Review and revision of the Research for Humanitarian Crises (R2HC) Ethics Framework

Final Report

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Executive summary

In late 2016, Elrha commissioned a review, revision and update of the R2HC Ethical Framework by Curry, Waldman and Caplan. The revision and update consisted of: a desk-based review of the existing framework and feedback on its use, a literature review, an online survey and a stakeholder consultation. Based on cumulative findings from this work, a revised and updated framework is proposed here. This new framework was developed to provide: a) ethical guidance specifically for humanitarian health research, but with wider relevance for other humanitarian research and potentially even humanitarian practice; b) a tool which encourages reflection, inductive and deliberative thinking and proactive response to ethical issues that arise in developing protocols, reviewing proposals and conducting humanitarian health research; c) interconnected, overlapping and repeated opportunities for reflection on ethical challenges based on an assumption that these reflections are guided by context-specific factors; d) a tool which has been developed through a firm grounding of the belief that reflection on ethical issues should be done throughout research projects, including before, during and after the research; e) a user-friendly, stand-alone tool, easily detachable from other accompanying literature. The new version of the R2HC Ethics Framework is graphically presented as a series of 'steps' without any hierarchical relationships. An explanatory section precedes the graphical framework to act as guidance for its usage and formative structure.

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1. Background

1.1. Research for Health in Humanitarian Crises (R2HC)

The R2HC programme, established in 2013, is a strategic partnership between the UK Department for International Development (DFID), the Wellcome Trust and Elrha which aims to improve health outcomes in humanitarian crises by strengthening the evidence base for public health interventions. Funded by DFID and the Wellcome Trust, the programme is executed and managed by Elrha. The R2HC programme has already funded over 35 projects worth over 7 million UK pounds.

1.2. R2HC Ethical Framework and project commission

In 2013, Elrha commissioned a group of ethicists to develop an Ethical Review Framework and Guidelines, to guide research proposal development and review under the R2HC programme. The Ethical Framework was developed after a review of the research ethics landscape relevant to public health research in disaster situations and humanitarian practice, conducted by the framework's authors. Since its publication in 2014, the R2HC Ethical Framework (1) has been available for use by R2HC grant applicants through three rounds of Calls for Proposals between 2014 and 2016. All applicants have been encouraged to use the Framework at proposal development stage and, if funded, for other stages of their research projects. The Framework is also available for use by the R2HC Funding Committee to support the proposal review process, and is intended as a tool for use by Research Ethics Committees (RECs).

In the second half of 2016, Elrha commissioned a review to explore the extent to which the Ethical Framework has been utilised by researchers since its release and the degree to which they believe it addresses their needs for ethics guidance in humanitarian health research. The main anticipated output of the review was a refined and updated Framework to better meet the needs of the research community.

After a successful bid, the revision and review of the existing Framework was awarded to our team. In line with the Terms of Reference (ToR) outlined by Elrha, our work aimed to review and revise the current Framework by exploring: the extent to which the R2HC Ethical Framework has been utilised (or not utilised) by stakeholders under the R2HC programme (i.e. R2HC applicants, Funding Committee members and Ethics Review Boards); the degree to which it addresses the stakeholders' needs for ethics guidance in humanitarian contexts at the stage of ethics approval; the recommendations that could be made for its improvement; and to provide an updated and consolidated version of the Framework. The project work has been fully guided by the ToR and was carried out between October 2016 and March 2017.

2. Methodology

The methodological approach to the project was fully guided by the ToR. Accordingly, the methodology consisted of:

1. A desk-based review of the existing Ethical Framework guided by previous feedback from donors and selected Funding Committee members from the Framework's initial publication in 2014, and a review of relevant literature produced since then.
2. A survey and key informant interviews (KIIs) to solicit feedback from the humanitarian health research and practitioner communities that constitute R2HC stakeholders.
3. An update of the Ethical Framework and selected R2HC proposal application templates to reflect stakeholder feedback on addressing ethical considerations in humanitarian contexts.

2.1. Activities

Activities carried out by the team are described under the three main areas of methodological approach.

2.1.1. Desk-based review

We conducted a comprehensive literature review in order to identify ethical considerations of crucial importance in relation to the ethics of research conducted in the course of humanitarian settings. This review mainly aimed to update the literature included in the previous version of the R2HC Ethical Framework published in January 2014. It was carefully designed to address some of the methodological gaps in the previous version, identified through a review of the Framework itself. Further, as discussions on this topic are influenced by the knowledge and experience of those involved in the various types of health research in humanitarian and emergency settings, we included frameworks and documents available from a variety of stakeholders involved in humanitarian research.

Our principal rationale for inclusion of literature was based on the following criteria:

a) Documents which structure their discussion of ethical principles and themes in a way that supports the revision process and the conceptualization of the revised Framework;
b) Articles where the term "ethical" or "moral" was not mentioned in their title but which discussed or mentioned ethical issues linked to humanitarian health research and practice in the main text were included.
c) Literature on non-health related humanitarian research was excluded.

We followed a modified systematic review methodology to find relevant literature. Our searches used the following keywords: "health research", "trauma", "humanitarian settings", "emergency", "ethics", "justice", "vulnerability", "vulnerable populations", "international aid work", "international humanitarian law", and "public health emergency response". The following databases and sources were searched: MEDLINE, Google Scholar, PubMed, Google, citation tracking, and relevant peer-reviewed journals such as *Bioethics, Developing World Bioethics,* and *Conflict & Health*. The search was limited to literature published between 2014 and 2016, as the primary purpose was to update the 2014 R2HC Ethical Framework.

