



Research for health
in humanitarian crises

| **elrha**

Research Ethics Tool

This tool is designed to stimulate reflection and discussion about ethical issues that could arise in research during humanitarian crises. The tool could be used at research team meetings, by sub-groups, or in discussions with stakeholders.

The questions are organised around the design, implementation, dissemination, and post-research evaluation of the project. The questions are intentionally general, and each will not apply to every project. The specific methods and context of the research will need to be reflected upon when using the tool. Community perspectives and concerns, as well as cultural context and norms, should be considered in all categories, not just those explicitly mentioned.

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: www.alnap.org/resource/10441, www.elrha.org/wp-content/uploads/2015/01/Evidence-Review-22.10.15.pdf

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.

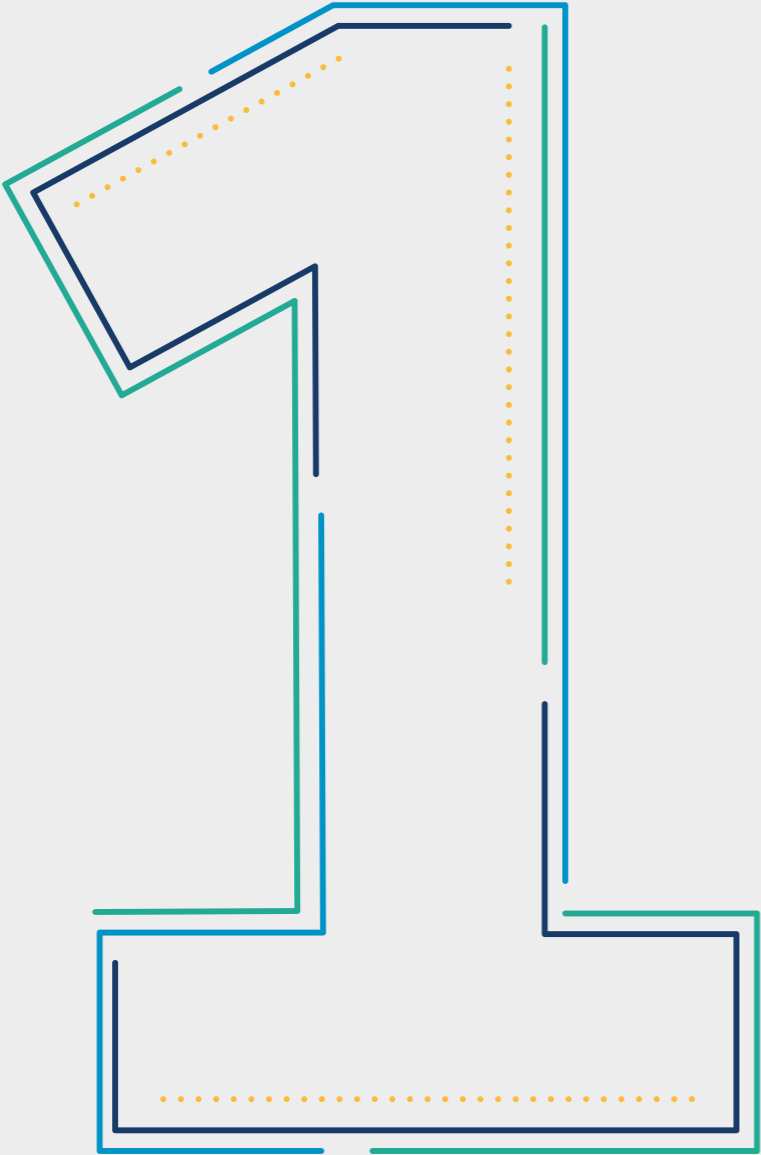
Different types of methodologies, participants, organisations and local contexts will require different ethical approval processes that use different forms and procedures. This framework provides sets of questions intended to stimulate reflection and discussion about ethical issues that arise within 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.

ETHICS REFLECTION QUESTIONS AS THE RESEARCH IS DEVELOPED



WHY?

- Why are you doing this research?
- What is the question you are trying to address?
- What evidence are you seeking?
- Why does this research need to be done in a humanitarian crisis and not in a non-crisis context?
- How was the local community, including relevant subgroups, consulted to determine their interest in engaging with this research?

HOW?

- What methodology best addresses the question in your research?
- What ethical issues does your methodology raise in the context of your research?
- How has the feasibility of the proposed research been evaluated for your setting?
- Might any part of the research be perceived as coercive by the participants or their community, and how will this be addressed?
- What competencies are required by all those involved in different phases of the research?
- What partnerships or collaborations are needed for the research?
- Have various types of resources been secured for all stages of the research and do any of these raise challenges for the local community?

BENEFITS

- What are the scientific/evidence generation benefits from doing this research?
- What are the key benefits that will realistically derive from this research for participants and their community?
- Are there any benefits in regards to people's rights or legal protections from this research?
- What benefits beyond the physical might arise from this research, such as emotional, psychosocial, spiritual or other benefits?

BENEFITS *(continued)*

- Are there different benefits for individual participants compared to their communities?
- What benefits may arise immediately compared to those potentially arising in the future?
- What are the benefits for individuals or organisations conducting this research?
- How will the benefits of this research be shared with participants and their communities?

