of peer advisory experts for the ethical oversight of research in conflicts. The findings provide a different model of ethical oversight that does not fit within these suggested mechanisms. Similarly, other similarities and contrasts are presented in the following subsections.

9.1.1 Another signpost about the move from the empirical to the normative

Following what I outlined earlier (subsection 5.2.6), the move from the empirical to the normative is guided by the coherence of the arguments rather than a priori moral judgments through what I refer to as “mutual scepticism”. By this, I mean that neither the empirical findings nor the mainstream research ethics guidelines are given a status of moral priority or immunity from criticism. The aim is to build a coherent argument, rather than to match the views of the participants or those emphasised by the mainstream ethical guidelines.

The significance of this position is not seeking a middle ground between the local and the official narratives. Rather, I aim to arrive at coherent arguments using the empirical findings of the project without falling into passive acceptance of the community’s values only by virtue of them being endorsed by the community members. Likewise, the mainstream research ethics guidelines and the ethical principles therein are not taken as moral benchmarks, because they also have their own inadequacies, as I explained in the relevant subsections. Overall, the discussion is meant to achieve a critical engagement with the moral experiences of those included in this project (Ives, 2008), so that the discussion

provides a sound basis for a philosophically robust and empirically informed normative framework. Overall, if the current societal practices in terms of the ethical governance of humanitarian activities are (or can be) morally grounded and philosophically defended, then there is no point in rejecting them. These practices could be accepted if this acceptance is *not* used as a springboard for accepting other community practices that do not have the same moral soundness and philosophical robustness.

The move from the empirical to the normative went through three main steps. First, I tried to explore the facts by studying the local settings within which the moral judgments are made. Then, I studied these judgments through traditional philosophical rationalization comparing what *ought* to be the guiding principles as demonstrated by the mainstream research ethics guidelines to the communities' moral realities. This comparison was done through the mutual scepticism I explained earlier, before concluding which moral values ought to guide the ethical conduct of humanitarian research. Finally, I present a draft ethical framework where the moral options can fit within the humanitarian system either as a new structure or as a structure complementary to the current system. How this system will look and what challenges it may face are presented in the final section of the Discussion.

9.1.2 Two possible narratives to interpret the findings

The views of the participants fell into two incompatible possible explanations, which I term the “official” narrative and the “field” narrative. The “official narrative” expresses what is supposed to happen, as viewed by the governance bodies,

while the “field narrative” describes what happens as expressed by the representatives of the humanitarian sector and the IDPs.

The official narrative is that of a formal, committee-based, and guideline-oriented approach to governance of all humanitarian activities, including what representatives of the governance bodies considered as “research”. This narrative discussed the humanitarian activities within the formal regulatory frames and assumed that these activities should comply with these frames.

In contrast, those in the field (NGO staff and IDPs) provided a significantly different picture of how the humanitarian activities, whether service provision or data collection, are implemented. This discourse showed that the international research ethics guidelines are not followed, nor are the national research guidelines known, let alone followed, and the RGBs are not consulted regarding the “research” activities in humanitarian settings.

There could be many ways to interpret this mismatch between the two narratives, but I focus on two discourses that I compare systematically. One possibility is that the humanitarian agencies failed to abide by the national research guidelines and governance systems, and so should be asked (and sometimes forced) to comply with the official governance system. I refer to this position as “the narrative of failure”, which suggests that the humanitarian sector failed to follow the standards and that the governance system ought to be empowered and equipped to correct this failure. I reject this discourse. I defend an alternative approach, the “local narrative”, which was detailed by the field representatives, who described a community-oriented and trust-based governance

system for humanitarian activities, including “research”. This discourse represents the backbone of the discussion. In this subsection, these two narratives are explored and the “local narrative” is defended as the more appropriate way to interpret the findings.

According to the official narrative, the humanitarian agencies have *failed to comply* (for various reasons) with the formal governance system. Within this “narrative of failure”, any activity that the governance bodies consider as “research” should be submitted for formal review. If such a “narrative of failure” is adopted, the discussion naturally leads towards calling for a stronger, more empowered, and committees-based research governance system aiming at making the field practices more compliant with the governance system. The starting point and the benchmark in this narrative are that the mainstream international (and national) guidelines are the legitimate indicator of ethical practice and thus ought to be followed. Consequently, practices that do not follow these guidelines may be judged as unethical. For both the research and humanitarian governance bodies, the “narrative of failure” better reflects their reaction to the findings, as this failure to comply could be evidence to support a more prominent role in research governance and more extensive control over humanitarian activities.

The alternative approach is the “local narrative”, which provides a detailed description of the realities of the societal structures and moral values and the humanitarian operational needs. In the local narrative, unlike the narrative of failure, the legitimacy of what is ethically defensible does not rely on the guidelines

and the formal system alone, but builds upon an understanding the local moral values and societal structures. I defend the interpretation of the project's findings within this "local narrative" for a number of reasons.

First, there are genuine doubts, as will be detailed later, about the legitimacy and relevance of the mainstream (international and national) research ethics guidelines to humanitarian research. Generally, the mainstream guidelines assume that the individual participants in research are the ultimate legitimate makers of research-related decisions. Such an individualistic view is not compatible with the socio-cultural structure, mindset, and beliefs of most of Sudan and probably other developing countries, as other authors have suggested (Lindegger and Richter, 2000; Mystakidou *et al.*, 2009; Tekola *et al.*, 2009; O'Mathúna *et al.*, 2010).

.Additionally, adopting the "narrative of failure" would suggest the false claim that the international guidelines are to be universally applied because they represent what is universally morally important. In turn, this claim to universality holds "the risk of over-generalizing moral discussion by appealing to abstract and absolutist moral formulations" (Dawson, 2013). The assumption that such formulations can provide guidance for research conducted in a context like that of Darfur or developing countries in general must be justified before being adopted. These guidelines are international in the sense that they are adopted by the main agencies that fund and/or conduct research. However, it is not practical to assume their acceptance by those who were not part of the guidelines' development and were not meaningfully consulted about the ethical principles they advocate. Here,

integrating empirical evidence with moral philosophising becomes important as a possible basis to claim or justify that the adopted set of ethical principles has the assumed universal acceptance. Also, as noted by Zwi et al. (2006), these guidelines are “structured around a set of normative principles that are largely biomedical in their derivation” (Zwi *et al.*, 2006, p. 265). They assume that a balance of power between the researchers and the researched exists or can be achieved. In the extreme circumstances of conflicts, where people may be struggling to survive, the relationship between the researchers and the researched is expected to differ significantly from that in non-emergency settings. Therefore, there is a need for a set of principles that can address the realities and the peculiarities of conducting research in conflict settings.

The second reason to favour the “local narrative” over the “narrative of failure” is that the participants’ unanimous acceptance of the current local governance “system” is difficult to ignore. Again, this does not entail a mere passive acceptance of the local status quo, but it does require us to take seriously the participants’ detailed and well-articulated expression of the legitimacy of community-related decision-making structures. Paradoxically, it is the narrative of failure that passively assumes the current official governance system is the ethically defensible option, only because it relies on international standards and because it is the dominant research governance model elsewhere. The participants who defended this narrative (mostly from the governance bodies) failed to provide a meaningful rational analysis of why the international guidelines should be followed and hardly provided any further argument for why the formal governance system should be adopted. Thus, following the methodology I detailed

earlier where only the discourse that provides a more robust and consistent argument would be defended; I found the local narrative worth endorsing as a more reliable and better-founded discourse.

Additionally, the local narrative represents a better expression of the ethical principles that research governance is meant to promote. For example, mainstream research ethics guidelines are meant to protect the participants in “research” activities. In the mainstream research governance model, this protection is assumed to be ensured by having the research proposal reviewed by a research ethics review body (RERB)⁴⁸. In contrast, the local narrative described a more sophisticated oversight system with multiple layers at which the proposed studies were considered and discussed. As such, the local governance system has the ability to monitor the implementation of the approved studies, which many RERBs cannot achieve even in developed countries (De Vries and Forsberg, 2002) and certainly not in Sudan.

The local narrative provides a more defensible view of the legitimacy of research-related decisions. Legitimacy is foundationally important because it is the justification of who has the true authority to make decisions about ethical guidance and governance. Many research ethics guidelines are based on the notion that it is the adequately informed, individual participant that is *the* source of such legitimacy. Exceptionally, when these *individuals* are not able to make such decisions, proxy decision-makers (usually individuals) may be sought. This reflects

⁴⁸ I introduce this term as a general term to avoid the confusion between how these bodies are named differently in different parts of the world. In the Sudan, the national guidelines refer to them as the institutional review boards (IRBs), while the National Health Research Council call them the research ethics committees (RECs).

an approach to legitimacy built upon appeals to individual autonomy as the dominant value, which could be a fair normative representation of the communities from which the authors of these guidelines come. In this project, however, the “local narrative” clearly demonstrates that there are other entities that perform parallel roles and could be the basis for an alternative conception of legitimacy. Such legitimacy is built upon community acceptance and the support for social structures such as camp administrations, community committees, community leaders, and the family. Legitimacy is thus represented through a multi-layered, community-situated continuum of approvals and negotiated decisions that involve not only persons but also institutional entities.

The notion of legitimacy will be discussed with reference to the two ethical notions of trust and autonomy, using the relevant literature, the participants’ views and examples from the humanitarian setting. Overall, I argue that trust, though emphasised by the participants, was sometimes missing and sometimes misplaced among the various stakeholders involved in the humanitarian activities in Darfur. I discuss both the conceptual and the operational implications of this absence or misplacement of trust.

Autonomy is examined as part of the discussion of the theme of consent. I compare the individualistic and relational notions of autonomy and apply them to the project’s findings regarding seeking, obtaining, and giving consent. I conclude that consent was described and employed by the representatives of the humanitarian sector in a significantly different way than that of informed consent as described in the mainstream international and national guidelines. Again, I

endorse the local narrative and reject the narrative of failure to interpret these findings.

After I have framed how the findings of the empirical project will be considered and what the key arguments are, I present the discussion of the main themes that emerged from the participants.

9.2 Iterative consent, relational autonomy and community representation

Zwi et al. (2007) suggest that researchers in conflict-affected settings should “seek stepwise consent: engaging group community structures, then family, and, lastly, individuals.” (Zwi *et al.*, 2006, p. 266) The empirical findings are consistent with this approach, which the participants presented in great detail. In this subsection, I discuss the findings related to consent by suggesting that a relational autonomy, community-negotiated consent approach is more appropriate than an individualistic, autonomy-informed approach to consent.

9.2.1 Mainstream guidelines’ approach to consent

The mainstream research ethics guidelines widely adopt an individualistic, autonomy-based, content-focused and information-based approach to consent, mostly in the form of informed consent. Currently, the mainstream model of consent to partake in research is based on the following premise: the potential research participant is an independent, competent person who is able to govern themselves and make choices independent of the choices of others. The researcher provides her with the relevant information about the study in which she is invited to participate without undue influence or interference (Stoljar, 2011).

Ultimately, the potential participant makes her informed choice regarding whether to participate in this study or not.

In this subsection, I justify why trust-based, community consent is both ethically and operationally more relevant to the humanitarian context compared to the traditional individualistic, information-based model of consent.

The consent of research participants is an ethical requirement for health research in all the research ethics guidelines. Consent is the application of the principle of respect for participants' autonomy. These guidelines present consent in various ways, yet agree on some common conditions for consent to be valid, like capacity, disclosure, and voluntariness (National Ministry of Health, 2008; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014; Protections, 2015). "Capacity" refers to the mental or intellectual ability to understand the research-related information and to appreciate the possible research-associated risks. "Disclosure" refers to the presentation of relevant information about the intended research to the prospective participant in a format and language they can understand. Lastly, "voluntariness" refers to a state of freedom from undue influence or coercion that could affect the prospective participant's decision on whether to participate in the study or not. Additionally, the researchers are usually required to document consent using a consent form that ought to be signed by the participant or her proxy to document that consent was given after fulfilling the above requirements (US Department of Health and Human Services, Office of Research Protections and National Institutes of Health, 2009).

Some guidelines attach templates of this informed consent form (World Health Organization, 2000; National Ministry of Health, 2008; WHO Research Ethics Review Committee, 2011) Furthermore, most medical journals require a statement that informed consent was sought and obtained from the participants in the study submitted for publication, with a few exceptions (International Committee of Medical Journal Editors, 2013).

Consent has received extensive scrutiny in the research ethics literature on both philosophical and empirical grounds (Dawson, 2003; Flory, Wendler and Emanuel, 2007; Sim and Dawson, 2012; Adlan, 2015). However, the discussion of consent here is focused mainly on the research ethics guidelines, which represent the main source of ethical guidance to researchers, and the research review committees.

The significance of consent is usually based on the view that all persons should have the right to control their lives and bodies, including the decision about what they can do to themselves, or what others can do to them (Kasule, 2015). It is generally accepted that the moral foundation of such a right is the principle of respect for autonomy, which Gillon defines as “the capacity to think, decide, and act on the basis of such thought and decision freely and independently” (Gillon, 1985, p. 1806). Beauchamp and Childress consider autonomy a form of personal liberty of action, where the individual determines his or her own course of action (Beauchamp and Childress, 2008). They also consider two conditions to be essential for autonomy: 1) liberty, the independence from controlling influences;

and 2) moral agency, the capacity for intentional action (Beauchamp, Athar and Childress, 2001).

The mainstream research ethics guidelines also emphasise the importance of *individual* consent, and tend to focus on the recording of a *signature* on the consent form as the standard way of giving consent (Health and Services, 1991; CIOMS, 1993; World Medical Association, 2013a; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014).

Some guidelines try to offer a less individualistic view to consent to give more legitimacy to collective, community-situated decision-making mechanisms. These guidelines emphasise the need to engage with the communities where the research is conducted (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014). The WHO Ethics Review Committee (ERC) emphasises that researchers “should follow an appropriate and culturally-sensitive process of information sharing leading up to, and including, obtaining the participant's signature on the informed consent form” and any departure from the standard consent procedure is allowed in “very few research situations which do not require the participant's signature on an informed consent form” (WHO Research Ethics Review Committee, 2015, p. 1). This exemption from the signing of consent forms requires the prior approval of the ERC.

The findings of this project suggest an appeal to a different collective, multi-layered, and community-situated decision-making process, rather than the

individualistic autonomy-based view of informed consent suggested by the mainstream research ethics guidelines. The project participants rarely referred to consent as an individual decision or as informed consent (at least as described by the mainstream guidelines). Alternatively, the norm is that ensuring the decision's legitimacy is delegated by the concerned individuals to others, who could be community leaders or other entities, like an NGO or the government. The mainstream guidelines seem to fail to capture the communal structures within which decisions are taken in non-individualistic communities. Predictably, conflict-affected populations tend to defend themselves by gathering in more hierarchical structures (Maxted, 2003), with more de facto delegation to their leaders to act as their representatives, negotiators, and gatekeepers (Leaning, 2001; Mystakidou *et al.*, 2009; Maxwell *et al.*, 2011).

Community-situated consent is more realistic for the current situation in Sudan. It shifts the legitimacy of decisions about research from the individual research participant to the collective group, represented by the community-situated multi-layered decision-making mechanisms described and widely accepted by the participants.

With such a discrepancy, one would expect the national guidelines to be reflective of the local narrative or at least to make some reference to the local norms. Interestingly, the national research ethics guidelines do not refer to these cultural exceptions. They mention “informed consent”, consistently referring to individual informed consent that is obtained from either the individual herself if competent or her legal guardian if incompetent. The only departure from the

standard signed consent form was the permission to obtain verbal informed consent, without any reference to community consent or any other non-individual form of consent.