In addition, as part of the desk-based review, we reviewed the existing Framework and incorporated feedback on the existing version received from the R2HC donors and the funding committee.

2.1.2. Stakeholder surveys and key informant interviews

We conducted an online survey (using Bristol Survey) to obtain input from key R2HC stakeholders about the existing R2HC Ethical Framework. Survey questions were based on the utilisation (or non-utilisation) of the existing R2HC Ethical Framework, and on challenges and processes in securing ethics approval (See appendix A). The survey consisted of a general information section and specific sections for R2HC applicants, Funding Committee members, and members of REC (See appendix B). We obtained ethics approval for the survey component from the Faculty Research Ethics Panel of the Faculty of Medical Science, Anglia Ruskin University (#SC/jc/FMSFREP/16/17 012).

The survey was sent to a total of 97 respondents including 51 shortlisted R2HC applicants, 34 current R2HC grant holders, and 12 funding committee members. It was open for a period of 45 days. Only fully anonymised data was collected. These data were stored securely and are only accessible to the research team and authorised individuals. Consent for the online survey was recorded through a section on the survey prior to actual survey questions. The survey was designed to be fully anonymous, but at the end of the survey participants were asked if they wished to participate in an interview. Those willing to participate were asked to provide their email address to allow contact about the interviews. The initial approach and circulation of the online questionnaire was through the commissioning agency (Elrha) and therefore both the funding agency and the research team adhered fully to relevant confidentiality and data protection laws. The overall response to the online survey was low (9%). We believe that adequate time was allocated for potential participants to respond.

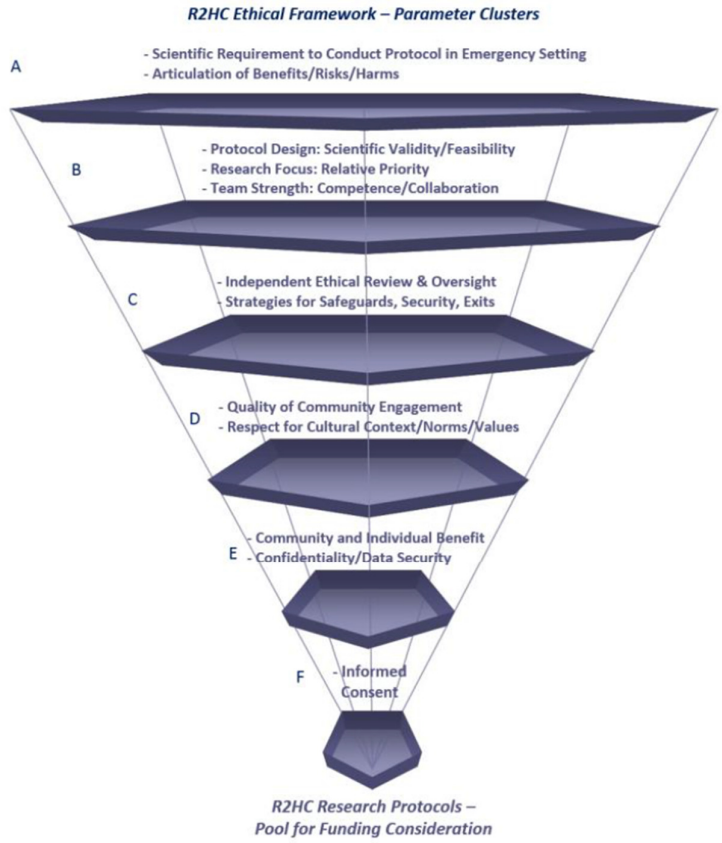
2.1.3. Revision and updating of the Ethical Framework and templates

The revision, updating, and formulation of the new Ethics Framework was guided by the findings from the desk-based review of literature, the online survey conducted among key stakeholders groups, and the previous Framework. We also contacted representatives from the Wellcome Trust and DFID for their feedback on the existing Framework. In addition, our collective experiences as bioethicists and humanitarian researchers have contributed significantly to the review process. A draft version of the new Framework was circulated to representatives from Elrha, Wellcome Trust and DFID and to a number of individual bioethicists and humanitarian health researchers for their review (See Appendix C for the full list). Their feedback was incorporated during the final revision of the Framework. At this point it was decided to call the new document an Ethics Framework, rather than the original Ethical Framework.

3. Existing version of the R2HC Ethical Framework (2014) – a critical evaluation

The current version of the 2014 R2HC Ethical Framework, developed by Curry, Waldman and Caplan (1), is built around six 'Parameter Clusters – relevant ethical principles 'grouped' and 'ordered' in the graphical shape of an inverted pyramid' (see below). The authors sought to provide a structure to the Framework, recognising that such a framework should have a mnemonic utility in its presentation (1). The graphical presentation is representative of the authors' attempt to provide a visually coherent explanation of how the parameter clusters are interlinked and work in practice (1).

Figure 1 - The 2014 R2HC Ethical Framework (reproduced)



They note that their *"….solution evolved to a graphic form which might suggest a "winnowing" of some theoretical group to protocols which might be under consideration for a given humanitarian crisis, or by a specific IRB/REB"* (1, p.22).