RISKS

- What are all the risks that participants are likely to be exposed to?
- Have the physical, environmental, emotional, psychosocial, spiritual and other holistic risks been considered?
- Are anyone's rights being put at risk through this research?
- How will the views on this issue of participants and their communities be determined?
- Are there different risks for individuals or various sub-groups compared to larger communities?
- How do issues of vulnerability impact on the potential risks?
- What sub-groups are particularly vulnerable in the context of this research and what mitigation strategies are in place?

RISKS *(continued)*

- What are the short-term and the long-term risks?
- What safeguards, referral mechanisms, security factors, exit strategies and other mitigation factors need to be introduced? e.g. for you, your research team or participants in a deteriorating local situation.
- What steps have been taken to explore differences in the risks identified by participants compared to researchers?
- What are the risks for researchers or organisations conducting this research?
- Are there risks attached to sourcing or availability of any required resources?

BALANCING BENEFITS AGAINST RISKS

- How will the various risks and benefits be balanced against one another?
- How have local priorities been considered and do they differ from those of the researchers?
- How will any differences be reconciled?
- How will risks or benefits to one sub-group be balanced against risks or benefits to another sub-group?

CONFIDENTIALITY, PRIVACY, DATA PROTECTION

- How will risks to confidentiality or privacy be identified? By whom?
- How will confidentiality and privacy be protected at each stage of the research?
- Will participants be expected to maintain confidentiality towards other participants?
- How will this be addressed if they can identify one another?
- Different strategies may be needed at different phases, e.g. during data collection in the midst of a crisis versus later during data analysis.

CONFIDENTIALITY, PRIVACY, DATA PROTECTION *(continued)*

- Will any situations arise where confidentiality may be violated?
- What legal basis might lead to this?
- How will this be justified and communicated to all involved?
- How will data, samples, images, etc. be collected, stored, distributed and protected?
- How will the identities of individuals, communities, sub-groups, organisations, regions, etc. be protected?
- Could alternative sampling strategies provide better protection of data, privacy or confidentiality?

INFORMED CONSENT

- How will informed consent be protected?
- How will participant information be developed and checked for understanding?
e.g. How will translation be undertaken to ensure consent is truly informed?
- Will oral, written or presumed procedures be used? Why?
- Will individual, group, or proxy strategies be accepted?
- How will gatekeepers be involved, if at all?
- Will consent be taken once or on a number of occasions, and why is this approach being taken?

WHAT APPROVALS SHOULD BE OBTAINED?

- Research ethics committee?
- Own institution or organisation?
- Regulatory body?
- Government agency or Ministry of Health?
- Local community leaders? Others?



ETHICS REFLECTION
QUESTIONS AS
THE RESEARCH
IS CONDUCTED



FIELDWORK

- How will unanticipated ethical issues be identified and addressed during the research?
- If human rights violations are identified in the research, how will this be addressed?
- Will researchers be assumed to take the role of advocate or neutral observer?
- How will ethical issues arising during participant recruitment or retention be identified and responded to?
- How will protocol changes and deviations be determined and approved to mitigate any ethical problems or concerns?
- How will ethical concerns and conflicts be managed during the research (for example, within the team or with stakeholders, with the community, over withdrawal of consent or ethical approvals, etc)?
- How will ethical problems within partnerships or collaborations be addressed?

ENGAGEMENT

- How will safety concerns be monitored during the research?
- How will all stakeholders be engaged with to identify safety concerns?
- Who will have responsibility to introduce new safeguards if required?
- How will ethical issues regarding exit strategies after the research be monitored and addressed?



ETHICS REFLECTION QUESTIONS AFTER THE RESEARCH IS COMPLETED



DISSEMINATION

- How will gratitude be expressed to participants and their community for their contribution to the research?
- How will feedback be provided to participants and their community about the research and its findings?
- How will feedback be obtained from participants and their community about how the research was conducted and disseminated?
- Will all findings be disseminated in open access outlets?
If not, why is this justified?
- Who are the people who will have access to data after the research is completed?
- How will the research findings lead to change in practice, policy or participants' lives?
- What steps will be taken to ensure the research findings are used to enact change? For example, having researchers act as a voice for participants, or exerting influence with other stakeholders.

SUSTAINABILITY

- How will the research and its findings help build and sustain specific local capacities?
- Do all stakeholders and local communities continue to express buy-in to the research and its aims? If not, how will the reasons for this be determined and responded to?
- Has funding been arranged so that benefits identified in the research will be continued after the research ends?
- How well have the partnerships and collaborations worked together?
- What ethical strengths and weaknesses exist within these partnerships?

POST-RESEARCH ETHICS AND PROJECT REFLECTION

- What is the plan for post-research evaluation of its design, methods and implementation?
- What is the plan to evaluate how well ethical issues were identified and addressed during the research, with special attention given to any unanticipated ethical issues that arose?
- What is the plan to evaluate the research's actual impact, short-term and long-term?

Acknowledgements

Chesmal Siriwardhana, Sapfo Lignou,
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1. 2017. Research Ethics Tool.

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Available at: elrha.org/r2hc

Do you have feedback on the tool? Contact us: r2hc@elrha.org

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 r2hc@elrha.org

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