

R2HC ETHICS FRAMEWORK 2.0

1. INTRODUCTION

Funded by the UK Government (DFID) and the Wellcome Trust, Elrha's R2HC programme aims to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises.

This tool¹ has been developed to guide public health researchers interested in applying to the R2HC programme for research funding. It is also available as a resource for other researchers working in humanitarian crisis contexts.

A DEFINITIONAL NOTE ON ETHICS:

Ethics in the context of this framework refers to reflection and deliberation that addresses questions about right action, moral behaviour and virtuous character. Research ethics has often focused on questions of governance, including ethical approval, informed consent, etc. Recent developments in research integrity highlight the importance of addressing the broader array of ethical issues that arise during all phases of research, including during research design, implementation and dissemination. This framework assumes such a broad understanding of ethics.

2. HUMANITARIAN CONTEXTS

A humanitarian crisis can be defined as any situation in which there is a widespread threat to life, physical safety, health or basic subsistence that is beyond the coping capacity of individuals and the communities in which they reside. Humanitarian crises can be caused by different factors, including natural (such as earthquakes, hurricanes, etc.), or technological disasters (such as industrial accidents, airplane crashes, etc.), famine, epidemics and armed conflict. They can be short-lasting or protracted in duration, and some are a complex mixture of different factors. Regardless of the name or cause(s), more reliable evidence is needed to help guide those responding to, or attempting to prevent, such events and their aftermath².

¹ Suggested citation: Chesmal Siriwardhana, Sapfo Lignou, Shannon Doherty and Dónal O'Mathúna. 2017. R2HC Ethics Framework 2.0.

² For more information

<http://www.alnap.org/resource/10441>

While the focus of R2HC funding is on public health research in the acute phase of humanitarian responses, this Ethics Framework may be of use to a broader range of humanitarian health research projects that arise beyond the acute phase and even to humanitarian practice in the absence of specific ethics guidance provided by other bodies. Various types of health research projects can be conducted to generate evidence and further understanding in humanitarian crises, and each raises particular ethical issues.

The particular context of a humanitarian crisis may exacerbate some ethical considerations compared to other contexts. Such considerations include the urgency (or otherwise) of initiating research soon after an acute crisis, potential dangers and insecurity in the location, lack of resources, infrastructure or local ethics review mechanisms, challenges with access, and interpersonal complexities as people come together with different cultures, languages, educational backgrounds, and ethical priorities. Humanitarian crises require that these and other ethical issues be considered carefully and discussed widely so that research undertaken serves and supports those impacted by the event. This is particularly important since the context creates a complex combination of vulnerabilities which must be central to ethical reflection. These are considered in the next section.

3. VULNERABILITY

Those impacted by humanitarian crises are often exposed to high levels of vulnerability in terms of people being at greater risk of harm. Research with vulnerable participants often raises particular questions about their protection. For example, concerns are raised that people may be re-traumatised by participating in research in humanitarian crises, especially using qualitative methods that ask people to discuss traumatic experiences and research on sensitive and taboo subjects. Other ethical concerns are raised about participants' understanding of research methods, language differences, coercion due to historico-political narratives, or whether they are vulnerable to misconceptions about the true nature of the research (i.e. whether the intention is to provide direct benefits or generalised knowledge for future similar scenarios).

On the other hand, vulnerability has been questioned as a poorly defined concept that can be applied to almost everyone, and may promote paternalistic attitudes towards participants as powerless victims to be protected by those with resources. If vulnerability leads to generalised categorisations of people, it provides little ethical guidance.

This brief introduction cannot adequately summarise this debate. Regardless of how it is defined, the concept of vulnerability is an important reminder of the ethical responsibilities of those conducting humanitarian research towards participants, especially those who have suffered serious losses and are often disempowered. Every research project should carefully identify the vulnerabilities likely to exist in their research context and delineate how these will be addressed in their research design and implementation.

In many situations, different ethical responsibilities will need to be balanced against one another. These include remembering people's fragility during and after crises, yet also their remarkable resilience and desire to tell their stories; the importance of protecting people from harm, but also remembering that some people are willing to accept the risks involved in research; the complexity and subtlety of various power issues; and the potent psychosocial influences on voluntary consent that can lead to subtle forms of coercion.