This tendency of the national guidelines to endorse an individualistic approach to consent in countries known for their strong collective community relations is not uncommon. Adlan (2015) concludes that the Saudi regulations and research ethics guidelines are autonomy-based and promote individualistic notions of informed consent, which are not the mainstream in the Saudi Arabia (Adlan, 2015). However, unlike in his study, there were other factors that contributed to the autonomy-based individualistic guidelines in Sudan. I have already mentioned them in relation to the gaps in the development of the guidelines in subsection 9.3.2, focusing especially the lack of public engagement and how the guidelines were developed as an expert-oriented exercise. Additionally, most of the mainstream guidelines are developed assuming a stable society, which is not currently the situation in Sudan, given the war. Overall, the guidelines seem to represent the literature more than the people and to be designed to fit a model of quasi-clinical research conducted in stable communities. Combining these factors makes them a questionable source of ethical guidance for the kinds of studies conducted in conflict-affected areas.

Participants used a wide range of meanings and synonyms when they referred to consent. They used terms like “acceptance”, “approval”, or “consulting” to describe the consent process. They were referring to consent not only as the communication between the researcher and the individual research participant,

but as the procedural approval the researcher needed from the local authorities and community leaders. They used “consent” to describe the layers of approval as a continuum rather than separating research consent from non-research approvals.

Despite the general emphasis on the role of the community leaders in research-related decisions, this emphasis does not override the importance of individual acceptance to participate in the intended study. When they were asked about individual approval, the participants mostly agreed that it is an ethical duty to seek the voluntary acceptance of individual participants and to respect their decision should they choose not to participate. Some participants cited methodological reasons for seeking and obtaining individual consent. For them, they could not trust the data provided by someone who was forced to participate. Up to this point, these views seemed consistent with the conventional mainstream views on informed consent in research. However, there were also significant differences that ought to be considered.

The first is the difference in the approach to obtaining consent. In the Results, I presented a diagram that represents the layers through which researchers have to pass to reach the persons targeted by the study (Figure 8-3). This is consistent with the conclusions of Zwi et al. (2006), who suggest that researchers ought to seek stepwise consent that engages the community structures, then family, and lastly individuals (Zwi *et al.*, 2006).

Second, some institutional layers are more powerful and could hinder or even stop the study without rational (or any) justification. The non-institutional

entities are arranged in a hierarchy that should be respected: the community leaders, then the male heads of households, then the women and children. For example, entering the community or trying to approach the households directly is not only a matter of disrespect for the community; it could be considered a severe offence and the researcher could be physically harmed.⁴⁹

Within such complexity, the conventional consent-seeking moral foundation (individualistic autonomy) and procedures (research-participant interaction) are not applicable or relevant. To interpret the societal realities as described by the participants, we need to discuss the decision-making mechanisms based on moral foundations other than individualistic autonomy. Relational autonomy and trust may be a better moral basis to discuss the findings related to consent. Relational autonomy, as explained below, is chosen to facilitate the conceptual shift of the legitimization of research-related decision-making from the individual alone to the individual within a group of people she trusts.

9.2.2 Relational autonomy and iterative consent

Relational autonomy, as Christman (2004) describes it, is “an alternative conception of what it means to be a free, self-governing agent who is also socially constituted and who possibly defines her basic value commitments in terms of inter-personal relations and mutual dependencies” (Christman, 2004, p. 143).

One key finding in this project is the complexity of the relationships among various stakeholders and especially among the IDP community members, whose

⁴⁹ In one of the surveys I participated in as a field supervisor, one team entered a sector in a IDPs' camp without prior permission of its leader; they were dismissed by angry women and children armed with tree branches and stones.

“inter-personal relations and mutual dependencies” were consistently expressed in almost every aspect explored with them. The community members depend on each other, on their leaders, on the officials and the NGOs to meet their needs. These self-imposed self-protection mechanisms seem a sensible reaction to their state of continuous displacement and instability.

In this subsection, I build on the participants’ views and the relevant literature to critically discuss the individualistic approach to autonomy and its applicability to conflict settings. I defend relational autonomy as a more relevant ethical approach to guide the research conducted in conflict-affected settings compared to the mainstream individualistic information-based approach for three main reasons⁵⁰.

First, the legitimacy given by the conventional approaches to informed consent relies on individual autonomy. That is, it assumes that moral agency is achieved through an autonomous rational reasoning within the individual based on the information provided in the consent process. However, such self-reflection is supposedly based on the moral agent’s autonomous capacity and what they view as important. This autonomous capacity is not equal in all individuals. There are differences that are influenced by factors external to the autonomous agent.

Conflict-affected communities represent a typical example of the effect of external factors beyond the control of any individual member of these communities. These communities are sometimes artificial in the sense that they are gathered in a specific geographical area (an IDP camp, for instance), though they originally lived in different areas. Nevertheless, they are forced to re-organise

⁵⁰ For more thorough critical discussion on the topic, see (C Mackenzie and Stoljar, 2000; Christman, 2004, 2008; Stoljar, 2011)

themselves within these new structures because this is sometimes the only way to be eligible for humanitarian aid. These new structures dictate similar changes in the relationships among the individuals. Interestingly, the camp to which I had access in Khartoum hosts members of two tribes who are fighting each other in Darfur. Nevertheless, they managed to find a way to organise the camp's affairs and to plan collectively to meet their needs.

Moreover, during active conflict, these communities are not stable enough to establish long-term beliefs or a sense of self in a way that would affect their access to what they need to survive. Thus, it was not surprising to find that the IDPs almost always referred to themselves as an entity rather than as individuals. It is not uncommon for those affected by conflict to keep moving to safer places. There is always a sense of temporariness. In this sense, adopting a relational conception of autonomy is more sensible as it stresses “the ineliminable role that relatedness plays in both persons' self- conceptions” (Christman, 2008).

Second, relational autonomy helps in shifting consent from offering “negative liberty”, which Berlin (1958) defines as the freedom to act unobstructed by external obstacles; to “positive liberty”, which he describes as freedom beyond being passively unobstructed, freedom to be a doer and “to be a subject – not an object” (Berlin, 1958). Relational autonomy gives the potential participants within their community structures the chance to not only decide on their participation, but to also express *why* they do or do not wish to participate through deliberative parliament-like gatherings where they can freely discuss relevant decisions. This

decision-making model offers better understanding of why a decision is made compared to the individual box-ticking and signature model.

Lastly, relational autonomy regards persons as “socially embedded and that agents’ identities are formed within the context of social relationships” (Mackenzie and Stoljar, 2000, p. 4). Within this discourse, autonomy needs certain interpersonal and social conditions to develop and “is not a quality one can simply posit about human beings” (Nedelsky, 1989, p. 10). The collective decision-making processes taking place in the studied community, expressed by the consistent reference to the self as “we”, reflects an extended sense of being, self-trust, and self-esteem; all of which are considered (within relational autonomy approaches) as necessary components of the capacity for autonomy (Stoljar, 2011).

As such, the concept of ‘consent’ moves from a passive procedural requirement that relies on a simple benefit-harm analysis of the intended decision to allowing the deciding person to make her decisions based on values that she views as important. Such qualitative deliberations are best done by positioning these values within the values of those surrounding the person asked to decide. In a conflict-affected setting, these collective deliberations present a chance to improve one’s self-esteem and self-trust; both can be badly damaged by vulnerability and heavy reliance on others (the government, the NGOs, etc.). In conclusion, relational autonomy is not only a better reflection of the moral values of the studied community but also a chance to empower them as decision-makers and thus improve their autonomy.

9.2.3 Normative analysis and the practical implications of community-oriented, trust-based consent

The participants described an approach to “consent” that is less information-dependent and more trust-based and continuous. This finding is not entirely novel, as its narrative matches, for example, what Mackenzie et al. (2007) note, namely that informed consent in these settings should be interactive, progressive and continuous (Mackenzie, McDowell and Pittaway, 2007a). However, it is worth noting that portraying consent as a continuum differs from the mainstream ethical guidelines. The latter present informed consent as a decision that is made once and can be modified later (if for example new information became available). Consent as described in this project is a process by which the researcher is granted access to the area and the people to be studied as long as she is trustworthy. Thus, community consent can be revoked if this trust is lost, regardless of the consequences of lost benefits or even the potential of straightforward harm, as demonstrated in the example of the IDP camp that refused to receive any health service unless from the NGOs that had been expelled by the government at the time. The two models of the mainstream guidelines and those represented in this project work within two different paradigms.

Gaining trust might not be easy, as the complexity of a conflict like that in Darfur sometimes makes it unclear who to trust. The related fears create increased suspicion that the researchers and humanitarian agencies ought to address. In return, once trust is established, most of the IDPs seem satisfied with relatively minimal information (if compared to the long lists of information required

by the national guidelines) and with multiple layers of agreement (compared to the guidelines' individualistic approach). Their emphasis is on the process rather than on the content of consent. This process-oriented approach to consent necessitates establishing a minimum level of trust between the researcher and the studied communities. Conflict-affected populations can misplace their trust in researchers, either by mistrusting the motives and independence of the researchers or by having unrealistic expectations from them (Mackenzie, McDowell and Pittaway, 2007a). It is thus assumed that the researchers, in return, should work on establishing their trustworthiness. Consent is a trust-based practice and this trust is based on many factors. An abundance of information does not seem to be one of these factors. A short consent process with little information provided by someone entering the community through its 'door' is more trustworthy than when more information is provided by someone the community does not know/trust.

Lastly, consent is not as informed as would be acceptable for most of the mainstream standards and is found to be sought and given verbally. The participants make no reference to any written format, let alone signing any consent forms. This finding is consistent with some guidelines that permit unwritten documentation of informed consent (Bioethics, 2002; Council for International Organizations of Medical Sciences and World Health Organization, 2002; World Medical Association, 2013b).

The tendency to obtain consent verbally could be part of a general culture to respect the spoken word to the same extent as, or more than, the written one.

Moreover, asking people for a signature is usually viewed with suspicion in Sudan and likely seen as more suspicious in conflict settings. Verbal consent is usually easier to communicate and takes less time. It is also more convenient for those participants who are not able to read and/or write.

Understanding this structural and conceptual complexity helps in understanding why the participants described any form of approval at any level as “consent”. In contrast to the mainstream approach of *informed* consent, the type of consent described in this project might be termed a “*negotiated* consent”. Although it is informed in the sense that relevant information is shared, the ultimate decision rests on a series of negotiations that are not based solely on the shared information but mainly on trust. consent is not a one-stop event. It is practised within a continuum of approvals; each happening at one level of the multi-tier approval system. This apparently complicated approach is meant to provide more protection, as the collective decision makes the responsibility for this decision collective as well.

Negotiated consent fills another gap in the concept of individualistic autonomy-based informed consent, which is usually portrayed as a research-related communication process between a researcher and a potential participant, usually on a one-on-one basis. The findings of this project suggest that such distinctions between individuals are blurred, if not completely absent. An illustration of this phenomenon is what I have noted in the Results regarding how Sudanese people generally use first person singular and first person plural pronouns interchangeably to refer to the same person or entity. The

interchangeable use of “I” and “we” is consistent with the literature on the extended definition of “self” developed in African philosophy and so-called “Black Psychology”. Hord and Lee (1995) describe this as moving from “I” to “we” and back from “we” to “I” (Hord and Lee, 1995). Mbiti (1990) describes this communal conception of the individual as follows:

“Whatever happens to the individual happens to the whole group and whatever happens to the whole group happens to the individual. The individual can only say: “I am because we are; and since we are, therefore I am” (Mbiti, 1990, p. 106).

In addition to Sudan’s overall strong hierarchal societal structures, conflicts and other crises lead those affected to seek support from one another by strengthening their community structures. This mutual need for support expands the communal sense of “self” to include all members of the group that share the same fears, needs, and hopes.

The philosophical interpretation and practical implications of this “I am we” notion are not always noticed. Instead, the researchers and the RGBs continue to apply the standard “I means me” approach to research ethics by simply following the guidelines, despite their departure from Sudanese cultural norms. This can be partially explained by the fact that most of the training in research ethics in Sudan, as the only national research ethics training manual suggests, is based on the principles of the mainstream guidelines (e.g. autonomy, beneficence, and non-maleficence) (Alkabba *et al.*, 2013). Other ethical principles are rarely mentioned or referred to in the national guidelines. Thus, it is arguably easier to re-

conceptualise a well-discussed moral concept like autonomy than to shift to a 'new' set of lesser-known ethical principles.

Moreover, it is not realistic to expect bioethics literature from the developing countries to be as rich, deep, or variable as that contributed by northern hemisphere philosophers. The latter enjoy living in political democracies where public engagement, free media, and academic freedoms are the norm, not the exceptions as they currently are in many developing countries, as many reports suggest (Freedom House, House and House, 2015; Reporters sans frontières, 2015; Vásquez and Porčnik, 2015). Without these freedoms, it is unlikely that bioethics will flourish to the extent that it does in the northern hemisphere (Hussein, 2009).

It is acknowledged that little contribution to the literature should not be an excuse for maintaining the status quo, where research governance systems in the developing countries follow the international trends rather than create more locally appropriate guidelines. Contrarily, as I recommend at the end of the thesis, the developing countries' ethicists, philosophers, researchers, and the public should be encouraged to contribute more to normative literature and moral philosophy and not only to empirical, mostly quantitative, studies.

9.3 Power, vulnerability, compromised autonomy and mistrust

9.3.1 Community structures and power (im)balances

The previous subsection discussed some of the philosophical foundations of consent by comparing the individualistic and relational approaches to autonomy.

In this subsection, I discuss a complementary finding, which is the integration of community and individual consent.

The general agreement on the importance of consent may explain why more studies in the systematic review reported obtaining informed consent than being ethically approved (subsection 7.4). About 13% of the included studies from the online search mentioned obtaining ethical approval, while none of those included from the CRED search referred to obtaining ethical approval. In contrast, the studies that mentioned obtaining informed consent were 42.6% and 8.9% of the studies included from the online search and the CRED search, respectively.

In the next subsection, I argue that the insistence on the information-based approach to consent is inadequate for humanitarian research and then call for a trust-based model of consent.

9.3.2 The need to shift from information-based to trust-based consent

Both IDPs and the NGO representatives agreed on the importance of individual consent. The IDPs emphasised that their personal (individual) consent should be sought, and listed the information they needed before deciding to participate in a study. The information they wanted about the intended study matched what the NGO representatives said they were willing to share. The following is an excerpt of an informed consent form from one of the studies conducted in Darfur:

Hello, my name is _____ and I'm working with 'NGO'... We are conducting a survey on the health and nutrition of your family. We would very much appreciate your participation in this survey. I would like to ask you about the health of your family. We will also weigh and measure your children who are

younger than 5 years of age. We would also like take a drop of blood from the finger of mothers and children, to look at anaemia and vitamin A. The survey usually takes 45 minutes to complete. Any information that you provide will be kept strictly confidential and will not be shown to other persons. Participation in this survey is voluntary and you can choose not to answer individual questions or all the questions. However, we hope that you will participate in this survey since your views are important. Do you have any questions about the survey? May I begin the interview now? Your answers will not affect your ration (World Food Program (WFP) *et al.*, 2006).

The information they require is quite basic: who the researchers are, their affiliation, why they need the information, and what benefits may result. Moreover, they seemed less worried about confidentiality and downplayed the risks associated with having their personal data falling into the hands of a rival armed militia.

This comparatively short list of information differs significantly from the national guidelines' 15-item table of what to include in informed consent (Appendix 10). Similarly, the CIOMS guidelines list 27 pieces of information that should be given to the prospective participant as 'essential' elements for informed consent (Council for International Organizations of Medical Sciences and World Health Organization, 2002). This attention to the content of the information provided assumes that the more the participant knows, the more informed they become and the more reliable their decision to participate in the intended research becomes. This assumption has been criticised for confusing the possession of knowledge with the comprehension of knowledge (Dawson, 2003). The latter should be the aim of the disclosure of research-related information, rather than the mere sharing of knowledge that the participant may not understand or be able to remember.

Without such comprehension, it is difficult to imagine how the amount of information shared can help in making the decision more informed.

In this project, the community's trust is based on many factors, described later in the thesis, and the provision of information does not seem a trust-enhancing factor. If consent is meant to respect the participants' autonomy by giving them the chance to make free informed choices, it should be left to them to determine the amount of information required, and they should be given the means to decide on how much information they need to make such decisions. These two factors vary across communities. The mainstream model represents the condition of freedom by making consent individual and the condition of information by providing detailed and lengthy forms. Other communities may have different views. Respect for autonomy should extend to respecting how people may choose to decide without forcing them to use ready-made decision-making templates that are not consistent with what they think or how they live.

