Human research in conflict settings: A mapping of the relevant literature

Ghaiath Hussein[1], Mosfer A Al-walah[2]

(1) Assistant professor, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia.
(2) Department of Physical Therapy, College of Applied Medical Sciences, Taif University, Taif, 21974, Saudi Arabia.

Corresponding author:
Ghaiath Hussein, Assistant professor,
King Saud bin Abdulaziz University for Health Sciences,
Riyadh, Saudi Arabia.
Email: ghaiathme@outlook.com

Abstract

Humanitarian and specifically conflict-related research ethics represent an intersection of at least four fields: public health ethics, humanitarian ethics, research ethics, and disaster ethics. The aim of this literature review is to summarize the literature related to the conduct of research on humans during conflicts. This review of the literature aims to identify the gaps that need to be filled. It is divided into two parts, the first briefly highlights the ethically relevant aspects in some of the technical and legal documents commonly used in humanitarian settings. The second section lays out the literature addressing the key ethical considerations in research during humanitarian interventions, especially in conflict areas. In both parts, the relevant gaps in the literature are highlighted.

Key words: ethics, humanitarian ethics, literature review, research ethics

Introduction

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 1). A full review of these fields is beyond the scope of this review. The focus is rather on how the three other fields could affect research ethics in relation to humanitarian contexts.

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

Regulatory Approaches To Humanitarian Interventions in Disasters and Conflicts

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.

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 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.

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 1).

F   1: D a   a   -   a   a   a

Public/global health ethics
National laws and guidelines
International health law

Humanitarian ethics
Humanitarian
principles;
Organizational code

Conflict-research ethics

Disaster ethics
Humanitarian
principles

Research ethics
National laws and guidelines
International guidelines

Tab 1: E a   a   a   b   a   a   a a

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)	**Humanitarian Principles** 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 Crescent Societies (IFRC), 1965)	These include the four above-mentioned Humanitarian Principles (and three additional ones of relevance to the Red Cross Red Crescent Movement, i.e., Unity, Voluntary Service and Universality) 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 in any one country. It must be open to all. It must carry on its humanitarian work throughout its territory. 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.

Table 1: Examples of the codes of conduct and core values set by some international organisations (continued)

Organisation	Document title	Scope and examples of core values
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)	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). 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 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 (The Sphere)	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)	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.

Table 1: Examples of the codes of conduct and core values set by some international organisations (continued)

Organisation	Document title	Scope and examples of core values
		sovereignty, territorial integrity and national unity of the State must be fully respected in accordance with the Charter of the United Nations. 7) Each State has the responsibility first and foremost to take care of the victims of natural disasters and other emergencies occurring in its territory. 8) 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. 9) In situations of armed conflict, civilians are protected under international law against attacks and other violations of international humanitarian law. 10) 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" (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 part, we summarise the literature relating specifically to research in conflict settings.

Ethical and Philosophical Approaches to Research during Conflicts

In this part, we present an overview of the literature on humanitarian research ethics, with a focus on the conflict context. However, we do not discuss the literature on pandemics and natural disasters, despite its potential relevance. Arguably, armed conflict settings constitute a more complicated context that 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) (Cecchine et al., 2013; Ferris, 2012), despite criticisms of the efficiency of civilian-military humanitarian coordination (Boon & Allen, 2014; Hofmann & Hudson, 2009).

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 part is on the literature related to research in conflict settings and not in other settings.

Overview of the Literature

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 2015). We have demonstrated above that the 'compilation' enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research. 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 & Menikoff, 2011). Levine has described the field of research ethics as "born in scandal and reared in protectionism" (Marshall, 2002).

Despite some variations among the different research ethics guidelines, some ethical considerations are common to almost all of them. Table 2 summarises these common considerations and their disaster-related applications.

Tab 2: C a a b a a a a a 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 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.	Participants in certain emergency-related activities should give their informed consent, especially when their identifiable information or biosamples are to be collected. Such consent can be given collectively (following community consultations) and/or individually.	CIOMS (General principles, and guidelines 4–6), Declaration of Helsinki (Articles 25–32), TCPS (Part 3, The consent process)
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)

Table 2: Core ethical principles and issues covered by the main guidelines and examples of their application in public health emergencies (Hussein, 2015a) - continued

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
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)
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 Part 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 (Part 9, Research involving the First Nations, Inuit and Métis peoples of Canada

Table 2: Core ethical principles and issues covered by the main guidelines and examples of their application in public health emergencies (Hussein, 2015a) - continued

Ethical principle or accepted good practice	Description	Examples of public health emergencies	Examples of guidelines that address the ethical principle or issue
	the primary vulnerable groups.		
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 (Part 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 (Part 5, Privacy and confidentiality)

¹Modified 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 we 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, 2015a, 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 part, we summarise the main trends of this literature and then identify the gaps that future research could help to fill.