They further note that *"the winnowing would occur through application of the ethical clusters and the "knock-out" of protocols at the various stages, yielding an ethically viable group of protocols. This led to sketches of pyramidal forms to suggest that winnowing phenomenon and which might also accommodate the six steps or thresholds associated with the ethical clusters. In the end, we applied the ethical clusters to an inverted pyramidal form and began to use it to present our thinking as expert interviews and meetings continued…"* (1, p.22).

Together with the graphical presentation of the Framework, a set of relevant questions for each parameter cluster was provided with the expectation that they be used by researchers and reviewers (1). Each set of questions is then further discussed by the authors, highlighting their assertions and rationale for why parameter clusters/questions considered are important (1). The 2014 version of the R2HC Ethical Framework was promoted by Elrha to potential R2HC grant applicants from the 2nd Call onwards as a necessary and useful document when thinking about latent ethical challenges in their proposed work (1). It was also promoted among funding committee members as a useful tool when reviewing funding applications.

3.1. Strengths and weaknesses of the existing Framework

We believe that the existing Framework has a number of strengths, and should be especially lauded for attempting to recognize the highly complex nature of ethical challenges in humanitarian research. As part of the formative work, the authors developed highly useful conceptualizations of: a) what represents the range of humanitarian health interventions (Figure 2), and b) what can be considered as 'research' in humanitarian settings (Figure 3) (1). We think that this early formative work has helped draw attention to these and other challenging topics, which are in turn relevant to the 'ethics of humanitarian health practice and research'.

Figure 2 – Health interventions in humanitarian crises (reproduced from (1))

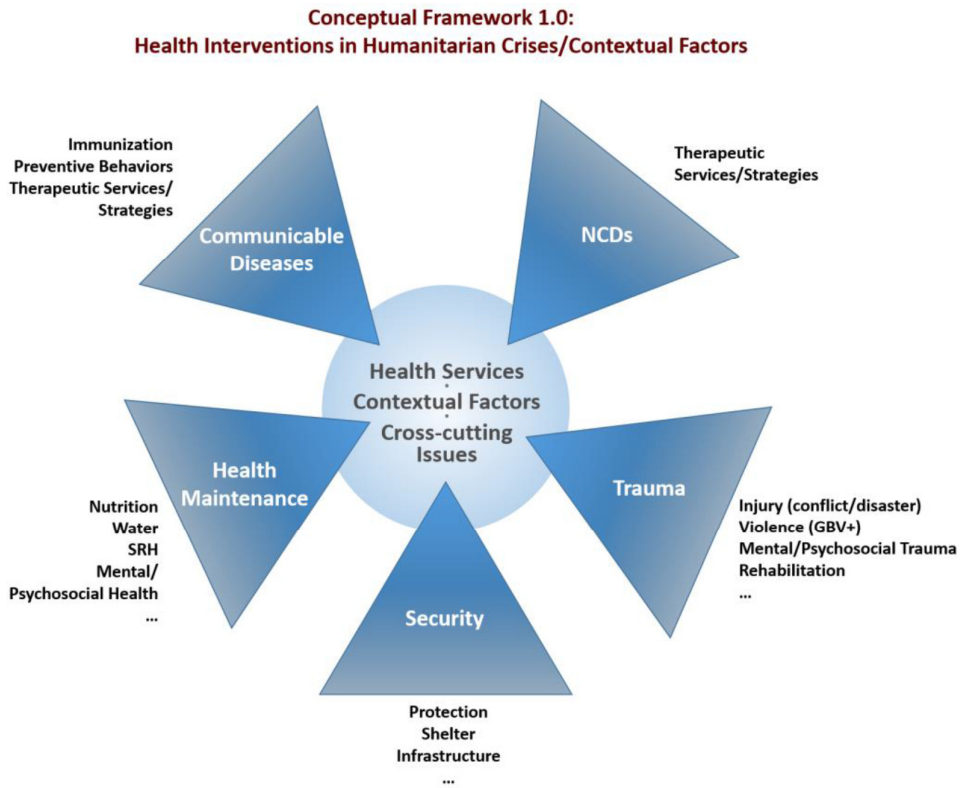
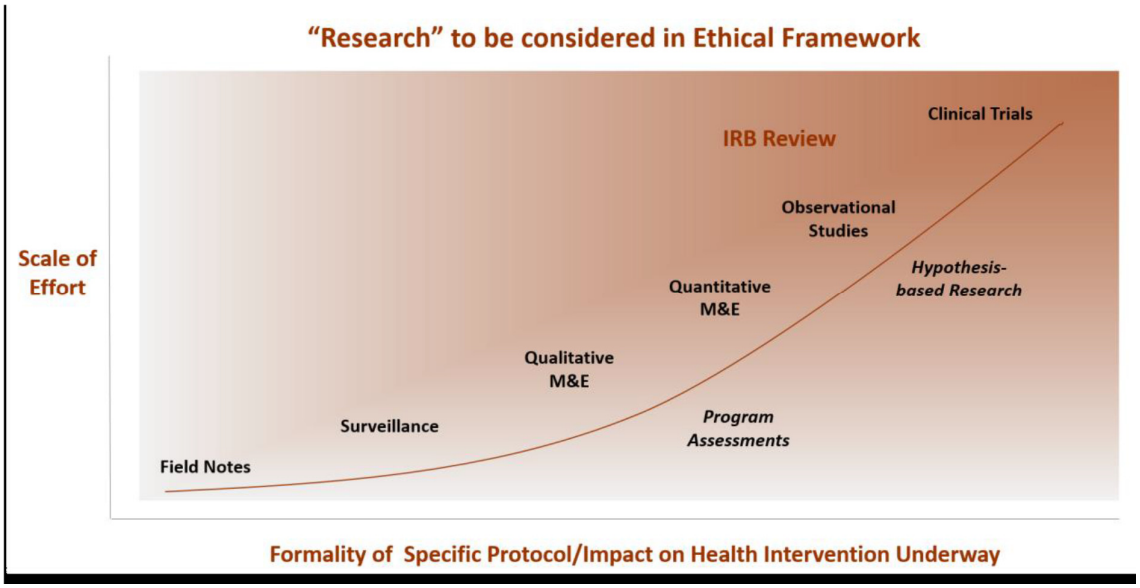