The findings of this project strongly suggest that trust-based relationships are what shape consent decisions and processes. Outsiders become trustworthy only by virtue of passing the trustworthiness test set by the community leaders. Only then do they agree to collaborate with any activity proposed by the newcomers. In summary, the conflict-affected populations' research-related decisions are based on two main factors: trust and need. The humanitarian situation for the sample of IDPs involved in this study is unique, in that their humanitarian needs are not fulfilled by NGOs (or anyone else), unlike the NGO-dependent IDPs in Darfur.

These limited options make them dependent on one another and expand their leaders' and community structures' roles in the community's decisions.

9.4 Vulnerability

Mackenzie et al. (2007) highlight some sources and forms of vulnerability of conflict-affected populations, including their exposure to various kinds of trauma, being subject to political or ethnic violence, the loss of close family members, and being "in many respects at the mercy of others" (Mackenzie, McDowell and Pittaway, 2007a). This classical picture is indeed anticipated in any typical conflict setting. However, this empirical project revealed two interesting findings. First, the community members involved in this project were not as vulnerable as I originally anticipated⁵¹. The second was the discovery of a new level/type of vulnerability, namely "institutional vulnerability".

Most of the literature assumes the vulnerability of conflict-affected settings, as I have summarized earlier (Section 4.2), including the two pieces within which I frame this discussion. Mackenzie et al. (2007) make the point that the "vulnerability of refugees and other displaced participants is one of the main reasons why refugee research is ethically fraught" (Mackenzie, McDowell and Pittaway, 2007b)

The findings of this project present a slightly different picture, where the representatives of the targeted community described a quasi-parliamentary, collective decision-making model where everybody (including women, though to a lesser extent) is involved. It is difficult to claim that this model is the mainstream in

⁵¹ I need to acknowledge that I did not meet the same group as originally intended

all IDP communities, given the limited access I was granted. Moreover, there were a few occasions where the power imbalance was in favour of the conflict-affected communities who could decide who received access to their communities and for which purpose⁵².

My initial thoughts were based on the literature on vulnerability that focuses on the vulnerability of individuals who are not able to defend their interests and thus need to have their interests protected by an external authority. This protective role is a cornerstone in justifying why research proposals ought to be reviewed by RERBs. I expected that only the conflict-affected communities could be vulnerable, having the least power to protect their interests. As the interviews and the discussions unfolded, this initial position gradually changed. The humanitarian institutions, both governmental and non-governmental, are not as powerful and autonomous as they might seem. In the Results, I have outlined some of the causes and sources of institutional vulnerability that I could identify (Table 8-3).

The importance of this finding is threefold. First, it provides empirical support for what has been discussed in the literature on the political difficulties that face humanitarian agencies in conflict settings (MacFarlane, 1999; Rigby, 2001). Second, however, the concept was presented neutrally in this project, in the sense that it did not exclusively label one category as vulnerable (say, the NGOs) and the others as invulnerable (e.g. the governmental departments). In effect, no category was viewed as immune from vulnerability. Lastly, ignoring these imbalanced relationships among the different stakeholders only because it is the

⁵² This project is an example where my access went through a number of negotiations with the officials then with the community leaders, and finally the male heads of households.

status quo will not help in establishing a meaningful and humanitarian-appropriate research governance system in the future. Thus, reporting on “institutional vulnerability” was important to make any future guidelines aware of these power imbalances so that they could address them.

9.5 Trust and mistrust

Hynes (2003), as cited in Mackenzie et al. (2007), highlights two contrasting positions in terms of refugees’ trust of others; one of mistrust, which is either generalized or a “particular mistrust of officials such as agency workers, translators or local community representatives”; and another of unrealistic expectations from the humanitarian agencies (Mackenzie, McDowell and Pittaway, 2007a). Both views are reflected in the empirical findings of this project.

Trust is discussed in this subsection in relation to the findings about the relationships among stakeholders where trust is lacking, which contributes to the state of “institutional vulnerability”. I conclude that this lack of trust between governmental and non-governmental counterparts ought to be addressed as an initial step in any endeavour to modify the current humanitarian governance system or to establish a new one.

Although a full philosophical analysis of the different approaches to trust is beyond the scope of this work, given the limited space, I will consider a few basic concepts pertaining to trust and trustworthiness to conceptually situate trust in this project.

Trust has been usually seen as a good attribute, and some moral philosophy literature takes the position that “disappointing known trust is always prima facie wrong, [and] meeting it always prima facie right” (Barbalet, 2009, p. 253). Trust is also praised for its inclusion of more meaningful and cooperative relationships between the trustor and the trusted (McLeod, 2015), in addition to its role in achieving the goals of clinical and public health care (Dawson, 2015).

Trust has been categorised in terms of either the benefits it provides, the dispositions of those who give trust, or the nature of the relationship between the trustor and trusted (Dawson, 2015). Trust is usually defined in relation to a state of voluntary vulnerability entered into by the trustor. Mayer et al. (1995), for example, define trust as “the willingness of a party to be vulnerable to the actions of another party based on the expectation that the other will perform a particular action important to the trustor, irrespective of the ability to monitor or control that other party” (Mayer, Davis and Schoorman, 1995, p. 712). Such vulnerability results from the fact that “an act of trust entails the possibility of the other’s defection from the relationship or the exploitation of the trust giver, for relations of dependence are inherently asymmetric” (Barbalet, 2009, p. 368).

This approach presents trust as a voluntary acceptance of vulnerability. In the context of this project, and probably other conflicts as well, the relationships become restructured based on the restructuring of the affected community itself. The destruction of houses, the loss of lives, and the lack of many basic necessities leads the affected communities to reframe the relationships among themselves and between them and their surroundings to keep them safe and have their needs

fulfilled. This could entail greater reliance on the community leaders, as clearly reflected in the findings, where these leaders were described as the “doors” and the “keys” to these communities. Mere reliance does not necessarily imply trust and is not always voluntary, as it could be an expression of the absence of other choices. In other words, if the community members do not trust their leaders, then whom should they trust, and what alternative do they have?

Arguably, the IDPs have no alternative but to trust their leaders to negotiate for their essential humanitarian needs. The abovementioned definitions of trust, to me, are relevant in a community of equals, where members can either protect their own interests or have these interests protected by a legitimate authority. In a humanitarian context of conflict, trust can be limited by two factors: the relationships between the trustor and the trusted are not always voluntarily chosen and there may be no meaningful alternatives to the trustor other than trusting in the trusted. To assess the dynamics of trust between the communities and their leaders, it is important to consider a complementary concept, which is trustworthiness.

Trustworthiness is described as “the properties of the individual or institution that are interested in invoking trust” (Dawson, 2015, p. 130), which enables the characterization of attributes, structures or behaviours that could encourage and consolidate trust. Mayer et al. (1995) outline three of the characteristics that can encourage trust, namely ability, benevolence, and integrity (Mayer, Davis and Schoorman, 1995). “Ability” refers to the possession of the competencies and characteristics that make a party worth trusting. “Benevolence” indicates the

assumption that the trustee wants (or is believed to want) to do good for the trustor, while “integrity” “involves the trustor’s perception that the trustee adheres to a set of principles that the trustor finds acceptable” (Mayer, Davis and Schoorman, 1995, p. 717). However, in many situations, trusted parties may not be trustworthy (Baier, 1986), and trust becomes misplaced, as some of the findings of the present study suggest.

Examples of misplaced trust are discussed in detail below, but I refer here to how misplaced trust could result from a lack of one or more of the three characteristics suggested by Mayer et al (1996). Within conflict-affected communities, ability, benevolence, and integrity are assumed to be possessed by their leaders, whom they trust. These leaders are not brought forward for critical rational selection, in an example of what Printzlau (2011) describes as “pre-reflective trust” (Printzlau, 2011). Pre-reflective trust is immediate and is experienced unless disturbed, and there seems to be no evidence of previous incidents where the IDPs’ community leaders have failed their communities’ trust. One interpretation might be that this type and level of trust between the communities and their leaders could be attributed to the similarities between the trusted and the trustors. The community leaders and members seem to possess the same set of guiding values, and it is for the benefit of every party to benefit the other, i.e. a benefit for one is a benefit for all. This might not be the case between the humanitarian agencies and the governance bodies, as will be exemplified later.

The relationship between the humanitarian agencies and the governance bodies seems to be more complicated, as they have different moral mandates. The governance bodies believe they have to protect the country's sovereignty and people, while the NGOs are accountable to their donors and follow a more global mandate that is focused on a specific country. During the decades-long relationship between the governance bodies and the humanitarian agencies, there have been many incidents where one party caused concerns, if not threats, to the slowly and tenuously gained trust. The participants from the governmental bodies used terms like "hidden agendas" and "other purposes" when describing the humanitarian activities.

Trusting, as suggested above, is an expression of one's choice to orient oneself toward the other. This orientation is either based on choices that have not been reflected on, as in pre-reflective trust, or on rational calculation, as in strategic trust. In either case, the decision to trust is more complicated than the individualistic approach to research ethics suggests. Trust cannot be interpreted within an abstract individualistic version of autonomy, neither conceptually nor practically. It needs to be seen within a wider understanding of human interaction, where decisions are not always informed or individually made, i.e. are not always based on rational, calculated decisions.

Trust is affected by and is the result of human interaction, one's relation to others, and the view of the self. In this sense, trust is presented in this discussion as complementary to the call for a wider view of autonomy, which is relational autonomy, as discussed in the next subsection. In a disaster context, engendering

and maintaining public trust is critical to the cooperation of disaster victims and consequently to the success of disaster research and disaster response efforts (Jesus and Michael, 2009). Having generally outlined the concepts of trust and trustworthiness, I now give some examples of how trust was (mis)placed among the participants in this study.

9.5.1 Examples of lack of trust

From the beginning of the influx of international workers to Darfur, there was only fragile trust between the non-governmental humanitarian sector and the GoS, particularly when it came to humanitarian studies. The government claims that some results of these humanitarian studies served the negative propaganda against it by “exaggerating” the humanitarian crisis. The often-used example is how these studies were used as “evidence” by the ICC to issue a Warrant of Arrest against the president in 2009. The government felt betrayed and took a series of actions that targeted the INGOs. The “fast-track” policy that facilitated the humanitarian agencies’ procedures was stopped, and 13 INGOs had their permissions revoked and were expelled. The INGOs that remained were exposed to new measures. They were required to obtain governmental permission to publish studies conducted in Darfur, despite the lack of the technical capacity on the GoS’ side to decide on the quality of these studies. In addition, the involvement of the NISS in regulating international humanitarian interventions became more direct.

These consequences were a hard lesson for the INGOs, both those who were expelled and those who were left to continue. Expulsion presents multiple

difficulties for any humanitarian organisation. Thus, the INGOs have tried since then to strike a balance between their mandates to their donors and beneficiaries and their fear of the undesirable consequences of fulfilling these obligations. In a sense, each party had a reason to be fearful of the others, which has created a complex situation of vulnerable institutions working within an atmosphere where signs of distrust are common.

Another indication of this lack of trust is the responses I received to the invitations to participate in this project, which also reflect the ambiguity surrounding the definition of “research” in relation to humanitarian interventions.

Apart from those who agreed to participate, I can categorise the other invitees’ responses as silence (not responding to any communications at all), explicit refusal with no explanation, and explicit, yet off the record, refusal.

From a typical ethics committee perspective, those who choose not to participate should not be asked to explain their decision as a sign of respect of this decision. It would have been useful, however, if all potential research participants were at least given the option of providing a reason for declining the invitation to participate, instead of just assuming that asking them for a reason is disrespectful of their autonomy. Arguably, not giving them the opportunity to explain their refusal to participate is more disrespectful of their autonomy, as it denies them a choice which they could have made freely and rationally. If reasons for the refusal to participate had been given, deterrents or barriers to participation might have been removed, thereby enabling greater representation or reducing recruitment costs. For instance, in the IDP community, I had a better chance to know why they

refused to have their wives interviewed, which allowed me to address their concerns by recruiting female research assistants. Moreover, the views of those who refuse to participate would also help to understand the trust dynamics of the research context.

Those who explicitly refused to participate in this project offered two main justifications. First, some did not consider their organisations' humanitarian activities as research, so they thought that this project was irrelevant to them. Second, others expressed informal apologies, justified by the sensitivity of the thesis' topic and its possible repercussions for them. Not to participate was a safer option for them, after the difficulties they had already had with the government. These two lines of reasoning might indicate a broader lack of clarity regarding what counts as "research", which was reflected by other participants in the focus groups.

There is another example worth mentioning, not regarding the lack of trust but the lack of trustworthiness of the trusted. In March 2009, in protest of the GoS' decision to expel 13 INGOs, the community leaders of one of the most crowded camps in Darfur (containing more than 90,000 IDPs) declared a state of self-embargo, blocking access to any humanitarian aid, including fuel, food distribution, vaccination and other health services to the camp, until the GoS reversed its decision to expel the INGOs (Sanders, 2009). The GoS did not reverse its decision, and this leader-declared self-embargo continued for three weeks, which led to significant impact on the IDPs, including a meningitis outbreak with 54 confirmed cases and two deaths (United Nations Office for the

Coordination of Humanitarian Affairs and ReliefWeb, 2009). One could argue that this was an extreme reaction that did not happen in other places. Still, there were other incidents where the community leaders led their groups to make similar (though less dramatic) choices, such as refusing participation in a specific survey or refusing the entry of a specific organisation to provide service needed by their communities. Nevertheless, these incidents per se do not justify completely distrusting the leaders or doubting the ability of the community-based structures to contribute to ethical oversight (only to the extent that one could argue that democracy is a bad political system because it may bring us bad leaders).

One advantage of the multi-tier governance system is that the community leaders, regardless their trustworthiness, represent only one of the many layers at which protective interventions may be granted if needed.

9.6 Reciprocity, risk, and benefit

The two articles used to frame this discussion highlight some of the potential risks associated with the conduct of research in conflict-affected settings. For example, there are the risks of (re)traumatizing the target communities by trauma surveys; the need to engage with non-state authorities when research exposes illegal practices, like sexual abuse or the recruitment of child soldiers; and the traumatization of the researchers themselves (Zwi *et al.*, 2006).

Research-related risk has been approached in various ways in research ethics guidelines. The Economic and Social Research Council (ESRC) defines it as “the potential physical or psychological harm, discomfort or stress to human participants that a research project might generate” (Economic and Social

Research Council, 2012). Other research ethics guidelines have also referred to non-physical harm, including emotional harm, stigmatisation, and the loss of privacy (World Health Organization, 2000; Council for International Organizations of Medical Sciences and World Health Organization, 2002; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014). Such a relatively broad perception of risk widens the concept to an extent that makes it difficult to define or categorize and makes its assessment relatively subjective. Such a lack of clarity on what constitutes a risk to participants makes it difficult for RERBs to decide how to prevent or minimize such risks.

The risk associated with research is the probability of harm occurring that is to be weighed against potential benefits. An acceptable risk is one where the potential harm is outweighed by the potential benefits. Many research ethics guidelines set this favourable balance as a condition, *inter alia*, for the ethical approval of research. The NGO representatives repeatedly emphasised the need to “rationalise the expectations of the IDPs” before conducting their humanitarian activities. This rationalization is important to differentiate genuinely expected benefits from those desired by the participants.

The empirical findings added other dimensions to the perception of risk beyond the mainstream characterization of risk, namely political risks, the risk to participants and the risk to data collectors.

9.6.1.1 Political risks

Political risks were frequently mentioned, both explicitly and implicitly, by the governance bodies that expressed concern about the intentions of some of the humanitarian agencies. They frequently cited how some humanitarian studies led to the warranty of arrest against the president. For them, this ‘political risk’ justifies their view of the need for more stringent oversight of humanitarian activities and research in particular.