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).

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. Future research 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 (D Schopper, 2009; Wood, 2006)) to institutions (mostly Médecins Sans Frontières (MSF) sharing their 'lessons learned' ((D Schopper, 2009; Karunakara, 2013; Sheather & Shah, 2011; Zachariah et al., 2010)).

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 et al., 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 ((Novitzky et al., 2015)). These seven principles were also the benchmarks for the first MSF REB framework ((Giacomini et al., 2009; MSF Ethics Review Board, 2013)), 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" ((Board, 2013)).

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" ((Winkleby & Cubbin, 2003, p. 97)).

Clarinval and Biller-Andorno propose a ten-step approach to ethical decision-making to assist humanitarian workers ((Clarinval & 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 3). This framework is meant to guide disaster-related humanitarian decisions; it does not provide ethical guidance for disaster research.

The second relevant framework is "[A]n ethical framework for the development and review of health research proposals involving humanitarian contexts" (Curry et al., 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).

Tab 3: S a HHEAT - a a a (F a a ., 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 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.

Tab 4: R a H a H a a a C (R2HC) E a F a a K Q (C a ., 2014)

Cluster A: Emergency Context Requirement/Benefits-Harms-Risks
• 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?
Cluster B – Protocol Design: Scientific Validity/Feasibility; Research Focus: Relative Priority; Team Strength: Competence/Collaborative Structure; Declared Interests
• 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
• 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?

Table 4: Research for Health in Humanitarian Crises (R2HC) Ethical Framework and Key Questions (Curry et al., 2014) - continued

Cluster D: Community Engagement; Cultural Context/Norms/Values
• 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
• 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
• 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. We could identify two distinct lines of operationally-oriented ethical guidance. The first is that related to pandemics, especially influenza (Kinlaw et al., 2009; World Health Organization et al., 2015) and Ebola ((Organization, 2014)), which as noted earlier is not included in this review.

The second, which we 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, 2013, p. 2). The relevance of this framework to future research is twofold. First, it is organized 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 the frameworks prepared by experts who lack such an extensive humanitarian experience.

In the following part of this review, we identify the gaps in the main types of literature we use in this review: research ethics guidelines and literature published in peer-reviewed journals.

Critique of international and national research ethics guidelines

We argue that both national and mainstream international guidelines are not appropriate for the review of humanitarian research. To support this conclusion, we provide two 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 future research for several reasons. First, 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.

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 & Childress, 1994).

The governments in most 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. 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 local people, who were not given the opportunity to evaluate them. To clarify, by reflecting the true moral values of the local communities is not a simple exercise of voting on this or that principle, or a meek 'what do you think' kind of question. We are referring to an in-depth reflective empirical work that studied those communities, using sound ethnographic, sociological, anthropological, or other qualitative methods.

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. 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 (Hyder et al., 2007; Motari et al., 2015; Rwabihama et al., 2010). 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 we 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 most of the countries in the southern hemisphere 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 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.

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 & Warren, 1995; Ford et al., 2009; MSF Ethics Review Board, 2013). 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.

Summary

The literature on ethical issues in conflict-related research has developed steadily over the last 25 years (Curry et al., 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.

References

Adlan, A. (2015). The biomedical ethics of donating blood for molecular and genetics research in Saudi Arabia. In School of Health and Population Sciences. http://etheses. bham.ac.uk/6085/

Beauchamp, T. L., & Childress, J. F. (1994). Principles of Biomedical Ethics, 4th edition. New York: Oxford University Press.

Black, R. (2003). Ethical Codes in Humanitarian From Practice to Research; Emergencies: Introduction: war in Liberia Humanitarian codes of conduct: tarianism the ethics of humani-. Disasters, 27(2), 95–108.

Board, M. S. F. E. R. (2013). MSF Ethics Review Board Standard Operating Procedures. http://hdl.handle. net/10144/294968

Boon, T. T., & Allen, L. (2014). Disaster management in Southeast Asia: issues and challenges.