Figure 3 – "Research" in humanitarian settings (reproduced from (1))



In addition, the authors provided detailed and in-depth discussions of important ethical questions in each parameter cluster, providing a way to stimulate discussion among the users of the Framework (1). The formative literature review is also useful as a baseline supportive platform to understand the various developmental stages of conceptual thinking, research, and guidance around the ethics of health research in humanitarian settings (1). The authors also produced a separate set of recommendations resulting from their work, to be considered in the overall R2HC programme on ethical issues in humanitarian health research (1).

During our review of the previous Framework, however, we noted several shortcomings that were supported by our literature review, feedback from stakeholders, and our survey. A key shortcoming was that, despite the authors terming the previous Framework as a *"tool - offering a practical and easily implementable approach in which key ethical principles are considered in a clustered, hierarchical order"*, (1, p.3); it was not perceived as an easily comprehensible or implementable 'tool' of practical value to researchers and reviewers. The clustered approach, although useful, is compounded by the hierarchical order. A fundamental confusion is whether the clusters are sequential – if so, the given hierarchical order requires significant re-arrangement (for example, informed consent (cluster F) needs to be considered at the levels of cluster C, D and E, and not only at the end of a sequential hierarchy). The hierarchical order appears to be somewhat arbitrary and not sufficiently supported by the formative work of the authors. The winnowing graphic model chosen to represent the clustered, hierarchical framework led to some confusion. At first glance, the Framework (in its graphical form) could suggest a skewed approach to determining the ethical priorities that require a researcher's focus. Similarly, some members of institutional review boards/RECs could make inappropriate decisions about protocols based on individual interpretations of the Framework (especially in its graphical form).

A gap in the previous framework is also the lack of discussion about, and consideration of, the post-ethical approval phases (i.e. field work and end of study) and related ethical challenges. Humanitarian research, often conducted in unstable, volatile situations with vulnerable populations, requires very careful attention to avoid potential ethical pitfalls during fieldwork and beyond the end of data collection (9). Consideration of ethical issues should not be limited to the pre-approval period, and any framework that seeks to guide researchers/reviewers should also illuminate ethical issues around post-approval and post-research periods. We believe that there should be a distinct focus on all three periods of a project (research or otherwise) – before, during and after.

In our opinion, the formative literature review conducted by the authors of the previous Framework had methodological weaknesses and was not presented in sufficient detail. It appears to have been a series of separate or interconnected literature searches, which are difficult to distinguish, with results not presented systematically. The search terms are not very well linked or complementary and the databases are fairly limited. These deficiencies were clearly apparent when we tried to duplicate the search strategy and were unable to obtain the same articles. We therefore designed our own comprehensive search strategy described earlier. As expected, this yielded a number of relevant publications that were published during the search period of the previous Framework, but were not included in the previous Framework report.

Another point of concern is that the current Framework is too deeply embedded in the final report submitted to Elrha. This limits its practical usefulness in its current format. We believe that the Framework component (graphical and explanatory parts) should be a separate, relatively brief document, easily detachable for quick reference (for example, for field use). In our opinion, the Framework should be in a more user-friendly format (for example, a two-page document of two sections – main framework in graphical form, with an accompanying explanatory, inductive and reflective section using straight-forward questions).

4. Ethical issues in humanitarian health research: a comprehensive literature review

In the following section we highlight key literature identified in our search as illustrating the key ethical issues in humanitarian research. A reference list to only these documents discussed in the report is provided at the end of the report. The full list of all references identified in our literature search is provided in Appendix B, arranged by order of publication year. This section provides a succinct yet comprehensive summary review of the most important ethical issues discussed in the literature. These issues were identified in current research ethics discussions to support the structure of the revised ethical framework. The literature review mainly focused on updating the bibliography of the previous Framework published in January 2014. The ethical issues are categorised into the following groups: appropriateness and rationale for conducting research in humanitarian settings, respecting and protecting research participants/communities, and implementation of research findings, to reflect a logical order of ethical issues to consider before, during, and after the conduct of health research in humanitarian settings. As mentioned earlier, we followed a modified systematic review approach to find relevant material. However, for this report, the findings are not conveyed in the format of a systematic review, as this was not our primary focus. In summary, we identified 100 publications directly related to the topic of our literature search (see Appendix B).