This argument regarding political risk is contestable in many ways. The officials who referred to this risk made the reference within wider justifications of the government’s role of protecting its people. This role is not only uncontested in the research ethics literature but also encouraged, where countries should establish “independent, multidisciplinary, and pluralist ethics committees at national, regional, local, or institutional levels” (UNESCO, 2005 Article 22.2). Nevertheless, the current governance model hardly fulfils any of these requirements. In terms of independence, the RGBs are independent within the politically permissible limits. The RGB representatives politely referred to the “special condition of Darfur” to defend why the HGBs (and not the RGBs) have the leading role in the governance of the humanitarian activities that they persistently described as “research”. In terms of multidisciplinary, most NREC members are clinicians, as is the case with many similar bodies in developing countries (Kass *et al.*, 2007; Sleem, El-Kamary and Silverman, 2010). The absence of the humanitarian agencies from the RGBs, as described by the NGO representatives, was highlighted as a major flaw in the current research governance mechanism.

“Political risk” is also difficult to define. In theory, it is the fundamental role of the studies conducted by the humanitarian agencies to expose the effects of the conflict on the humanitarian needs of the affected population. The findings of these studies are frequently used for such purposes as planning, evaluation, advocacy, and fund-raising, which require their dissemination to various stakeholders. This duty to disseminate the findings brings forward conflicting interests. The government, as part of the armed conflict, would like to avoid being blamed by the international community should the findings of these studies prove to be negative, while the NGOs rely on the same findings to advocate for the need for more resources. In a way, these negative results help the NGOs obtain the help they need to address the humanitarian situation.

Obviously, the dissemination of these findings ought to be given priority, because the vulnerability of the affected communities is greater than the government’s vulnerability, and the anticipated impact of such studies is to help these communities. These findings have political implications because of the government’s decisions related to the conflict. Thus, this assumed political risk is not a standalone justification for the official narrative’s labelling of the humanitarian activities as “research” to justify submitting them to the existing governance systems.

Related to this discourse is whether the humanitarian agencies are in a position of a conflict of interests and whether some of the humanitarian studies are not done in good faith. This possibility of this being true cannot be completely excluded, but the reports of these studies seem to follow internationally adopted

methodologies. Moreover, of the surveys with “unsatisfactory” results were done jointly with representatives from the governmental counterparts. For example, one of the first major pan-Darfuri studies that provided evidence of a humanitarian crisis in Darfur, the Crude Mortality Survey (2005), involved representatives from many governmental entities (World Health Organization and Federal Ministry of Health, 2005a).

9.6.1.2 Risks to participants and data collectors

I expected the participants to acknowledge the psychological risks of asking IDPs about their war-related memories, or what Zwi et al. (2006) refer to as the risk of re-traumatization, “particularly when there are no follow-up support structures in place to assist those in need or those who may be re-traumatized by the research experience” (Zwi *et al.*, 2006, p. 268). This risk of traumatization seemed to be held as important by those I interviewed. Some participants showed indifference to such concerns and considered them trivial. However, we need to be careful in interpreting these responses.

I suggest that to use research-related risks as a justification for the ethical oversight of “research” or similar activities, this oversight should fulfil four conditions. First, the ethical oversight should be based on a full understanding of what the relevant activities entail. It is not possible to assess the risks associated with an activity that is unclear or unknown to the assessor. Second, the extent of the oversight should be proportional to the risk. Third, the risk of an activity should always be weighed against the expected benefits. Finally, ethical oversight should include similar activities that carry the same potential for risk if they are labelled as

“research”. These conditions will be the basis for the discussion of research governance in the following subsection.

9.7 Which research governance model should be implemented?

Zwi et al. (2007) portray the relationships between the three key players—the researchers, the researched, and the ethical oversight bodies—as a triangle “to depict the space bounded by researchers, researched communities, and bodies charged with ethical oversight” (Zwi *et al.*, 2006, p. 270). Tensions might arise due to the complexities in negotiating their relationships, which can ultimately lead to undesirable consequences such as proceeding with research without adequate ethical oversight. In addition, researchers may “misrepresent, minimize, or deny important community issues in their findings”, or valuable research might even be prevented from taking place. Zwi et al. call for a shift away from the primary researcher-RERB relationship to a researcher-researched relationship. The empirical findings of the present study suggest that this shift has been partly put in place through a de facto oversight system, not only for the ethical oversight of research but for almost any community-related activity.

In this subsection, I present how the guideline-oriented, committee-based research oversight system in Sudan is an inadequate model for the ethical oversight of research conducted in conflict-affected areas. Then, I argue for a consideration of the trust-based, community-oriented governance model that the affected communities have developed to decide on any decision that could affect the whole community as a complementary pathway that can help bridge the gaps left by the mainstream governance model.

Despite the lack of agreement among the participants regarding whether to label these activities as “research”, there was general agreement that they ought to be ethically guided and overseen. Still, the provision of such ethical oversight is another example of two mismatching narratives. The official narrative insists that the best model to provide this oversight is the mainstream research governance model, while the field narrative described a more sophisticated model of governance.

Ideally, research governance systems include several interrelated but distinct functions and responsibilities and are not limited to the ethical review of research proposals. These roles include the development of research policies, regulations, and guidelines to facilitate and guide the ethical conduct of research. The roles of the governance system also include providing education and assistance to researchers to improve the quality of their research. Finally, it includes the review of research proposals to determine their ethical acceptability and the monitoring of on-going research. Eventually, when the necessary procedures, systems and structures are in place, the attempt is to ensure a particular desired end, which is maintaining public accountability.

In contrast to such an expanded view of research governance, the views of the participants represented in the official narrative seem to be narrower, reducing research governance to the ethical review (and security checks) of intended studies. The focus of the official narrative is on a centralised review that mainly focuses on the scientific and ethical aspects of the reviewed studies.

9.8 The status quo and alternative ethical governance models

In this subsection, I discuss the current ethical research oversight mechanism, mainly represented by the NREC, where I highlight some of its main gaps. Then, I outline the suggestions of the participants regarding how research conducted in the humanitarian setting of Darfur ought to be ethically overseen.

9.8.1 The status quo of research governance in Sudan: A vision in transition

The mainstream models of research governance have many components necessary to their functioning, such as the presence of guidelines, policies and procedures, review committees, and training. Of these components, I have decided to focus on two main elements of research governance: guidelines and structure.

In the introductory section, I discussed the gaps in the mainstream research ethics guidelines that make them insufficient as the main sources of ethical guidance for research conducted in humanitarian settings, so I do not repeat them here. Rather, I focus on one of the suggestions that some participants thought could help in improving research governance in Sudan, which is the “need for more guidelines”. As a reminder, one of the gaps that I identified earlier (subsection 4.3) is that the national guidelines were developed relying mostly on the literature and the communities in which they should be applied. In a sense, they represent an adaptation of the international guidelines. If the call for more guidelines is meant to be means to rectify the current research governance system, it should be clear that these new guidelines should not address the gaps in the current ones. To be adequate, the ethical guidelines need to be developed

in an atmosphere where they are proposed, freely debated, modified, and then followed. This in turn requires calling upon the stakeholders, including the conflict-affected communities and the field workers, to engage in a meaningful dialogue. Only then would the ethical guidelines reflect the valued set of ethical principles.

The other element of the governance system I will discuss here is the structure through which research governance is usually implemented, which I collectively refer to as the RERBs. I conclude that the RERBs have moral and operational gaps that make them unsuitable for the ethical oversight of the humanitarian activities under consideration unless modified. To address these gaps, I discuss three strategies I developed based on the analysis of the participants' views. These are to amend the current research governance system, to shift ethical oversight to the humanitarian sector, and to provide this oversight through a joint mechanism.

There is a growing body of literature that questions the RERBs' suitability as the primary ethical overseers of research on practical and moral bases. A full discussion of these criticisms is beyond the scope of this chapter, but these bodies have been criticised for their bureaucratic and ineffective procedural requirements that "restrict the liberty of researchers and participants, consume scarce social resources, and impede the ability of more nimble and knowledgeable agents to produce important social goods" (London, 2012). They have also been criticised for the inefficiencies and inconsistencies of their judgments of research proposals submitted for review (Edwards, Ashcroft and Kirchin, 2004; Grady, 2010; Abbott and Grady, 2011).

These criticisms may also apply to the research governance system in Sudan, which is certainly worth exploring in its own right. However, to maintain the focus of the discussion, I concentrate on three main issues. These are the lack of a clear sustainable vision, the lack of legal power, and the lack of moral representativeness of the national guidelines. I suggest that these missing elements have made the system be unstable, toothless, and morally unrepresentative of the conflict-affected community, respectively.

First, the lack of vision is the key gap in the current research governance system in Sudan, and not the lack of resources or the lack of the capacity to conduct or review research. For resources to be efficient and make a difference, they should be based on a plan to achieve a certain set of goals that ultimately achieve the institution's vision. Planning for health research within the Federal Ministry of Health may not be possible if the body responsible for it, the Research Department, is continuously changing its functions, structures and affiliations. The reformations of the department, which is the heart of health research governance in Sudan, have been too frequent. The repeated reforms could be seen positively as the manifestation of an interest in making the department function, but in effect, they merely reflect the absence of an understanding of what this research department should do.

The second factor is the lack of empowerment of the RGBs. The NHRC was less empowered compared not only to the HGBs but also to the other regulatory entities such as the National Medicines and Poisons Board (NMPB). Without

proper legal cover, the NHRC is unlikely to enforce the role of the NREC in the ethical oversight of the humanitarian activities under study.

A closer look at the laws that regulate the work of the NHRC, NMPB, and HAC demonstrates the significant legal powers of each of these bodies. For example, the only mention of the NHRC in legal documents was in three ministerial decrees (Appendices 4-6) and in the Public Health Act (2008). These decrees and the Act established the Council and detail its procedural authorities, such as the authority to delegate ethical review to other bodies. The Public Health Act (2008), in Chapter VI, lists the Council's terms of reference (ToRs), which were to:

- 1) Recommend policies and strategies
- 2) Raise funds for research
- 3) Approve the annual health research policy
- 4) Establish the technical committees needed to help it in its tasks
- 5) Issue the ToRs regulating its meetings and related tasks.

There is no reference to the NHRC's functions beyond the regulatory procedures needed.

In contrast, the legal framework on the humanitarian governance side, represented by the Voluntary and Humanitarian Work (Organisation) Act (2006), is detailed, specific, and clear regarding the legal powers given to the HGBs. There are also clear powers given to the HGBs to control the activities of humanitarian

(non-UN) agencies in many ways, such as the authority to register and de-register these bodies and monitor their financial accounts. There is even a chapter for contraventions, sanctions, penalties and appeals (*The Voluntary and Humanitarian Work (Organization) Act*, 2006). As a result, it is not possible for an NGO to conduct any activity in a conflict-affected area without a series of approvals from the HGBs, including the army and the NISS.

As things stand, the RGBs are not related to humanitarian activities in any meaningful way; not in their composition, moral reference, or their legal framework. In the following subsection, I discuss how to address these gaps and what the RGBs' possible role in humanitarian research is.

9.8.2 Alternative governance models for improved research relationships with conflict-affected populations

Zwi et al. (2007) call for developing the relationships in conflict-affected research settings, where “communities, researchers, and HRECs [health research ethics committees] all have, potentially, opportunities to participate, both conceptually and practically, in the research” (Zwi et al., 2006, p. 271). However, they acknowledge that there is a lack of clarity on how to achieve this when it comes to how to involve the researched communities. They discuss some ideas, including participatory research designs, to consider the perspectives of local professionals and practitioners, and to request multiple ethical approvals. They, then suggest adopting a model of iterative ethical approval, “where an initial phase of research is approved with subsequent stages dependant on meeting reporting obligations, demonstrating appropriate research behaviour, and responding sensitively to on-going ethical challenges” (Zwi et al., 2006, p. 272).

In this subsection, I discuss the three main categories of suggestions made by the participants to provide the ethical oversight needed for humanitarian studies conducted during conflicts. Afterwards, I describe in further detail what research governance might look like if a trust-based model were adopted.

There was overall agreement among the project's participants on the need for ethical oversight of the humanitarian activities under consideration to fill the gap in the current research governance model. This agreement, however, should be cautiously seen as a hypothetical agreement on the need to change a system that is little known and seldom used. Thus, the views expressed are more of a characterisation of how the governance system *ought to be* than a critique of what *it is*.

Despite the variation in the suggested governance models, the participants in the project agreed on three common features: inclusiveness, feasibility, and compliance with the national guidelines and laws (subsection 8.7.3). The participants also acknowledged the importance of the role of the communities in approving the study, which has previously been suggested by other authors and guidelines (Downie and Cottrell, 2001; Shore, 2007; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014).

The participants' suggestions fell into three categories: 1) modifying the current research governance mechanisms, 2) merging humanitarian and research governance in a common mechanism, and 3) substituting the purely humanitarian review for the current research governance mechanisms. I briefly discuss each of

these suggestions and then explain why a common governance mechanism is most appropriate for a conflict setting.

First, the suggestion to modify the current research governance system was common, even among those running that system. The main suggestion was to develop a less stringent review and less centralised structure. Applying the mainstream committee-based centrally run research ethics review to humanitarian activities was seen as leading to a complicated process that is not necessarily more protective of those involved in these activities. Without adequate representation of the researched communities, accurate assessment of risk is not possible. Currently, most members of the national review bodies are physicians, who may or may not have had adequate exposure to research in conflict-affected settings. Therefore, there is no point in insisting on the application of a governance system designed for mainstream clinical research (as implied by the national guidelines) that is seldom used in humanitarian contexts.

Contrarily, a complicated reviewing process delays many activities that should be done quickly, although they may not be urgent or life-saving interventions. Currently, the NREC system is completely paper-based. The Principal Investigators (PIs) have to be present in person and submit up to five hard copies of their proposals. Then, the PI waits for the next NREC meeting, and then for the feedback of the review, which almost always includes the need to make changes to the proposal. Although most of the INGOs have their HQs in Khartoum, where the NREC is based, the physical location and the manual

handling of the submission/review results is time-consuming and increases the administrative load of these agencies.

Less centralised governance seems a practical approach, and is already in the minds of those running the RGBs. However, the establishment of these local structures ought to be based on a sound moral foundation, i.e. the aim to be more reflective of the moral values of the communities they serve. Otherwise, these local structures will only address the operational gaps and leave the moral gaps in the current governance mechanisms unresolved. Even from an operational viewpoint, these local committees need to be composed of trained staff that are independent of the humanitarian agencies. The reality is that many of the local governmental staff in the states of Darfur are affiliated to NGOs in one way or another.

These NGOs are the main suppliers of the funds, resources, and training for the local governmental departments. Moreover, many of the governmental staff work directly with these NGOs, either in part-time or full-time jobs⁵³, and are paid three to eight times their government salary (de Goyet *et al.*, 2006). In North Darfur state alone in 2014, NGOs have employed 1,390 health personnel, supplied 70% of curative health services, and contributed 52.9% of the state's health budget (Yagub, 2014). To overcome the difficulty of finding independent staff, there could be a critical mass of ethically trained personnel, and closer monitoring and evaluation from the NREC can be a safeguarding measure.

⁵³ Some ministries of health in Darfur allow their staff to join an INGO for a given period of time (up to one year) without losing their governmental posts.

Nevertheless, the homogeneity in membership will remain a major gap, which was addressed in the second suggested governance model.

The second line of suggestions was to merge humanitarian and research governance in a common mechanism. Though such a suggestion was motivated by pragmatic and field-related considerations, it can be ethically justified in many ways. First, such a common forum will provide an opportunity for the involvement of the conflict-affected community representatives, which in turn would empower them as partners rather than passive victims (Newman and Kaloupek, 2004; Ben, McLeish and Elkin, 2006). This positive role of the affected communities will also address the lack of community representation in the current RGB structure. In addition, a common review mechanism would improve the dialogue among the various stakeholders, which seems to be lacking in the current model. Such direct dialogue is both operationally and ethically important. Operationally, it enhances collaboration and increases the efficiency of the use of the available resources. Ethically, the advantage of a common platform is the continuity of stakeholders' dialogue, in contrast to one-off events like workshops or conferences. Such continuity can help in shaping a more relevant set of ethical principles that can guide not only the research activities in humanitarian settings but also other "non-research" activities. The stakeholders forming this common platform may have different expectations and working models, but this difference could help in achieving a balanced review, where all voices are heard. However, a major setback in the common governance model relates to the power imbalance between these stakeholders. Some stakeholders, such as the HGBs, have more

power than most of the others, which could lead to disagreements over who should lead such a common mechanism.