Cecchine, G., Morgan, F. E., Wermuth, M. A., Jackson, T., Schaefer, A. G., & Stafford, M. (2013). The U.S. Military Response to the 2010 Haiti Earthquake. In RAND Corporation. https://doi.org/10.1214/07-EJS057

Clarinval, C., & Biller-Andorno, N. (2014). Challenging Operations: An Ethical Framework to Assist Humanitarian Aid Workers in their Decision-making Processes. PLoS Currents, 6. https://doi.org/http://dx.doi.org/10.1371/ currents.dis.96bec99f13800a8059bb5b5a82028bbf

Curry, D., Waldman, R., & Caplan, A. (2014). An Ethical Framework for the Development and Review of Health Research Proposals Involving Humanitarian Contexts: Project Final Report January 2014 (Issue January). Enhancing Learning and Research for Humanitarian Assistance (ELRHA): R2HC Programme. http://www. elrha.org/wp-content/uploads/2015/01/FINAL-R2HC-Ethical-Framework_Final-Report_24-January-2014_0.pdf

D Schopper, R. U. F. M. J. S. S. B. (2009). Research ethics review in humanitarian contexts: the experience of the independent ethics review board of Medecins Sans Frontieres. PLoS Med, 6(7), e1000115. https://doi. org/10.1371/journal.pmed.1000115

Demi, a. S., & Warren, N. a. (1995). Issues in Conducting Research with Vulnerable Families. Western Journal of Nursing Research, 17(2), 188–202. https://doi.org/10.11 77/019394599501700206

Dhai, A. (2014). The research ethics evolution: From Nuremberg to Helsinki. South African Medical Journal, 104(3), 178–180. https://doi.org/10.7196/SAMJ.7864

Emanuel, E. J. (2000). What Makes Clinical Research Ethical? Jama, 283(20), 2701. https://doi.org/10.1001/ jama.283.20.2701

Emanuel, E. J., & Menikoff, J. (2011). Reforming the Regulations Governing Research with Human Subjects. New England Journal of Medicine, 365(12), 1145–1150. https://doi.org/10.1056/NEJMsb1106942

Ferreria, R., Buttell, F., & Ferreria, S. (2015). Ethical Considerations for Conducting Disaster Research with Vulnerable Populations. Journal of Social Work Values and Ethics, 3, 379–384.

Ferris, E. (2012). Future directions in civil military responses to natural disasters (ACMC Paper 5/2012). https://www. brookings.edu/wp-content/uploads/2016/06/05-civ-mil-disasters-ferris.pdf

Ford, N., Mills, E., Zachariah, R., & Upshur, R. (2009). Ethics of conducting research in conflict settings. Conflict and Health, 3(1), 7. http://www.conflictandhealth.com/ content/3/1/7

Fraser, V., Hunt, M. R., Schwartz, L., & Laat, S. De. (2014). Humanitarian Health Ethics Analysis Tool (HHEAT) Handbook (Issue July). https://doi/ISBN: 978-0-9938354-0-7

Giacomini, M., Kenny, N., & DeJean, D. (2009). Ethics frameworks in Canadian health policies: Foundation, scaffolding, or window dressing? Health Policy, 89(1), 58–71. https://doi.org/10.1016/j.healthpol.2008.04.010

Giarratano, G., Savage, J., Barcelona-deMendoza, V., & Harville, E. W. (2014). Disaster research: A nursing opportunity. Nursing Inquiry, 21(3), 259–268. https://doi.org/10.1111/nin.12049

Goodhand, J. (2000). Research in conflict zones: ethics and accountability. Forced Migr Rev, 8, 12–15.

Hofmann, C.-A., & Hudson, L. (2009). Military Responses to Natural Disasters: Last Resort or Inevitable Trend? Humanitarian Exchange, 44(44), 29–31. http://odihpn.org/wp-content/uploads/2009/10/humanitarianexchange044.pdf

Hunt, M. R., Schwartz, L., Sinding, C., & Elit, L. (2014). The ethics of engaged presence: a framework for health professionals in humanitarian assistance and development work. Developing World Bioethics, 14(1), 47–55.

Hussein, G. (2015a). 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. In W. H. Organization (Ed.), Ethics in epidemics, emergencies and disasters: research, surveillance and patient care\r (pp. 32–42). World Health Organization (WHO). http://apps.who.int/bookorders/anglais/dartprt1.jsp?codlan=1&codcol=93&codcch=331

Hussein, G. (2015b). 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. In W. H. Organization (Ed.), Ethics in epidemics, emergencies and disasters: research, surveillance and patient care (pp. 32–42). World Health Organization (WHO). http://apps.who.int/bookorders/anglais/dartprt1.jsp?codlan=1&codcol=93&codcch=331