These highlight the importance of approaching participants with humility and respect so that researchers take due account of vulnerability and contribute to ameliorating it, not reinforcing it. Vulnerability can arise from many sources, and should be carefully considered at all stages of research. Vulnerability can also vary considerably between individuals, groups, and cultures. Therefore, research should incorporate methods of assessing and responding to participants' vulnerability. For example, participatory action research allows participants a greater role in all phases of the research, yet in doing so this raises additional ethical issues that must be carefully considered.

4. WHAT TYPES OF RESEARCH PROJECTS SHOULD USE THIS TOOL? ---

This framework uses the term 'research' even though this term can be defined in various ways. Debates often arise regarding what sorts of research or projects require ethical approval from research ethics committees (RECs) or institutional review boards (IRBs). Regulatory and legal frameworks vary in different jurisdictions and apply differently to various types of research. This ethics framework does not attempt to resolve such debates, or focus on one particular definition of research. While the term 'research' is used here, other evidence-generation and data collection activities may raise similar ethical issues that deserve careful reflection.

The most important question is not whether IRB or REC approval is required. Rather, the principal question is how the planned research can be conducted ethically in ways that promote respect for individuals and their communities, and at the same time provide answers or evidence to address an important question.

R2HC addresses public health research in humanitarian crises, and this is the principal focus of this ethics framework. The primary users of the Framework are foreseen to be applicants to Elrha's R2HC programme, and the technical experts and Funding Committee members tasked with reviewing those proposals. At the same time, this guidance should have wider relevance for multi-disciplinary humanitarian research and may have some potential for humanitarian practice. This is especially the case if such ethical guidance is not available from other bodies.

For example, R2HC funded researchers can share this tool with RECs that are not familiar with the specific ethical challenges related to conducting public health research in humanitarian contexts. Exactly how the ethical issues will be addressed and responded to will vary with the research, its participants and its methods.

Whether researchers are conducting clinical trials, qualitative research interviews, audits of healthcare experiences, public health surveillance, or evaluations of humanitarian interventions, the research should be designed, conducted and reported ethically.

This tool aims to help identify and stimulate reflection on the most relevant ethical issues and hence lead to optimal ways to address them. Only then can the research promote trust and integrity among all involved as it aims to provide reliable evidence to address important humanitarian questions.

5. HOW TO USE THIS TOOL

This ethics framework builds on the earlier R2HC Ethical Framework and was developed after review of recent literature, analysis of other research ethics guidance, and consultation with various stakeholders. A report detailing its development along with a bibliography is available at the R2HC website. Rather than being prescriptive, this tool is intended to be used deliberately and reflectively by all those involved with a particular piece of research.

Different types of methodologies, participants, organisations and local contexts will require different ethical approval processes that use different forms and procedures. This framework provides sets of questions intended to stimulate reflection and discussion about ethical issues that arise within health research in humanitarian crises. For this reason, the questions are intentionally general and not specific to particular research contexts. Reflection should be promoted by and among all those involved in the design, implementation and dissemination of the research, and wherever possible with participants and their communities. Different people will see different ethical issues in the same piece of research and therefore broad consultation is best.

The tool is based on the assumption that ethical issues arise at every stage of research. Ethical discussions should not be left until the research is ready to start and ethical approval sought. Many steps within the design of a research project have scientific, pragmatic, political, economic and ethical components. Ethical issues influence many decisions; for example, whether to include one group as participants and not others, whether to ask certain types of questions and not others, or whether to spend limited funds on one thing and not another. These questions are not intended to rule out any particular type of research in any particular context, but to help researchers and others identify the relevant ethical issues that need to be identified, balanced and justified to all stakeholders.

The tool is divided into three sections. Certain ethical issues are more relevant as research is being designed, others as it is being implemented, and others after data has been collected and the findings are being disseminated. Within each section, the questions are organised around a number of areas widely considered to raise ethical issues in research. The steps are not organised around a hierarchy of ethical issues, but reflect a general set of steps involved in most research at different stages of development.

The community in which research is conducted should be actively consulted with and listened to at all stages. For example, the research should be of relevance and importance to the community, and not conducted only out of convenience for organisational or academic purposes. This is especially the case in humanitarian crises where many other activities call for funding, attention and time. Local representatives are essential to ensure, for example, that all relevant benefits and harms from the research have been identified, or that information on the research is presented in ways appropriate to the local, cultural context. Researchers also need to ensure that they engage with and listen to perspectives from multiple community stakeholders, especially those who may be marginalised or disenfranchised within the communities where the research will be conducted.