Finally, there was the suggestion of shifting the whole ethical oversight process to the current humanitarian governance system, which is primarily composed of the HGBs and humanitarian agencies, mainly through UN-led clusters. I found the alternatives in this direction worrying, because the gaps in the research ethics model cannot (and should not) be dealt with by excluding the research governance mechanisms altogether from ethical oversight. Research ethics differs from the humanitarian management system. Though they have guiding ethical principles in common, they are not the same, and so cannot be easily unified.

The humanitarian management system is an operational field that requires a wide spectrum of expertise in field epidemiology, logistics, finance, human resources, and management, guided by the IHL and a set of professional codes. In contrast, to run an ethical review system, there should be background knowledge about research ethics and the different meanings and interpretations of frequently used ethical principles, as well as experience in establishing and running the RERBs. None of this project's findings or those of previous empirical studies suggests that this level and variety of knowledge about research ethics is available in either the HGBs or the NGOs. For many of the participants, this was their first exposure to research ethics guidelines and RERBs.

This position should not be understood as an argument that only ethicists (or those trained in ethics) should review or lead the ethical review of research.

Rather, it is a sensible contention that no one can run a system without proper knowledge of what this system is composed of and what it is trying to achieve.

9.9 Why should a common trust-based research governance mechanism be adopted and what might it look like?

To answer this key question, I justify why out of the three suggested alternatives discussed above, I defend a common ethical oversight mechanism in which all the relevant stakeholders are represented fairly. I then outline how this common trust-based research governance mechanism might look.

For a research governance mechanism to be both morally representative and practically feasible, it ought to engage to the extent possible with the three categories of stakeholders: the researchers, the researched communities, and the current governance systems. Such a common governance mechanism is more likely to endorse the ethical principles that are more representative of the societal realities of the conflict-affected areas in Sudan. This joint governance system will also benefit from two complementary sets of ethical guidelines (research ethics and humanitarian ethics) that have usually been considered separately, in addition to the local communities' moral and societal values. Working together represents a learning opportunity, where the humanitarian and the research governance models can learn from each other and from the communities they serve. Similarly, the likelihood of having the humanitarian activities ethically assessed will increase through agreed-upon mechanisms.

The suggested ethical oversight mechanism should be proportional and flexible. Proportionality indicates that the level of ethical scrutiny given to the

activity under review ought to reflect the level of risk represented by that project; i.e. the riskier the activity, the more scrutiny it should receive. This notion is based on an understanding of ethical review as an exercise in which research protocols need to be assessed against a set of ethical principles so that the participants (and the community, in general) gain the best possible benefits with the least possible harm. Accordingly, the research protocols are assessed based inter alia on their potential to cause harm to the participants based on the participants' state of vulnerability. If a study is judged as risky for its intended, the ethics review bodies assesses it with its full membership, while if the study's risk is considered minimal, then the study protocol receives lesser scrutiny, because what justifies higher level of scrutiny is minimal or absent.

A proportional review process has recently been advocated in some key documents. The TCPS 2 has adopted it as the recommended ethical approach, aiming to facilitate research progress and the adherence to the core ethical principles of research (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014). Recently, the US government issued a Notice of Proposed Rulemaking (NPRM) to the Common Rule, which includes "making the level of review more proportional to the seriousness of the harm or danger be avoided" (Protections, 2015). A WHO Technical Group has also proposed proportionality in ethical oversight specific to public health practices during pandemics (Group, 2009).

Proportional ethical review has been criticised on the basis that the assessment of risk could be subjective (Wilson and Hunter, 2010) and depends on the vulnerability of the participants in the proposed activities (Boulanger and Hunt, 2015). The findings of this project have addressed these two possible shortcomings through the community-situated collective decision-making process. During this process, there are many layers at which the proposed humanitarian activity is assessed by various people, such as the community leaders, the heads of the households, and then the community members. The purpose of these layers is twofold. First, they provide a form of mutual support that could minimize (at least in theory) the vulnerability of those targeted by the intended study. For example, those who can read and write can provide further explanation of the information sheets left by the researcher or NGO. Second, these community structures provide a more accurate assessment of what is risky for them than that made based on theoretical literature or experience alone. Moreover, the leaders of these communities are tasked with negotiating with the researchers and the surveying agencies to maximise the community's benefits and minimise the possible harms, as defined by the community itself.

Flexibility refers to the adjustability of the review procedures in order to ensure timely research while maintaining the diligence of the review (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 2014). Overall, risk can be the basis for ethical oversight but this review should be in turn based on four conditions: 1) to be based on a full understanding of what those activities entail, 2) to be proportional to the risk, 3) to compare the

risk to the expected benefits, and 4) include similar non-research activities that carry the same potential for risk.

9.9.1 Structure and tasks

In this subsection, I outline how the trust-based system could look and how it may function. The suggested structure is not meant to be a ready-to-use prescribed model. The aim is to demonstrate its main features, leaving it to the stakeholders to decide on its goals and structure.

Overall, there will be two levels, a macro (federal) level and a micro (field) level (Figures 9-2 and 9-3). These two levels are meant to represent a continuum rather than a series of consecutive steps through which the researchers should proceed. As a continuum, this governance model represents an integrated system, where undergoing formal ethical review and obtaining approval is integrated with the community-level oversight, where the community representatives need to check the trustworthiness of the researchers before and during the conduct of their study. Although the power of each level (and stakeholder) needs to be negotiated, the main role of the community members as empowered partners and not passive subjects should be maintained.

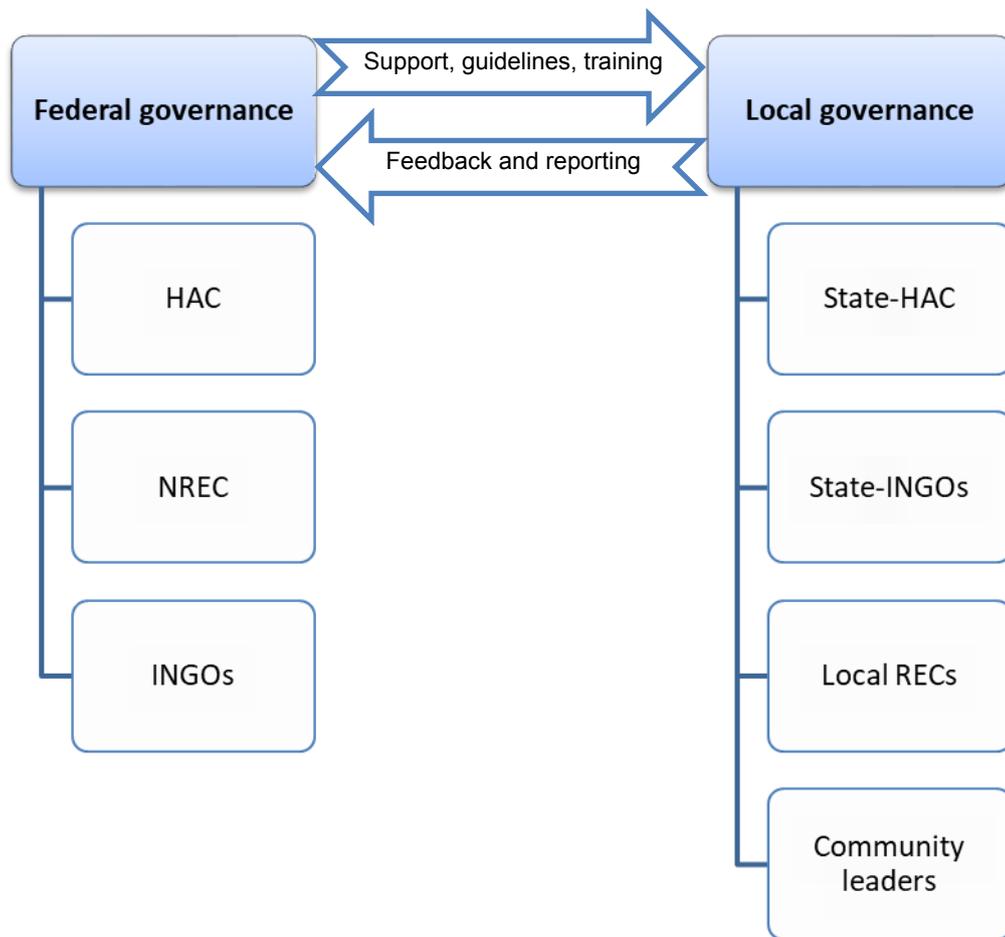


Figure 9-1 Structure and tasks of the joint research governance mechanism

The federal level should comprise the federal bodies included in the planning and conduct of research activities in conflict-affected settings, namely the HAC, the NREC, and the INGOs' HQs. The main tasks at this macro-level are to:

- 1- Identify, clarify, and unify the guiding ethical principles for the humanitarian activities within their remit
- 2- Develop clear mechanisms to decide on what among the humanitarian activities should be ethically reviewed, when they should be reviewed, and what the criteria are for ethically assessing these activities

There seems to be no need to form a new body. All these stakeholders (except for the RGBs) already convene in the cluster meetings. Representatives of the NREC can be invited to these meetings; however, there should be a clear understanding and agreement on the significance and role of the NREC representative. Jointly, the members can decide on the mechanisms through which the planned surveys or assessments can be ethically overseen in coordination with the field/community level described below. For this joint mechanism to be initiated, however, there should be several preparatory meetings, where the humanitarian and research governance teams inform one another about who they are and what they do.

Along with the federal level, there are complementary mechanisms at the state and community levels, which include the local counterparts of those represented at the federal level as well as representatives of the researched communities. The tasks of this community-situated mechanism are to:

- 1- Assess the acceptability of the federally-approved values and the feasibility and acceptability of the approved mechanisms
- 2- Undertake a local review of the sub-activities conducted within the affected communities
- 3- Follow up on the adherence of researchers and data collectors to the agreed-on principles and procedures
- 4- Report regularly to the federal joint mechanism on the reviewed activities and the researchers' compliance with the agreed-upon standards and procedures.

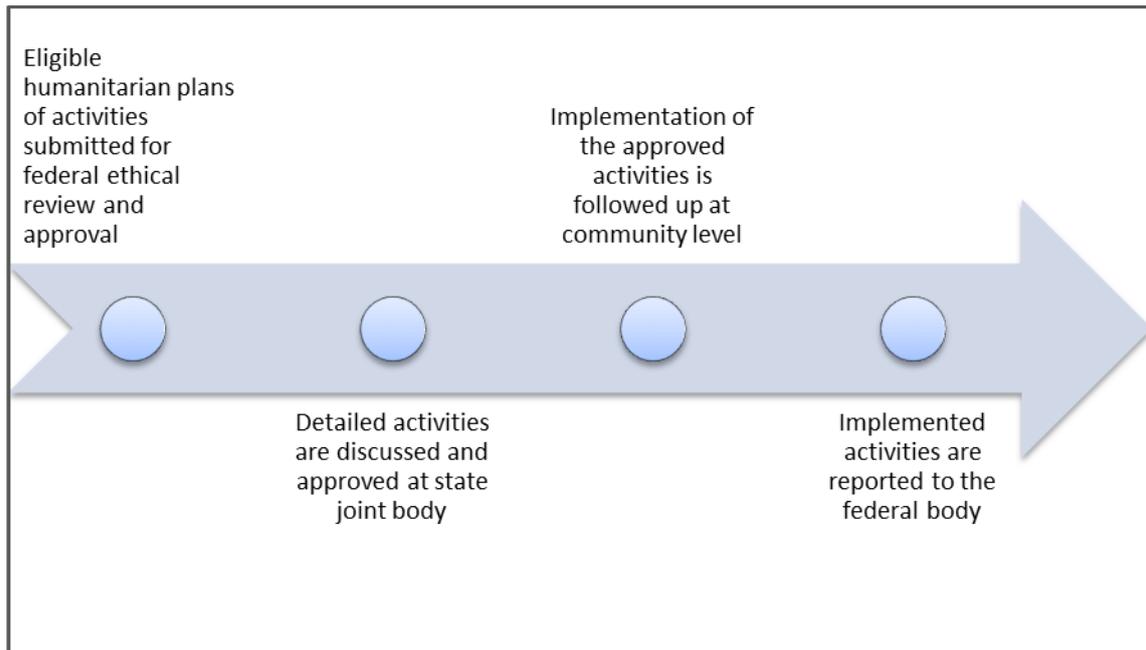


Figure 9-2 Sequence of ethical review, approval, follow up, and reporting of humanitarian activities

9.9.2 Challenges facing a common trust-based model and how to overcome them

A common humanitarian research governance model can face many conceptual and practical challenges. Conceptually, there will be a need to reach an agreement about contested issues such as which humanitarian activities need to be ethically overseen through which mechanism. Additionally, each side's shift away from their conceptual comfort zone could be challenging. Both the humanitarian and the research sectors have been using certain terminology to indicate specific meanings. Introducing new terminology and understanding it to be able to use it could be challenging, but is not impossible.

Practically, the main concern is related to the power imbalances between the various stakeholders (See Institutional Vulnerability, subsection 9.4.1). A common

platform may perpetuate these power imbalances instead of resolving them if the members of the forum do not clearly agree on their duties and rights. In addition, there are many socio-political issues related to humanitarian activities that are beyond the mandate of ethical oversight. Maintaining the focus on ethical issues and not being distracted by the associated political issues may also be challenging, considering the governmental affiliations and legal powers of the governance bodies.

For such a model to serve its functions efficiently, it should maintain the conceptual foundations on which any chosen model should be based, which are the roles and guiding principles. This is important to avoid reducing it from research governance to procedural review, so it should be clarified upfront that the aim is to establish a governance system and not just another ethics committee.

Second, agreement is needed regarding this mechanism's ethical guiding principles, i.e. how the intended activities will be ethically assessed and against which moral standards this assessment will occur. Currently, the ethical judgments are based on the national and international guidelines through the RERBs' interpretation of their stated ethical principles. The local cultural norms ought to be sociologically and empirically studied, not just speculated upon or assumed. To decide which ethical principles ought to guide research in conflict settings, these principles should be representative of the moral values in the communities in which the studies are conducted. I described this earlier in the discussion as the "local narrative".

To achieve this representativeness, we need to conduct empirical qualitative sociological studies of the communal structures and moral values and to engage in deliberations that encourage public involvement in discussing the ethically relevant issues. The sociological studies will provide empirical evidence that is vital to understanding the societal realities rather than just assuming or speculating about them. For example, there is a general impression that developing countries' communities have strong family ties and they are predominantly masculine. However, it seems that the strength of the family structure and the roles of men and the elderly have changed to some extent within the Sudanese community. This extent is not known for sure in terms of its magnitude or its depth. Until such sociological evidence is made available, the existing long-held beliefs will be used (as they are in this project). In the recommendations, I call for the need to support this under-researched area.

9.10 Why ethical approval was not mentioned in the studies included in the systematic review

In this final part of the discussion, I focus on the findings of the systematic review (Subsection 7.4), specifically the proportion of the reviewed studies' reports that mentioned gaining ethical approval (0% of the CRED studies and 13.2% of the online studies).

At the pre-field stage of the project, based on what was mentioned in the reviewed reports alone, I suggested five possibilities to explain these findings (see 7.5.4). The findings of the empirical study seem to support two of these possibilities: 1) the studies that did not mention ethical approval were not actually

submitted for formal ethical review, and 2) the data collection tools used were ethically reviewed and thus no formal ethical (re-)review was needed.