We begin by presenting an annotated summary of documents, which discuss ethical issues that should be considered before the implementation of a study. Then we present ethical challenges that may be met during and after the completion of a study in humanitarian settings. This section also draws attention to ethical considerations not considered in the 2014 Ethical Framework.

4.1. Appropriateness and rationale for conducting research in humanitarian settings

A recent and growing debate in the research ethics literature is whether patients should have the chance to try experimental drugs. Arie (2) explores ethical and practical concerns in conducting research in emergency situations and epidemics. As the author explains, a serious dilemma arises if the drugs work because there could be a sudden clamour for them to be given to millions of people when few doses exist (2). In the adverse situation, if the drugs failed, there could be a huge backlash against the doctors who administered them. Arie (2) states that this leads to an important question: who should take responsibility in such cases? According to Arie, this becomes a difficult question to answer as the United Nations (UN) and international organisations are hamstrung by bureaucracy, are averse to risk taking and drug companies are not willing to take on the legal responsibility, (2). The author concludes that ethical debates in conducting research in emergency situations or epidemics are similar to concerns in neglected tropical diseases research. By referring to the example of plague vaccines, which were developed by testing experimental treatments on victims, she notes that it is in everyone's interests to change our perspective on experimental treatments (2). An additional document focused on appropriateness and rationale when conducting research in humanitarian settings is by Ahmad and colleagues (3). This work reviews the reasons for, and main principles in, evidence-based practice. The authors provide ethical justification for the generation of evidence to guide future disaster responders and give examples of problems that may be raised when such evidence is lacking or not followed (3).

4.1.1. Research question and methodology

Another article discussing ethical concerns related to research questions and methodology focused on randomised controlled trials (RCTs) for Ebola is that of Adebamowo et al. (4). According to the authors, RCTs should not be considered as the only research method to gather reliable information about the safety and effectiveness of potential Ebola therapies (4). They note that innovative but proven trial designs exist which might be more appropriate for identifying drug regimens that more quickly improve outcomes over existing methods of care, and which can be recommended by the World Health Organization (WHO) so that lives can be saved (4). Adebamowo et al. (4) conclude that it is ethically appropriate and more responsible for researchers to use these existing methods, rather than insisting on gold standards that were developed for different settings and purposes. This situation triggered an extensive debate over the best methodology for humanitarian health interventions which is addressed by several articles listed in Appendix B.

4.2. Respecting and protecting research participants/communities

4.2.1. Informed consent

A comprehensive presentation and discussion on different standards regarding the informed consent requirement in health research in humanitarian settings is missing in the previous Framework published in 2014. Speaking to this issue, Annas (5) addresses the question of whether research on the survivors of disasters can be ethically conducted without their consent. Annas (5) draws on a wide range of previous research conducted without consent or with dubious consent, and concludes that consent to research involving risks is an ethical requirement that should not be waived in disaster-related research. He notes that if this makes some research impossible, such research should not be conducted (5). This view however, contradicts claims made a few years earlier on this subject, such as the views by Nieburg (6). Nieburg claimed that what we should be asking in such situations is what kind of consent is necessary and feasible for different types of emergencies, at different stages and for different types of data collection or research. Nieburg (6) also claimed that explicit consent is not necessary in surveillance or outbreak investigations.

4.2.2. Vulnerability

The concept of vulnerability is frequently highlighted in the context of humanitarian research ethics, yet it remains without a widely accepted definition and its practical usefulness is often questioned (7). One paper discussing the issue of vulnerability is that of Ferreira, Buttell and Ferreira (8). They use examples to illustrate how decision-making capacities of participants in disaster research may differ from those in other types of research involving human subjects due to the psychological impact of being subjected to a disaster (8). They note that although there should be adherence to an ethical standard of practice when conducting research after or during disasters, not all of the allied professions can rely on an established code of ethics to guide research with vulnerable populations (8). For this reason, the authors propose the implementation of a universal code of ethics, which could provide a better understanding of populations exposed to disasters and make researchers more aware of ethical

concerns related to their study (8). They recommend that several important factors should always be taken into account when a study involves vulnerable populations. Examples given are: deciding when it is appropriate to begin and end a disaster research study, screening methods for including participants based on their decision-making capacity, vulnerability, respecting cultural norms, and incorporating a professional code of ethics into one's research (8). By taking these factors into account researchers can then ensure that both controversy and stigma are avoided and provide more effective assistance in future disasters.

Another article covering issues related to the protection of research subjects and their communities in health research is O'Mathúna's work (9). The author argues that although research into health interventions used in disasters presents distinctive ethical issues, seven ethical principles developed for clinical research should also apply to disaster research: health research must have value, be scientifically valid, rely on fair subject selection, rely on a harm-benefit ratio, be independently reviewed, fulfil the informed consent requirement and ensure respect for its participants (9). To demonstrate how these ethical principles can be applied, he uses practical examples from disaster settings. He notes that such examples reveal that research ethics needs to be seen as much more than a mechanism to obtain ethical approval for research (9). He adds that research ethics must also consider the role of virtues in research because this can help ensure that researchers do what they believe is ethically right and resist what is unethical (9). To truly protect participants and promote respect, research ethics must include training in ethical virtues to ensure disaster research is carried out to the highest ethical standards.