Hyder, A. A., Harrison, R. A., Kass, N., & Maman, S. (2007). A case study of research ethics capacity development in Africa. Academic Medicine, 82(7), 675–683. https://doi.org/10.1097/ACM.0b013e3180674484

Karunakara, U. (2013). Data Sharing in a Humanitarian Organization: The Experience of Médecins Sans Frontières (Vol. 10, Issue 12, p. e1001562 PLoS Medicine-e1001562 PLoS Medicine). Public Library of Science. https://doi.org/10.1371/journal.pmed.1001562

Kilpatrick, D. G. (2004). The ethics of disaster research: A special section. Journal of Traumatic Stress, 17(5), 361–362. https://doi.org/10.1023/B:JOTS.0000048961.75301.74

Kinlaw, K., Barrett, D. H., & Levine, R. J. (2009). Ethical guidelines in pandemic influenza: recommendations of the Ethics Subcommittee of the Advisory Committee of the Director, Centers for Disease Control and Prevention. Disaster Med Public Health Prep, 3(Suppl 2), 185–192. https://doi.org/10.1097/DMP.0b013e3181ac194f

Marshall, M. F. (2002). Born in Scandal: The Evolution of Clinical Research Ethics.

Motari, M., Ota, M., & Kirigia, J. (2015). Readiness of ethics review systems for a changing public health landscape in the WHO African Region. BMC Medical Ethics, 16(1), 82. http://www.biomedcentral.com/1472-6939/16/82

MSF Ethics Review Board. (2013). MSF Ethics Review Board Standard Operating Procedures. http://hdl.handle.net/10144/294968

Novitzky, P., Smeaton, A. F., Chen, C., Irving, K., Jacquemard, T., O'Brolcháin, F., O'Mathúna, D., & Gordijn, B.

(2015). A Review of Contemporary Work on the Ethics of Ambient Assisted Living Technologies for People with Dementia. In Science and Engineering Ethics (Vol. 21, Issue 3, pp. 707–765). Kluwer Academic Publishers. https://doi.org/10.1007/s11948-014-9552-x

O'Mathúna, D. P., DP, O., O'Mathuna, D. P., O'Mathúna, D. P., O'Mathuna, D. P., DP, O., & O'Mathúna, D. P. (2010). Conducting research in the aftermath of disasters: ethical considerations. Journal Of Evidence-Based Medicine, 3(2), 65. https://doi.org/10.1111/j.1756-5391.2010.01076.x

Organization, W. H. (2014). Ethical Considerations for Use of Unregistered Interventions for Ebola Virus Disease: Summary of the Panel Discussion, 12 August 2014. Geneva, Switzerland.

Petrini, C. (2010). "Broad" consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. Social Science and Medicine, 70(2), 217–220. https://doi.org/10.1016/j.socscimed.2009.10.004

Rwabihama, J. P., Girre, C., & Duguet, A. M. (2010). Ethics committees for biomedical research in some African emerging countries: which establishment for which independence? A comparison with the USA and Canada. J Med Ethics, 36(4), 243–249. http://jme.bmj.com/content/36/4/243.full.pdf

Sheather, J., & Shah, T. (2011). Ethical dilemmas in medical humanitarian practice: cases for reflection from Médecins Sans Frontières (Vol. 37, Issue 3, pp. 162–165). https://doi.org/10.1136/jme.2010.038448

Sphere Project. (2011). The Sphere Handbook: Humanitarian Charter and Minimum Standards in Humanitarian Response. The Sphere Project, at http://www.sphereproject.org/handbook. https://doi.org/10.3362/9781908176202

The National Commission for the Protection of Human Subjects. (1979). The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research: Vol. null (null, Ed.; Null). U.S. Government Printing Office. https://doi.org/10.1002/9780471462422.eoct093

United Nations Inter-Agency Standing Committee (IASC). (2010). Workshop for Humanitarian Coordinators: International Humanitarian Norms & Principles Guidance Materials.

Winkleby, M. A., & Cubbin, C. (2003). Influence of individual and neighbourhood socioeconomic status on mortality among black, Mexican-American, and white women and men in the United States. Journal of Epidemiology and Community Health, 57(6), 444–452. https://doi.org/10.1136/jech.57.6.444

Wood, E. J. (2006). The ethical challenges of field research in conflict zones. Qualitative Sociology, 29(3), 373–386.

World Health Organization, Organization, W. H., & Organization, W. H. (2015). Ethics in epidemics, emergencies and disasters: research, surveillance and patient care (p. 276). World Health Organization (WHO). http://apps.who.int/bookorders/anglais/dartprt1.jsp?codlan=1&codcol=93&codcch=331