The paucity of the research activities submitted for formal ethical review was usually defended in apologetic tones by the representatives of the humanitarian agencies. Contrarily, the representatives of both the RGBs and the HGBs thought these (low) percentages were reflective of what they tried to portray as reluctance from the humanitarian agencies to submit the research to the national governance mechanisms. In this subsection, I outline the participants' arguments as to why the studies conducted in Darfur were not submitted for "formal" ethical review. I categorize these into study-related, institution-related, and/or context-related arguments.

First, the study-related arguments cited the low risk of the humanitarian research activities to the participants and supported this view by the lack of any adverse events in their humanitarian studies. In principle, these studies used data-collection methods and tools of less risk than those used in other interventional studies. Nonetheless, the absence of evidence of risk, represented by the lack of previous incidents, is not evidence of the absence of such risk. To overcome possible bias in the assessment of risk, it ought to be assessed by independent reviewers who are not part of the study but have adequate knowledge of the context in which the study will be conducted. This will provide a middle way between the extremes of the overprotective assessment of risk represented by the current governance model and the self-defensive underestimation of risk by some of the representatives of the humanitarian agencies.

The second line of argument was institution-related, i.e. it referred to factors related to the institutions to which the researchers were affiliated. Researchers were mostly conducting their studies as part of broader humanitarian activities, which are regulated by funding and humanitarian regulatory bodies through a different set of procedures that do not include a formal ethical review. The bottom line of this argument, as presented by those who defend it, is that the humanitarian governance and funding mechanisms offer the necessary assurance that the humanitarian activities are ethical. Thus, there is no need for formal ethical review. When reflecting on this argument, one finds some supporting evidence and two gaps. The supportive evidence is the presence of relevant ethical principles in some of the main humanitarian guidelines, such as the Humanitarian Principles and the Fundamental Principles of the Red Cross and Red Crescent (see Table 3.2). However, a closer look at the humanitarian management system in Darfur reveals two gaps, one related to the content and another related to the structure.

In terms of content, the ethical humanitarian principles (e.g. humanity, impartiality, neutrality, and independence) are focused on humanitarian interventions in general and not on research-specific ethical issues. For example, the ethical issues related to ensuring respect for human beings cannot be easily deduced and hence guided by such general principles. Therefore, the claim that these principles are an appropriate alternative to more direct, research-specific ethical principles and guidelines is hard to defend.

Second, in terms of structure, a typical (formal) research ethics review should include members who are at least aware of the main ethical issues in research involving humans. In most cases, there are members who have received advanced training in research ethics. The presence of such expertise is essential to ensure that the main ethical issues in the study being reviewed are adequately discussed. The representatives of the humanitarian sector agreed that the humanitarian clusters and their meetings had no representation of the FMOH-RD or the NREC. Without evidence that these clusters have the necessary ethical expertise, it is hard to defend replacing the current research governance systems with the current humanitarian governance structures.

The third line of argument related to the context and used time-related factors to justify why these studies were not submitted for formal ethical review. I refer to this argument as the “urgency argument”. The urgency argument relies on giving moral priority to helping the people affected by the disaster (Darfur conflict in this case) over any other procedural requirements. In the project, I used the urgency argument as a probe in the interviews with the representatives of the governance bodies, who rejected this argument for two reasons.

First, the governance body representatives argued that the humanitarian situation in Darfur is now more than a decade old, so the people there may still be needy but are not at imminent risk of losing their lives. Additionally, they argued that the surveys undertaken by the NGOs indicate, by default, the presence of some level of settlement within identifiable geographical units, which enable the researchers to use multi-stage cluster sampling. It seems contradictory from the

researchers' side to on the one hand use methodologies that assume the presence of stable demographic settlements and then to claim urgency on the other.

Second, they argued that surveys already take a long time and consume a great deal of resources. Activities include sending the data collectors to training courses, contracting international experts, spending months in meetings to discuss the technical aspects of these studies, and the weeks needed for training, piloting, and feedback. Any formal ethical review, however lengthy, would not take more than two months, and would not require fewer resources than those needed for the logistic preparation of the survey itself. Moreover, adopting a flexible ethical review model would reduce the time and resources needed for such submissions.

Both sides of the time-argument have legitimate viewpoints and shortcomings. To begin with, the core of the time-related argument is legitimate. There are many occasions in humanitarian settings where there is a need to act quickly, even in a decade-old crisis like that in Darfur. For example, in November 2015 alone there were more than 150,000 newly displaced IDPs in Darfur (OCHA, 2015). The displacement of such large numbers in a short time creates a new urgency on top of the already fragile humanitarian situation. Still, such urgency comes in waves and is associated with predictable events like the outbreak of hostilities between the combative parties. Otherwise, humanitarian interventions are conducted at more or less stable pace. Therefore, the presence of some urgent situations within an on-going crisis could be given exemptions proportional to these situations and should not be assumed as the norm.

It should also be noted that the humanitarian situation in Darfur began more than a decade ago. Ideally, the region should be in a recovery and rehabilitation phase, which is accompanied by a shift from rapid and temporary procedures to establishing proper systems and control (Hees *et al.*, 2014). Overall, the claim that formal ethical review will delay humanitarian interventions is not a valid one, because the longest time taken to review a study proposal at the NREC is eight weeks (National Ministry of Health, 2008).

Although I do not defend the time-related argument, I find that the counter-argument based on demographic stability is not a valid one. That is, the demographic stability needed to apply the sampling methods of a survey cannot be compared to the demographic stability resulting from post-conflict settlement. The demographic stability that is needed for a survey is only needed at the time of the conduct of the survey. For example, if the survey takes a randomly selected sample of IDPs in randomly selected clusters, these selections are done on the IDPs available in these clusters at the time of sampling. For the survey to be conducted, the selected populations need to remain in the sample areas for the duration of the conduct of the study and no longer. There were occasions where the security situation in the selected areas changed and these areas became inaccessible and had to be replaced by other representative areas (Hussein, 2006).

On a final note to this subsection, the possibility that many of the activities included in the systematic review may not have been submitted for formal ethical review should not mean they were not conducted in an ethical manner. The

empirical findings have shown rather a stringent type of review and approval system for activities like those included in the systematic review, which as I have argued earlier is in many aspects a more efficient system than the formal mainstream research governance system.

10 CHAPTER TEN: A FRAMEWORK FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMANS CONDUCTED IN CONFLICT SETTINGS

10.1 Introduction

In the previous chapters, the ethical issues related to research conducted in humanitarian settings have been presented and discussed using two main sources. In Section Two (mainly Chapters Three and Four), the main international research ethics guidelines and humanitarian codes were discussed, along with the relevant national guiding documents and governance systems. The conclusion at that stage was that there is lack of consistency in defining “research” and there is an assumed universality of the ethical principles in these codes and guidelines. The methods and results of the systemic review of studies conducted in Darfur involving humans were presented in Chapter Seven. The main findings were the low percentage of these studies that reported being ethically approved and obtaining informed consent from their participants.

The main expected outcome of this project is a logically consistent, empirically supported framework that can fulfil the purpose of helping in the ethical review and guidance of humanitarian research. As such, it would be more likely to be used in practice if it included the values those who will use accept and are familiar with (Ives, 2007). To this end, a qualitative empirical project was conducted that involved the key stakeholders in the humanitarian setting of Darfur. The methods of this project were explained in Chapters Five and Six, and its results were presented in Chapter Eight and discussed in Chapter Nine.

One of the key findings of the empirical project was that the current committee-based, centrally-run governance model and the informed consent

model are not consistent with the socio-cultural context of the communities under study. As an alternative, there was a call for and a demonstration of a community-situated, multi-tier local governance system that applies to all humanitarian activities, not only research. Also, there was a strong tendency in the participants' descriptions of their experiences towards a trust-based, participatory consent model as opposed to the individual informed consent model.

It is the purpose of this final section to outline the normative framework for the ethical review of humanitarian research and research-like activities in conflict settings. This framework was developed along with the qualitative analysis of the themes that reflect the different stakeholders' moral values. It takes into consideration the contextual factors within which these values exist and how these factors may affect the current practice of humanitarian activities including what we might call "research". In addition, I subjected these societal realities to philosophical analysis guided by the literature. This back-and-forth intellectual exercise, moving between the realities and the literature, was an iterative process that sought to reach reflective equilibrium (De Vries and Van Leeuwen, 2010), as described in detail earlier (subsection 5.2.6).

On a final note to this introduction, I have to reiterate that I present this provisional framework with modesty, bearing in mind that it is not the first attempt and may seem similar to other frameworks that have tried to achieve the same goal (MSF Ethics Review Board, 2013a; Curry, Waldman and Caplan, 2014). The main difference (and strength) lies in how it was developed. This framework evolved from a systematic empirical bioethics project that involved the main

stakeholders, including the members of the affected communities, and is not only the result of experts' opinions or mere philosophical theorization.

10.2 A provisional ethical framework for the conduct of humanitarian “research”

This provisional framework provides a summarised approach to answer three key questions related to humanitarian activities that might need formal ethical oversight:

- 1- Which humanitarian activities should be submitted for formal ethical review?
- 2- What are the ethical principles that ought to guide the ethical oversight of these activities?
- 3- How should humanitarian activities that include the collection of data and/or biosamples be ethically reviewed?

The following matrix only provides examples of the questions that could be asked, the criteria that ought to be met, and the guiding principles that could guide these activities. It should be left to the stakeholders in each humanitarian context to reframe and bring forward their own questions, criteria, procedures and guiding principles.

The framework is divided according to the three main phases of any research project, addressing the key ethical issues encountered before, during and after the study. For each phase, there are key questions that should be answered, an indication of who should be involved, and a statement of the guiding principles and corresponding responsibilities.

Phase	Questions and criteria	Who is involved?	Guiding principles and duties
<i>Pre-field phase</i>	Key Question: Does the activity need a formal ethical review?	Joint assessment committee: - FMOH-RD - NGOs/UN - Community representatives	Relational autonomy: Duty to respect the target community's structures and decision-making mechanisms; Duty to respect the community members' preference to voluntarily delegate other family/community members to make activity-related decisions on their behalf; Duty to respect the community members' choice regarding how
	1- Is the data collection activity necessary? a. Data are not and cannot be made available except by active data collection, b. Data are not already available/accessible elsewhere c. The activity is requested by the target community d. Intervention is not possible or will not be effective without active data collection		
	2- Does the activity involve the collection of biosamples? a. What are the methodological justifications for collecting these samples? b. How and where will these samples be analysed? c. What does the community want to be done with their biosamples within or beyond the activity's objectives? For example, they may like to have them discarded, the leftovers returned to them, or grant their storage for use in other research.		
	3- Do the activity's benefits outweigh its potential harms?		

Phase	Questions and criteria				Who is involved?	Guiding principles and duties	
	Who is affected?	Expected benefits		Harms			much information they need about the activity
		Short-term	Long-term	Assumed/anticipated	Real (assessed by community representatives)		Inclusiveness and transparency: Duty to openly share the relevant activity-related information with the humanitarian counterparts (whether governmental or non-governmental) and the community; Duty to rationalize the community's expectations of the intended activity and not play on their need/hope to make them participate in
	Government						
	NGO/UN agency						
	Community						
	Examples of benefits: provision of healthcare, establish healthcare facility, training of staff or community members, health education, etc.		Examples of harm: conflict-related harm to data collectors, harm to women/children, psychological/social harm, (e.g. deception, manipulation)				
	How will the surveying agency (Gov./NGO/UN) approach the community?						
	a. What are the steps through which the community leaders (or structures) will be approached? b. What is the information that will be provided to the community representatives? c. Is the activity-related information accurate and simple enough to be understood by the target community?						

Phase	Questions and criteria	Who is involved?	Guiding principles and duties
<i>Field phase</i>	How will the activity be approved by the community?	<ul style="list-style-type: none"> - Local authority - NGO's grass-roots representatives - Community leadership 	<p>the activity</p> <p>Reciprocal Justice:</p> <p>Duty to include only those whose inclusion is needed and beneficial to them;</p> <p>Duty to prioritise those included in the activity in any potential benefit(s) from the activity, current or future</p>
	<ul style="list-style-type: none"> a. Are there functioning community structures that will be informed about the activity before it is conducted? b. How will the individual consent of the directly involved participants be sought, if needed? c. Are there any incentives (cash or in kind) that will be provided to the community leaders or the participants? What are the justifications for providing such incentives? 		
	How will the activity be monitored while implemented?		
<i>Post-field</i>	How will the results and/or benefits of the activity be shared with the community?		
	A detailed description of which results/benefits will be shared and the steps that will be taken by the activity-conducting agency to share each of them.		

The framework tries to clarify the roles of the community members and leadership as partners in the different phases. They should not be treated as ad hoc or post hoc auxiliary players. The involvement of the official (governmental) bodies is essential, regardless of the potential role of the government in the conflict. Usually, the UN agencies and INGOs build strong partnerships with the service-providing local authorities, whose role is technical and not political. In contrast, the framework does not make clear reference to the political or military players, as their direct involvement would affect the framework's integrity and practicality. These politically-oriented bodies have interests that they would try to promote, citing "national sovereignty" and "we are the country", as one of the participants (representing a governmental governance body) put it. I have explained earlier why humanitarian governance bodies cannot and should not take the lead in the ethical oversight of humanitarian activities, including research.

The guiding principles have been chosen to reflect the values accepted by the studied communities. They are aligned with the overall call of this project to shift ethical oversight to fit within the current complexity of the existing relationships in the field among the NGOs, the communities, and the governmental bodies. Additionally, it emphasises the shift from an information-based, individualistic model of consent to a trust-based community consent, provided that the joint assessment bodies are overseeing the process.

I will conclude this subsection by comparing this provisional framework to the two main frameworks I mentioned earlier (subsection 3.2) as the most relevant to this project, the MSF - Research Ethics Framework (2013) by MSF-ERB (MSF

Ethics Review Board, 2013a) and the ethical framework for the development and review of health research proposals involving humanitarian contexts, abbreviated as the R2HC (Research for Health in Humanitarian Crises) Ethical Framework Project (Curry, Waldman and Caplan, 2014). These two frameworks were chosen for three main reasons. First, both are products of an institutional effort that developed from extensive previous experience in the field, which makes them more credible than literature written by independent authors, whose experience may vary widely. Second, both documents are structured in a way similar to the framework resulting from this project, where “key ethical principles are considered in a clustered, hierarchical order” (Curry, Waldman and Caplan, 2014, p. 3).

Lastly, as with this project’s framework, both documents present their proposed frameworks as living products, i.e. as open to reflection and refinement based on their implementation in humanitarian settings.

Despite these similarities, there are some differences worth highlighting. First, both frameworks were developed by experts in the field based on their institutional experience. For example, one of the justifications for updating the MSF Guidance Document is that “ERB members reflecting upon their practice and use of the framework feel that it is not attuned as well as it could be to the kinds of research undertaken by MSF” (MSF Ethics Review Board, 2013a, p. 1).

In addition to the institutional experience, the development of both frameworks included an extensive review of the literature. However, most the literature in the field is based on the authors’ experience, rather than on empirical projects that reflect the views of the communities in which these studies are conducted.

Therefore, the principles and approaches both frameworks adopt are mostly advanced modifications of the mainstream research ethics guidelines. This project's provisional framework presents additional principles and modalities of implementation that are not mentioned in either document. The remainder of this subsection highlights these differences.