As ethical challenges in research in humanitarian settings are often raised because of the vulnerability of researched populations, it is important to mention the work by Siriwardhana (10). Motivated by his experience in mental health research among forced migrants, and faced by a lack of guidance on sharing ethical lessons learnt, he explores vulnerability-related issues and developing enhanced protective practices. He suggests a mechanism for reflection that researchers working with vulnerable populations can use based on a concept of post-research ethics audit (10). Based on the author's view, this mechanism could constitute a coherent post-research strategy to critically examine the quality of ethical frameworks, debrief researchers on their experiences, and explore ethical challenges in research implementation, which is currently unavailable (10). Siriwardhana (10) claims the suggested strategy is supported by empirical evidence based on its applicability, adaptability and feasibility and can present a viable way of identifying discrepancies between existing guidance and actual in-field implementation of research. Additionally, the suggested strategy could help identify participant community needs, and ultimately, enhance researcher-driven ethical practices and promote participant involvement.

Discussion of ethics oversight in the previous R2HC Ethics Framework by Curry Waldman and Caplan (1) conveyed a narrow focus on adverse events from medical procedures and did not take into account other kinds of vulnerabilities (e.g. social and psychological) to which those conducting research should respond. To address this problem, we considered it important to include in this summary the article by Asgary and Lawrence (11). This paper offers an insight into the unique experiences, characteristics, and motivations of experienced medical humanitarian workers. According to the authors, this understanding is critical when dealing with the high turnover rates, low retention, high stress levels, and increasingly complex and limited humanitarian space unique to the current humanitarian field. As they

note, despite regular use of the language and ideology of rights, and concepts like solidarity and accountability, tension exists between the philosophy and practical incorporation of accountability into operations (11). They conclude that emphasis on humanitarian principles, and ethical policies and practices, is crucial to improving aid worker retention and organisations' growth, and to create a culture of internal debate, reflection, and reform (11).

4.2.3. Accountability

There is a vast amount of work on humanitarian accountability in the literature. A particularly illustrative example of this wider discourse is Tan and von Schreeb's work (12). The aim of their report is to explore and assess how accountability in the humanitarian context is used and/or defined in the literature. They note that although in the last 12 years, the number of "Quality and Accountability" initiatives and instruments more than tripled, to date there is no single accepted definition of accountability in the humanitarian context (12). In particular, their findings show that the concept of accountability is defined poorly in many humanitarian organisations and that other aspects of accountability, such as its "measurability" and by whom it is measured, similarly lack a common understanding and community-wide consensus (12). Moreover, they state that often discussions concerning humanitarian provider accountability do not refer to the same concepts, which contributes to the semantic and practical complexities of the term. They also note a lack of emphasis on "enforcement/enforceability", and conclude that what is important to explore is the extent to which these vague definitions of accountability may affect the work of various agencies in the field (12).

4.2.4. Research ethics governance

The need for ongoing oversight in disaster research has been raised in many discussions and suggested ethical frameworks. One example is an article by Eckenwiler, Pringle, Boulanger and Hunt (13). Their main argument is that ethical disaster research requires researchers and RECs to have ongoing, critical engagement with disaster affected populations, which may not be warranted in less exceptional research (13). After presenting two cases where they identify concerns that those involved in disaster research may express, they explain how this ongoing engagement might be conceptualised and utilized. They use the concept of real-time responsiveness (RTR), understood as both an ethical ideal and practice, the aim of which is to lessen the potential for research to create, perpetuate, or exacerbate vulnerabilities and contribute to injustices already suffered by the affected populations (13). They explain that in contrast to the ex-post evaluations that humanitarian agencies have historically tended to conduct, their concept aims to promptly improve the effectiveness of an intervention when that intervention is still in process and in an ongoing state of change (13). They then revisit the cases where those ethical challenges were initially identified in the article and explain what RTR might look like in the practices of researchers and RECs (13). They conclude that since even the most rigorous and informed ethical review cannot predict how ethical concerns may evolve in disaster research, RTR could significantly enhance the moral capacities of researchers and REC members (13).

Ethical concerns related to respect and protection of research participants and communities in humanitarian health research governance are also discussed by Schopper (14). This article argues that standard practice in research ethics review ought to be open to challenge and revision irrespective of the actors and the context of the research. The article refers to research conducted by Médecins Sans

Frontières (MSF), although Schopper (14) suggests that MSF's findings can be applied to other studies. She explains that research ethics should not be regarded as a set of rigid, fixed standards irrespective of time and context. Schopper (14) further argues that it is important that current research ethics practice develop an empirical basis, which will permit critical reflection and discussion, instead of the adoption of legalistic rules. Five innovative practices are described in this paper to contextualise the proposal for changes in research ethics governance: a new framework to guide ethics review, the introduction of a policy exempting a posteriori analysis of routinely collected data, the preapproval of "emergency" protocols, general ethical approval of "routine surveys", and evaluating the impact of approved studies (14). Schopper (14) notes that some of the innovations in both the review of proposals and the interaction between the REC and MSF research, may run counter to many standard operating procedures. For instance, Schopper (14) suggests that the ethics review procedure and its stringency should be commensurate with the type of research based on an estimation of the potential harm. Schopper (14) also claims that although the new framework is more engaged with the specific MSF research context, such innovations in research ethics governance may be relevant for research in fragile contexts by other organisations and for RECs reviewing such research. We believe that both these articles on research ethics governance offer useful insight and can stimulate a more vigorous debate in the ethics of health research in humanitarian settings.

4.2.5. Applicability of existing ethical frameworks in humanitarian settings

Chiumento, Khan, Rahman and Firth (15) discuss ethical issues raised before and during the conduct of a health study, and in particular of mental health research. They note the need to establish rigorous ethical research practice to underpin the evidence-base for mental health services conducted in emergencies. They discuss a South Asian mental health case study where key ethical considerations such as voluntary informed consent, community mistrust, ethical review, and risks to the research team and others, are identified and highlight their applicability to post-conflict settings in lower and middle income countries (15). Each challenge is discussed in relation to wider ethical standards of research practice, and the applicability of existing normative frameworks to a post-conflict context is critically assessed. They conclude that a move is required away from rigid implementation of ethical principles and they reflect upon empirical evidence of research practice to stimulate consideration not only of procedural ethics, but also of ethics in practice (15).

An important article focusing on the protection of researched populations before the conduct of research by Mukherji, Ganapati and Rahill (16) examines fieldwork challenges in post-disaster research settings. The authors discuss three separate research projects following natural disasters and identify several unique ethical challenges in this area that are not discussed extensively in current guidelines. They conclude that there are six main aspects that should be considered before research implementation in disaster settings: the critical role of language, logistics concerning transport and living accommodation, methodological matters, the researcher's position in the field (e.g. ethnicity), fieldwork blues, and ethical concerns (16). Finally, they suggest several solutions to these challenges such as understanding the target community prior to embarking on the fieldwork, planning ahead for institutional review approvals, forming research collaborations, and others.

It is generally acknowledged that despite development of high-level principles for humanitarian innovation, there is a lack of guidance for how these principles should be applied in practice. Sheather et al. (17) deals with the protection of researched populations before and during the conduct of research and focuses on the avoidance of research harms. The authors emphasise the need for ethics guidance for innovations specific to humanitarian action, which fall outside the purview of formal research ethics review and intend their framework for nonmedical innovators with little or no knowledge of medical ethics (17). The authors describe an ethics framework developed by MSF for humanitarian innovation to help researchers identify and calculate the harms and the benefits of their work. This framework focuses in particular on the needs of more vulnerable groups—a central moral concern for MSF. As Sheather et al. (17) explain, harm to either individuals or populations can occur during health research, and there also exists the potential for harm to the research staff along with the research process and reputation. For this reason, an ethics framework should aim to be practically oriented, to promote and inform reflection throughout the innovation cycle, and to avoid excessive bureaucratic oversight. In addition, the MSF-developed framework specifies the meanings of each ethical principle in a given decision and how claims arising from different principles should be weighted or adjusted (17). They then suggest several steps to be considered by the researchers, such as: clearly identify the problem you are seeking to address and what benefit you expect the innovation to have, describe the distribution of harms and benefits, ensure that the risk of harm is not borne by those who do not stand to benefit, ensure that the beneficiaries have access to the innovation, and others (17).

4.3. Implementation of research findings

Stakeholders in health research in humanitarian settings may encounter ethical problems after the completion of their study. Moodley (18) discusses such issues in an article about biological samples collected from South African research participants. The author argues that in the recovery phase of acute disasters post-research obligations to populations must be honoured. She goes on to argue that research conducted in acute disasters must be seen through to completion and that publication is critical (18). Moreover, the author reviews the role of RECs in South Africa and claims that the safe conduct of appropriate research during disasters (both acute and chronic) is an ethical imperative (18). Thus, according to the author, RECs have an obligation to ensure that healthcare needs are met first. To conduct sound research, RECs should conduct risk-benefit assessments of proposed research and ensure cultural and contextual appropriateness of consent processes given that South African populations often have enhanced vulnerability (18).

5. Summary of online survey analysis, feedback on previous version and other stakeholder input

From the 9 responses received, all R2HC funded researchers (n = 5) were aware of the 2014 Ethical Framework and had used it at the application stage, and 60% had used the framework for guidance when seeking ethics approval for their funded projects. According to respondents, the Framework was easy to find and helped to anticipate potential ethical challenges related to their projects. All R2HC funding committee members who responded (n = 4) were aware of the Framework and 50% had used it when reviewing proposals. Interestingly, some funding committee members indicated that the Framework was difficult to understand, not applicable to the proposal(s) they reviewed, and not helpful to anticipate ethical challenges related to the proposal(s) being reviewed. Suggestions from funding committee members to improve the existing Framework included "incorporating ethics into the funding application more clearly" and a "short series of key points/questions could be helpful".

The 2014 Ethical Framework and the separate set of recommendations produced and presented to Elrha by Curry, Waldman and Caplan (1) were reviewed by the representatives from the Wellcome Trust (WT), Elrha and the World Health Organization (WHO) before its publication. We reviewed this feedback and present a summary below.

In general, the reviewers from WT, Elrha and WHO were appreciative of the 2014 Framework and its recommendations. However, a reviewer noted that *"Everything in the 'framework pyramid' is not unique to this type of research….surely this is a critical point……how many of the issues will be context specific…….what are the issues that are universal, what are the issues that are context specific?"* Another comment noted some confusion about the pyramidal structure of the Framework: *"Is the 'Parameters cluster' meant to be sequential? Surely at C, the independent ethical review stage you need to be aware of E and have already worked out F?"* Most reviewers noted that a number of recommendations required significant funding and raised concerns about feasibility of implementation. A table containing the set of recommendations and a summary of reviewer comments on those recommendations was developed during our revision process (table 1).