Both frameworks emphasise independent ethical review, which is also emphasised in most of the research ethics literature and guidelines (Emanuel, 2000; World Health Organization, 2000; O'Mathúna, 2015; Council for International Organizations of Medical Sciences and World Health Organization, 2016). This project's framework introduces integrated rather than independent oversight, in which all the stakeholders have various roles at each stage of the research, from planning to implementation. As I have discussed earlier, it is difficult to ignore the complexity of the humanitarian realities, as well as the community's self-protection structures and the values its members. Alternatively, this project's framework suggests endorsing these structures in a continuum of joint (community-humanitarian-ethical) ethical oversight. This joint approach is more appropriate because it overcomes the problem of having the review as a single event without a meaningful ability to follow up on the researchers' compliance when they enter the field. Even worse, the independent reviewers' assessment of the researched communities' interests and how to protect them may differ from these communities' beliefs. For example, one of the questions listed in the MSF framework to assess the protocols is "Why is the research question(s) important to the community affected?" (MSF Ethics Review Board, 2013a, p. 5). This question is best answered by the community members or

leaders. Therefore, this joint oversight is a more comprehensive alternative to the “Community Engagement” proposed in both frameworks as a step or “cluster” (as it is called in the R2HC framework). A joint continuum would incorporate the views of both those conducting the studies and those with whom they will be conducted. It also ensures the feasibility of requirements and safety measures, unlike those set by ethics experts⁵⁴ who may lack a complete understanding of the operational and moral realities of the field.

The other difference I want to highlight is related to consent. Both frameworks emphasise that the “requirement to inform participants is often seen as being an important way to show respect and promote patient autonomy and welfare” (MSF Ethics Review Board, 2013a, p. 7) and that “voluntary informed consent is the anchor ethical imperative associated with any research involving human subjects” (Curry, Waldman and Caplan, 2014, p. 30). Both views seem similar to mainstream research ethics guidelines and leave some room for the researchers to obtain informed consent in a “culturally appropriate” manner. Both frameworks acknowledge that attaining credible informed consent is “likely to be difficult, and perhaps not even realistic, in some crisis and emergency contexts” (Curry, Waldman and Caplan, 2014, p. 30), and thus the MSF framework considers that “in exceptional cases it may be justifiable not to seek informed consent” (MSF Ethics Review Board, 2013a, p. 8).

In this project’s framework, the consent model is fundamentally different, in that its focus is not on the information but on the ability of the researchers to pass

⁵⁴ I consider myself one of them as only because of this project I could have a better understanding of the structural/hierarchical complexity of the conflict humanitarian settings.

the trustworthiness checks set by the community leaders and members. Indeed, some basic information should be provided to the participants, but this information is not the marker of credible consent. Again, the early and continuous involvement of community members/leaders can help in deciding on the amount of information needed and how to deliver it.

11 CHAPTER ELEVEN: CONCLUSION, LIMITATIONS, AND RECOMMENDATIONS

11.1 Conclusion

The aim of this thesis was to conduct an empirically informed and philosophically robust ethical analysis of health-related human research undertaken during armed conflicts with a focus on Darfur, west Sudan. To this end, I set out to conduct an empirical and ethical exploration of humanitarian activities with certain ethically relevant features. The methodologies used to achieve these objectives included a review of the relevant literature, a systematic review of the studies involving humans that were conducted in Darfur during the study period, followed by an empirical qualitative project and finally the development of a normative theory. The latter task was done using an empirical bioethics approach, in which I used the empirical data to inform the normative framework. The critical discussion of the participants' arguments and the relevant literature was the foundation for a normative ethical framework for the ethical governance of humanitarian research and research-like activities.

I am aware of the controversies surrounding the use of empirical bioethics methodologies. However, I still maintain that empirical bioethics is the best methodological approach to study the moral issues in a way that can have policy implications. Overall, I believe that one major achievement of this study was giving insight into the moral views of the conflict-affected population, which was then used as the backbone for the normative product of this project. Though the findings and the conclusions are not entirely novel, they may help in redefining and reworking the way in which humanitarian research ethics (and research ethics

in general) is traditionally approached. My call for a trust-based community-oriented ethical governance system represents a paradigm shift in the way in which relationships are constructed in conflict settings. Furthermore, the normative framework can be a helpful tool for future humanitarian governance system reforms.

I believe that if a trust-based reconceptualization of the humanitarian research governance system is undertaken, the conflict-affected communities will move from being passive vulnerable groups of people to empowered partners in the entire cycle of planning, conducting, and utilizing humanitarian research. Moreover, this would help both the humanitarian agencies and the governance bodies to perform their functions more efficiently.

This project has contributed, within its limits, to highlighting the moral intuitions of the conflict-affected and how they can be aligned with those discussed in the literature and held by the humanitarian agencies. The central role of trust as a strongly held and lived moral value and guide is a significant finding. The two main arguments presented in the discussion are as follows. First, the governance of humanitarian research conducted in Darfur lacks the moral relevance and operational feasibility needed to provide guidance for these activities. The second argument is that a trust-based bioethical framework, not the autonomy-based mainstream research ethics guidelines, is the ethically relevant governance model for the kinds of humanitarian activities included in this project.

The humanitarian activities among conflict-affected populations in Sudan have been crucial to helping these populations survive for more than a decade.

The collection of personal data and sometimes biosamples from selected members in these populations are also integral to these humanitarian activities. Unfortunately, the humanitarian situation may not be completely resolved anytime soon, given the rise in frequent inter-tribal conflicts in addition to potential armed conflicts and the low-level conflicts in other parts of the country.

This situation needs an ethical governance system that represents the moral views of the communities served and is feasible within the humanitarian context. This governance system is currently not in place. The humanitarian activities are guided by various inconsistent sets of organisational, national, and international guidelines and regulations.

The current humanitarian governance model is imbalanced. There is an emphasis on the control of the humanitarian activities and their political implications for the government, rather than their potential ethical implications for the affected population. In contrast, research governance is almost absent from the overall humanitarian governance structures, which are not currently ready for such a role, given the frequent reformations they have gone through and their reliance on the mostly international autonomy-based bioethical frameworks. These frameworks are not representative of the hierarchical Sudanese socio-cultural context and its widely-held trust-based moral norms.

There is also a lack of enhancing factors that I argue are necessary for meaningful bioethical development in Sudan, including democracy, freedom of expression, and the rule of law. This lack of proper ethical governance of humanitarian studies is complicated by the lack of trust and the power imbalances

among the various stakeholders, namely the governance bodies, the INGOs, and the served communities.

As a possible remedy to these conceptual and operational gaps, I have discussed and provided examples of the kind of changes to disaster research ethics suggested by Zwi et al. (2007) and Mackenzie et al. (2006), along with the presence of some enhancing factors like advocacy, inclusiveness, trust, and public engagement. The aim of this call is to come to a common agreement among the various stakeholders on what the guiding moral values ought to be and how to implement them. We should acknowledge that reaching such an agreement is not an easy task, and whilst its success cannot be guaranteed, trust-based bioethics represents the more sensible alternative, given the socio-cultural challenges.

On a final note to the conclusion, I need to acknowledge that no single project, however inclusive and extensive, can provide indisputable answers to the questions it tries to address. It should be also considered a sign of success for any research project to be able to raise more research questions whose answers ought to be pursued. To this end, I believe this project was successful in reaching conceptually sound, well-articulated answers to the project's empirical and normative questions. Moreover, it is a contribution to the research agenda of this under-researched discipline (Hunt *et al.*, 2014) that can be a basis for future research.

11.2 Limitations

Every study has its limitations and this project is no exception. Given the sensitivity of the topic and the socio-political complexities attached to it, there were

some problems. I have tried to deal with them in the most professional way possible within the available time and funds and the given permissions. As a reminder, this study did not aspire to provide a finalized ready-to-use product. It rather aimed to provide empirical evidence that can guide further research and that can act as a baseline for those interested in humanitarian research to improve and build upon. Despite the limitations I discuss in this section, the overall aims of this project have been achieved and the key research questions have been satisfactorily answered, notwithstanding some gaps that I have discussed earlier. One initial conceptual limitation is that although I formulated a working definition of “research”, I did not consider what “ethics” means to the participants. Different understandings of ethics may have influenced participants’ views. However, asking the participants to give a succinct account of ethics from their point of view would have been too abstract a task for the population of interest.

The methodological limitations related to the systematic review have already been addressed (see Section 7.6). Here, I discuss the methodological limitations of the rest of the project, followed by issues related to the generalizability and applicability of the project’s findings.

First, I was granted access only to the Darfuri IDPs residing in Khartoum. They are mostly from Arab tribes who were supposedly targeted to a lesser extent by the Sudanese Armed Forces (SAF). They fled from tribal conflicts and did not live in housing conditions like those of the IDPs in Darfur. As they were outside the usual settings in which humanitarian agencies work and conduct their studies (the

IDP camps), they are under-researched. Thus, their views may differ from those of the Darfuri conflict-affected populations.

Second, though all the targeted categories of institutions were included, key UN agencies and INGOs did not participate. It is possible that the contribution of these agencies could have added new dimensions and a deeper understanding of the themes under study. However, I have considered this absence itself a finding, as discussed earlier, and I believe that the empirical findings are a fair representation of the current humanitarian situation in Sudan. The shortage of interviews was compensated for by the group discussions, which were more informative and discussed the themes in more depth.

Lastly, there was the inevitable shortcoming related to the translation from a Sudanese dialect to translatable traditional Arabic and then to English. Due to a lack of qualitative research experience among the translators in Sudan, the most sensible option was to do it myself with proper checks (for greater detail regarding how this was remedied, see subsection 6.4). Overall, I am satisfied that the final English translation was an accurate representation (though not verbatim) of the original Sudanese Arabic texts and that none of the quotes I have used was inappropriately edited or misinterpreted.

11.3 Recommendations

I now outline a set of recommendations that may help both humanitarian agencies and research governance bodies to establish a culturally sensitive and operationally feasible ethical governance system for research conducted in

humanitarian settings in Sudan and beyond. I try to make the recommendations as concise and as specific as possible in the following list.

- 1- The framework that I have presented as one of the main outcomes of this thesis needs to be validated, used and evaluated, preferably by the humanitarian sector and the current research governance authorities.
- 2- The socio-cultural structures of the conflict-affected communities need to be qualitatively studied and not just assumed. These studies require funds (like those granted to me by the Wellcome Trust), interested researchers (preferably from the affected countries), and responsive humanitarian agencies that want to improve their ethical humanitarian performance.
- 3- The research governance systems in Sudan (and probably other developing countries) should seriously reconsider how they develop their research ethics guidelines. These guidelines, as I have consistently argued in this thesis, should reflect of the morally relevant principles of the communities they mean to serve. As I have mentioned in the previous recommendation, these principles ought to be determined through proper research to make the proposed guidelines morally valid and operationally feasible.
- 4- I strongly recommend that researchers planning to conduct similar studies in conflict-affected settings should have the methodological imagination and flexibility to survive inevitable uncertainties like the ones I faced in this project. More importantly, I call on the ethics committees reviewing the protocols of projects similar to this one to have similar

ethical and methodological imagination. Leave room for the genuine credibility of the researcher, especially if she has previous experience with research in conflict-affected areas.

- 5- Following the difficulty I faced in finding eligible studies for the systematic review, I call for more contributions to the global databases for disaster research, namely CRED and ReliefWeb. International humanitarian agencies should be incentivised, financially or otherwise, to contribute the reports of their studies conducted in disaster settings.
- 6- The current humanitarian and research governance mechanisms, both governmental and non-governmental, need to seriously discuss the means by which the ethical issues in humanitarian activities are assessed, addressed and anticipated.
- 7- The longer-term solution will always be the establishment of a stable national research governance body that has the capacity to endorse the various types of research conducted in Sudan and not only clinical research. Decentralisation of the ethical review process is an important factor to facilitate and enhance the ethical oversight of human research; however, this should be done through proper delegation to well-trained staff in efficiently functioning structures.

11.4 Considerations for future work

I am aware that this project is at best a starting point for an empirical bioethics approach to humanitarian “research” ethics. Nonetheless, this thesis can be expanded in future projects in many ways that I can summarize as follow:

- 1- To use the same method but on a wider scale in Darfur itself or beyond
- 2- To update the systematic review to include other conflict-affected countries and a wider date range
- 3- To compare the findings of the conduct of research in conflicts to that conducted in natural humanitarian settings or other events of mass injury
- 4- To validate the provisional ethical framework resulting from this project
- 5- To conduct a comprehensive qualitative systematic review of how international research regulatory documents define “research”

I would like to finish with a call for ethicists, especially those with knowledge of moral philosophy in developing countries to make a greater and deeper contribution to the body of ethics literature beyond the predominantly cross-sectional descriptive studies. This in turn could help in developing our understanding of the status quo to be able to recommend evidence-informed changes.

12 APPENDICES

Appendix 1. The topic guide for the INGOs interviews

1- Self-introduction (5 min.), the researcher will

- Thank interviewee for taking part in the research.
- Introduce him, and suggest that the interview will last up to 40 minutes
- Explain the purpose of research and few ground rules (e.g. breaks if needed, mobile phones)
- Reassure re: confidentiality
- Presentation of the information sheet, and gain a written consent

Topic discussion (30 minutes)

2- Please tell me about the activities that your institution (organisation) conducted in Darfur between 2004 and 2012?

Prompts:

Did any of these activities involve the collection of personal data and/or any kind of biological samples from the target population?

3- Can you tell me about how your institution prepared for the conduct of these activities?

PROMPTS: what kind of committees or departments was responsible for these preparations? Please tell me more about their structure and hierarchy. (Probe: do they follow you directly or under another department)

4- What did you or your sponsors consider were the essential requirements to be fulfilled for any project to be conducted?

PROMPTS: are they technical? Logistic? Financial?

5- Please tell me about any changes that have taken place in the process of reviewing and approving the research undertaken by your institution since 2004, or since you have been in this post if any?

Prompt: if no, go to Q6 directly. If yes, ask for details in the changes in terms of:

- What initiated such changes?
- What did these changes target? E.g. technical issues, methodological issues, or ethical issues
- How were these changes applied?
- How did they affect the actual undertaking of research in the field?

6- Thinking about your time in your current position, please tell me about anything that any of your data-collection teams have encountered that they (or yourself) considered raising some ethical issues?

Prompt, if yes: can you give one or two examples of these issues

7- Do you think that there should be a prior ethical review of activities that involve the collection of personal data or some biosamples (e.g. urine, stool, or blood)? (If NO, go to Q 12)

Prompt: if yes, ask the following questions and if no go to Q 12

8- Have you had these activities ethically reviewed?

Prompt: refer to the examples from the findings of the systematic review with studies that were undertaken by the interviewee's institution, if without ethical approval

9- How do have these activities ethically reviewed? By whom? Inside the NGO or outside it?

10- Do you face any difficulties in having these activities ethically reviewed?

11- If yes, what are the difficulties that you face in having these activities ethically reviewed?

Prompts: no committees? The national committee is not efficient? No local committees in Darfur? Time consuming? Lack of clear guidance?

12- If no, why do you think that these activities do not need to be ethically reviewed?

Prompts: they are not research? emergency and ethical review are time-consuming? No committees? No guidelines? Not requested by the NGO sponsors?

13- If the answer is 'not research', then what would define the research that should be ethically reviewed?

Prompt: how do you think that these activities differ from the characterisation of research that you have just described?

Are there any conditions that would make your NGO consider submitting this kind of activity to ethical review?

14- For other options, then say "if I got your point clear, you think that (fill with the answer provided to the question or prompt) is the main reason for not considering your NGO's activities for ethical approval. Am I right?"

If yes, go to Q 15, if no, then say, "sorry for not getting your point clearly, so can you please restate to me the main reason why your NGO would not consider these types of activities to ethical review"

15- Then if the (chosen option in Q 13) is resolved, would you consider applying these activities to ethical review?

Prompt: if yes, ask: how would you suggest the best approach to the ethical review of humanitarian activities that involve the collection of personal data and/or biological samples?

Prompt: If the answer to Q 15 is No, ask: so, what do you think needs to be resolved to consider these activities for ethical review?

Summary and closing (5 minutes)

18- The PI will summarise conversation and what has been discussed throughout the interview, then ask the interviewee:

- Is there anything else that you'd like to add or discuss?
- Any questions?

Thanks and close

Appendix 2. The topic guide for the INGO' research officials' interviews & focus groups

1- Self-introduction (5 min.), the PI will

- Thank interviewee for taking part in the research.
- Introduce self and notify the participant that the interview will last up to 40 minutes
- Explain the purpose of research and few interview rules (e.g. phones silent)
- Reassure re: confidentiality
- Presentation of the information sheet, and have the consent signed

Topic discussion (30 minutes)

2- Please tell me about the structure and functions of your department/committee?

Prompt: date, staff/membership, functions, facilities, meetings, workload, etc.

Prompt: relation with the UN agencies and the INGO

3- Sudanese (national) research ethics guidelines state that “international research done in Sudan should be only reviewed and approved by the national committee”, do you think that this includes the research undertaken by the INGO in Darfur?

Prompt: given that these activities involve the collection of personal data and sometimes biosamples from Sudanese citizens (If No, go to Q 6)

4- If yes, then can you tell me how did your department/committee manage to ethically review these activities since 2004, or since you have had this post?

Prompt: refer to the findings of the systematic review about how many studies were ethically reviewed by which committees? The number of studies submitted for ethical review from the INGOs in Darfur for the last year, for example.

5- If no (to Q 3), why do you think that these activities that involve the collection of personal data and/or biological do not fall within the characteristics specified in the guidelines?

6- Please tell me now how your department is currently handling the protocols for research to be undertaken in Darfur?

PROMPT: compare to the answer of Q4.

7- On a scale of 1-5, where 1 is very unsatisfied and 5 as very satisfied, how would you rate the overall role of your department/committee regarding the oversight and coordination of the research activities in Darfur?

8- Why did you give such a level of satisfaction?

9- Do you think that the current structure of the department needs improvement in relation to research conducted in Darfur? [If yes, go to Q12]

10- Do you think that the current coordination and ethics review procedures need improvement in relation to research conducted in Darfur? [If yes, go to Q12]

11- Do you think that the current ethics guidelines need improvement in relation to research conducted in Darfur? [If yes, go to Q12]

12- PROMPT: if his rate in Q7 is 3 or less, OR if his answer on Q9, Q10, or Q11 is 'Yes'.

Ask: What do you think needs to be improved regarding [structure/procedures/guidelines] on the research undertaken in Darfur? NOTE: make sure all the three questions (Q9 on structure, Q10 on coordination, and Q11 on guidelines are asked)

Summary and closing (5 minutes)

13- The PI will summarise conversation and what has been discussed throughout the interview, then ask the interviewee: • is there anything else that you'd like to add or discuss? • Any questions? Thank and close

Appendix 3. The topic guide for the Focus Groups Discussions

There will be two approaches to the FGDs. The PI may shift between them as needed to make the participants come with as much interaction and information as possible. The use of two approaches to the FGDs aims at generating the needed amount or path of data relevant to the project. The first approach will be using a case scenario and have it read to them, and then focus on attitudes to the case scenario. A second approach is a stepwise approach that uses probing open-ended questions in relation to their previous experiences as research participants.

1- Self-introduction (5 min.), the PI will

- Thank interviewee for taking part in the research.
- Introduce self and notice that the interview will last up to 45 minutes
- Explain the purpose of research and few ground rules (e.g. breaks if needed, mobile phones)
- Reassure the need for confidentiality and to refrain from sharing any information shared within the discussion outside it
- Presentation of the information sheet, and have the consent forms signed

2.2.1 Approach A: discussion of a scenario, or case study

Topic discussion (30 minutes)

2- The PI (or the research assistant in the female FGD) will be reading an example of an informed consent that was used in a household survey that was undertaken by an international humanitarian aid agency in Darfur between 2004 and 2012. The example informed consent will be that of Sudan Household Health Survey that was conducted in Darfur in 2006 because it involved the collection of personal data as well as performing anthropometric measures on children under 5 years old in the selected households. This is the excerpt of the informed consent used in the household questionnaire (Damian and Damundu 2007):

“Household questionnaire:

We are from Sudan household health survey which is concerned with family health and education. I would like to talk to you about this. The interview will take about 45 minutes. All the information we obtain will remain strictly confidential and your answers will never be identified. During this time, I would like to speak with the household head and all mothers or others who take care of children in the household.

May I start now? If permission is given, begin the interview.”

Examples of the probing questions to initiate discussion of this consent are:

- a) What do you think about this informed consent form?
- b) Tell me about your previous experiences with data collectors asking your permission to collect data from you
- c) What else would like to be considered by the data collectors when they approach you in similar (research) activities?

3- The PI will summarise conversation and what has been discussed throughout the interview, then ask the interviewee: • Is there anything else that you'd like to add or discuss? • Any questions?

Thank and close

2.2.2 Approach B: previous personal experiences

Topic discussion (30 minutes)

4- Tell me about your experience with one of the times where the humanitarian workers came to your household and asked you questions about your health, food, education, etc.

Prompt: any biosamples were taken? Blood? Urine? Stool?

5- Did they ask for permission before they start asking questions? (If No, go to 6)

6- If yes, can you describe to me how did they take these permissions?

Prompt: which details told? In which language? Who took the permission?

7- If no, what made you let them ask you questions or take samples?

Prompt: trust in the NGO? Needed to answer to get aids? The camp leader told them to? Other reasons? Explore.

8- Do you know what happened to the data or samples you gave?

Prompt: if yes, let them give examples of what could have happened to the data and the samples

9- If no, what do you think the data and samples could have been used?

10- Are there any data collection activities currently going in your camp?

- If yes, how they are done?

- Do you think there are any problems related to them? [Yes/No]

Prompt: if Yes, can you elaborate more on what do you see as problems? 11-

If yes, you want them to continue as they are or what are your suggestions to make these activities better for you?

12- If no, why not?

Appendix 4. Ministerial Decree 12/2007: Establishing the States' Research Review Committees



Appendix 5. Ministerial Decree 13/2007: Establishing the National Research Review Committees



Appendix 6. Ministerial Decree 14/2007: Establishing the Federal Hospitals' Research Review Committees



Appendix 7. A sample of initial encoding of the interviews

GH This takes me to another point. In respects to the coordination or the arrangements that take place for these surveys, there are, for example, technical arrangements or logistics arrangements etc. If possible, would you explain to me the arrangements for such procedures whether those the organizations give them (i.e. their surveys) to you ready and then you enter with them only in the implementation? Or is there another form of coordination with them or arrangements before the survey?

Procedural
→? not too strict
→ HAC as "guardian"
"coordination"
? interview

MNA: Oh Yes. [This] can be in the form of pre-arrangement of the survey. As I told you there must be prior coordination because if you want to do a survey, even if, we suppose not in the purely technical side. You want to do a survey in Darfur, for example, you want to, for example, take a plane, or [you] want to do your survey anywhere, say in the Blue Nile [State] and you want to ride a vehicle. Then certain procedures need to be followed here. The permit you need for travel with a plane from here to there as a team survey is done with me here.

Best quotes for think

What I want to say that there is a prior arrangement ... You are as an organization must come to me... by the way we have specific authority within which there are the "specialized entities", by which we mean the security, the intelligence, and so on and so forth. Because I do not want to say that any the work of a foreign organization has [bad/hidden] dimensions. This is not in our minds and we do not begin by considering that he (referring to the NGO) has a hidden agenda or something like that. This is completely out of the question in our mind, but we take precautions and we put what guarantees to us that we have fulfilled all our information and fulfilled our (incomplete sentence). We stayed [with such measures] assured that the team with 5 foreigners in this specific survey (incomplete sentence). That is all coordination or a series of procedures taking place within the Commission,

Technical

HAC as Restriction - Authority - Trust - Reliability & Accuracy

Therefore, certainly, the Commission represented in the "procedures" complex until the exit of the team [to the field]. [This is done] through our participation with our (i.e. HAC's) staff and the staff seconded to us from the relevant ministry take place in HAC. And sometimes we move further in the arrangement and coordination more than that, whether in the form of the questionnaire or the methodology used in the survey. We got to the point (where) the case has reached the extent that we refused an approach used to the implementation of the survey named MIRA. If it passed you (Multi-Integrated Rapid Assessment) for our own dimensions and considerations as a Commission and as a government and as a country. We rejected this approach completely. I want to tell you that we went further than that because it is not allowed to work with this methodology of survey in our country - a country with sovereignty, with a regime with so on and so forth.

GH: I have another aspect I want to focus on. Have you, during your work, felt that there is an ethical aspect in the sense that I mentioned [to you earlier], specifically in the rights of people included in survey's sample on? Is there, at any point of time, that the people felt that the rights of the people participating in these surveys are under consideration? Or some procedures related to the surveys were raised or, for example, caused some debates, or brought up some discussions, like the standards organizing them, as well as procedural and logistical standards and ... and ... etc.? In addition to the scientific standards; there are standards on the rights of the participants. Were there any discussions on this subject? Or any type of guidance specified to the rights of people participating in these surveys

MNA: If I understood you right, you're talking about, for example, that you want examples. As I told you this survey (incomplete sentence). The survey findings can be possibly used for any purpose. Now I have opened my country, and let you into hot places and you collected information, but [regarding] the employment of this information - here we should [have a] pause, even with their (referring to the survey's findings) containment.

Trust Sphere of Fear "blow in Target"

You know that humanitarian affairs and humanitarian affairs' gate had dragged us to the criminal. It is information after all ... Information, studies and research, blah, blah from which the people extracted information and documented it. They raised these reports to the United Nations and so on.

This issue exists as practice but what I want to say is that people are aware of it and putting them in mind. I do not want to say completely, but to some extent we managed to direct some

¹ A short reference commonly used in the Sudan to the International Criminal Court (ICC) on Darfur crimes, which warranted an arrest order for the Sudanese president Omar Al-Bashir in relation to the claims on his role in the atrocities in Darfur.

Appendix 8. A sample of 'least intervention' approach to interviews

→ Example of least intervention approach.

The Registrar General is concerned with the registration of voluntary entities, whether national or foreign, or networks. Even the Registrar, since you (she's referring to the NGO staff) come, you find that he has registration conditions,

You are talking about ethical controls if I understood you, you gave them ethical standards with the same understanding and you called them so, but when we come to project them to the practice in the Commission, I say that we have the registration conditions, whether for the national or foreign organization, I'll give you an outline, Doctor, and I will attach to you these things in detail ...

A foreign organization when they want to enter or request to allow it to work in the Sudan, it comes through us under certain conditions.⁷

The procedure starts from our embassy in the country concerned. It is known that organizations have different nationalities.

So in any country from which it [the NGO] is coming, [when] the foreign organization wants to be permitted to operate in Sudan; if we have [a Sudanese] embassy; the process starts there. And if the concerned country does not have an embassy; they [the NGO staff] are referred to the Sudanese embassy in the nearest country. It starts the procedure with filling Form A, but as I told you that I do not want to waste your time [in technical details] because I've already attached them to you [in the email] in detail as a reference,

The national organization comes with certain conditions. The normal procedures [for example]... to have a general assembly and specific conditions and to have a Founding System, in addition to other procedures if you fulfil them, you do not have any problem if you identified areas of your business, you will be granted a certificate of registration, you become an organization that has the right to work within your constitution and your Founding System that you came with, by specific areas, such and such. This is one of the criteria you are talking about. This is [done] from the start - from the Registrar General.

[When] The Registrar General has given [them] the certificate of registration, now they want to conduct their work. At that time, they enter the Department of Organizations and Projects, and it is concerned with the work of both national and foreign organizations ... which is tied to their projects implemented in Sudan, good? This is the work of the department...

For the foreign organization, of course, they have their documents that facilitate the work, [there is] something called the procedures' manual that explains all the necessary procedures that the organization should know or adhere to when they request for anything ...

It is known that the organization has foreigners working [in it]. I want to emphasize that we in the Commission, we have a contractual relationship, or what we call them, we have units. They are responsible of the procedures and [they] belong to other ministries. We are, in our mechanism, or our work, we have affiliated relevant ministries and agencies that we are dealing with. They are related to the procedures the foreign[ers] need for their entry, either a work permit, [so] we have Ministry of Labour has an office with us, there is complex here is named Unified Complex of Procedures and you find it in any action which you need - all in one window

GN: Yes, I noticed even the traffic department exists

MNA: Yes, it is located in the south building, even traffic department - as kindly said - they are concerned with organizations' vehicles. Work Commission is concerned with the jobs, whether for nationals or foreigners. You also have [the unit responsible for] travel permits because the organization that comes does not only work in Khartoum but wants to move from Khartoum to Darfur, or from Khartoum to any other state they have activity in. All the people from the [Ministry of] Interior [Affairs] are all present; the staff for passports, customs, finance, etc. It [the Unified Procedures Complex] is a complex to facilitate, in which the facilities are provided to organizations.

This is a form of the required documents ... the procedures' manual. We also have directives, we have directives that are renewed each year in accordance with the developments in which all variables are endorsed, and we have now (incomplete sentence).

Handwritten notes:

- Persons
- Practical not related or diff. intent
- Trust & Control
- Official vfy docs OK
- NNGBs
- Persons
- NGOs
- Relations
- official proc
- procedures & trust
- use of - foreigners - not - not!!
- Relationships (contractual)
- Gov't & Relationships
- Procedures
- procedures - trust

Appendix 9. Summary of the 'meeting' I had with NISS officer

During the 'discussion' he asked me about "my intentions", "why a doctor like me leaves medicine (referring to clinical practice) and chooses a topic about Darfur", "who is paying for me?", and that "he met smart people like me who would sell themselves to the devil for the sake of money or to stay in Europe". He told me, "You know how these studies led us to have our president wanted by the ICC." He repeatedly mentioned the "conspiracies against the State" and the "fifth Reich in Sudan". He questioned my nationality and my religion because "many people look Sudanese and Muslim but work against their country and religion".

Only because I am Sudanese, he said, I was allowed to enter his office with my cell phone, paper and pen, as he "would not mind even if I were recording". He stated that if I tried to enter the Darfuri community without prior security clearance, I would be immediately "brought to him". When I told him that some preliminary results of my study already showed that some foreign organizations were not adequately mentioning obtaining ethical approval from the relevant Sudanese authorities, the conversation tone changed. He asked me if I have "the courage to publish these data and resist the pressure of those who paid the money for me". I told him that the funding agency does not interfere in the results of a study and that the University has no interest whatsoever in the results of my study, and promised him that I would publish these findings. He granted me the security approval. At the end of the meeting, he reminded me that if I "did not follow the agreement"; I would be "brought to him" and hinted that the security clearance could be revoked.

Appendix 10. Information requirement for informed consent for research in Sudan

(National Ministry of Health, 2008)

1. The individual is invited to participate voluntarily in the research, explaining the reasons for considering him/her suitable for the research
2. The individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled
3. The purpose of the research, [and] the procedures to be carried out by the investigator
4. The expected duration of the individual's participation
5. Whether money or other forms of material goods will be provided in return for the individual's participation and if so, the kind and amount
6. The subject will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their health status
7. The subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure)
8. Any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a

subject's spouse or partner

9. The expected benefits of the research to the community or to society at large, or contributions to scientific knowledge
10. Whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them
11. The provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified
12. The limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality
13. The possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken during clinical care
14. Whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed
15. An ethical review committee has approved or cleared the research protocol

Appendix 11. Authors' Questionnaire on the ethics of health research involving humans undertaken in Darfur (2004-2012):

Available at: <http://www.tfaforms.com/315475>

I. Information about the researchers who conducted health research in Darfur

I. General Information

1.1. Authors' Full Name

1.2. Authors' Affiliation

1.3. Authors' Email

II. Information about the health-related research you conducted in Darfur

2.1. Title of the (latest) study/manuscript

2.2 Places of publication (e.g. name of the journal, website, database)

2.3. Date of Publication

2.4. Did your research involve the collection of human personal data from the people in Darfur?

Yes No Not sure

2.5. Did your research involve the collection of human biological samples from the people in Darfur?

Yes No Not sure

2.6. Did your research involve the collection of anthropometric measures (e.g. height, length, weight) from the people in Darfur?

Yes No Not sure

III. Ethical Approval of the research you conducted in Darfur

3.1. Was your study protocol ethically approved before undertaking the study?

Yes No Not sure

IV. Informed Consent for the research you conducted in Darfur

4.1. Have you obtained an informed consent from those involved in your study?

Yes No Not sure

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