Table 1 - Recommendations and reviewer feedback on the 2014 Ethical Framework development

Recommendations by Curry and colleagues	Summary of WT, Elrha and WHO reviewer comments
Implement "full transparency" on all R2HC processes, funded protocols, key results, documentation, etc.	Difficulties in implementation due to projects being conducted in 'politically contentious environments', lack of clarity around nature of risk involved and how 'full transparency' would mitigate these risks.
Establish/Require Ethics Training for Funding Committee/R2HC Secretariat/Funded Research Teams	Training courses should have a humanitarian/emergency response focus/sections, should be 'light', and the funding committee should not become a de-facto REC.

Fund "Technical Assistance" Capability to Strengthen Ethical Viability of R2HC Protocols with Technical Merit	Peer review process should be sufficient, if implemented, should be a short process and should be based on demand.
Assure Capability for Continuing and Summary Oversight of Protocol Ethical Performance by REB(s) and DSMBs (Data-Safety Monitoring Boards)	Difficult to request various IRB/REC to adhere to, and for researchers to negotiate, costly and burdensome. Suggested alternative is for funded projects to report back regularly on ethical issues related to their on-going work.
Create/Fund an Independent, Global REB Focused on Health Interventions Research in Humanitarian Crises/Complex Emergencies	Establishment of an 'Ethics Guidance Group', which respects local mandates and functions independently. Difficulties in creating local buy-in, legitimacy. Costly to implement. Previously tried and failed.
Explore/Establish Registry for Research on Health Interventions in Humanitarian Contexts	Perhaps build a registry linked to the WHO International Clinical Trials Research Portal (ICTRP), or a web portal as a feasible alternative. Encourage researchers to publish their experiences.
Clarify Funding Levels/Limits for Round 2 Applications around Key Ethical Dimensions of Protocol Design	What are the merits of this approach?

In addition, as noted earlier, during our revision process we approached representatives from the WT and DFID for more detailed views on the 2014 Ethical Framework based on three broad questions. The questions were: a) What are the key strengths and weaknesses of the current R2HC framework (from a funding body perspective)? b) What are the key requirements to improve the uptake and application of the framework? c) What are the expectations from such a framework?

We have summarised the responses received from WT below. We have attempted to keep the tone and language of the original communication intact as far as possible when summarising.

1. What are the key strengths and weaknesses of the current R2HC framework (from a funding body perspective)?

- The key strength is that within its considerable length, the document does contain several useful sets of questions/considerations which should help someone who wants to reflect on the ethics of their research idea.
- Sections 1-4 are interesting and provide useful background for the funders on how and why the framework was developed as it was. This is important in terms of the funders being assured of the evidence that informed the framework. However, this detail distracts from the practical framework described in sections 5 and 6.
- A weakness is that it's too long, covering some quite basic ground earlier on, has a long annex section. A shorter, more succinct and focused document would better serve the funders'

interest in having a framework that has good uptake by researchers and research ethics committees.

2. What are the key requirements to improve the uptake and application of the framework?
   - The prerogative of increased uptake should be carefully considered against scientific rigour of submitted funding applications and a need for such frameworks.
   - The scope and purpose of the Framework should be clear and distinct.
   - Clear indication from the funders about their alignment with the Framework (perhaps through an accompanying document) would provide more authority to the Framework and presumably increase uptake. In the 2014 Ethical Framework, it is not clear how far the funders are in agreement with the assertions of the authors.

3. What are the expectations from such a Framework?
   - The Framework should be seen more as guidance than a set of absolute dos and don'ts. Different activities might be ethical or unethical in different contexts for different reasons as in humanitarian crises situations, contexts (and consequently what weighting is given to different considerations) could vary significantly.
   - A clear indication about ownership/endorsement and the intended primary audience of the Framework is required. For example a Framework from the funders setting out the expectations they have of researchers (including both requirements - if there are any - and points that the researcher should consider and articulate/justify their position on). This would help clarify the language and tone, promoting a consistent 'voice' across the Framework. In turn, the Framework would become a document that research ethics committees or the funding committee could use to check whether researchers have covered the key points in their application.
   - Clarity is needed if the Framework is intended to address the needs of the scheme or be a document for the field more broadly. Fostering collaboration and bridging the gap between research and practice are important points that do not present themselves as clear principles in the current framework. The Framework could usefully include some guiding principles.
   - An introductory section could set the scene explaining why a specific framework for this context is required and reference could be made to the standard research ethics considerations. The purpose of the body of the Framework, however, should be to focus on and clearly articulate what are the unique ethical considerations when conducting research in humanitarian crises.

6. Development of the revised R2HC Ethics Framework

In the light of our collective findings, including the preceding literature review and our deliberations during the course of this work, we developed the revised version of the R2HC Ethics Framework based on five points of departure from the previous Framework.

1. The framework should provide ethical guidance specifically for humanitarian health research, but with wider relevance for other humanitarian research and potentially even humanitarian practice.
2. The framework should be a tool for reflection, inductive and deliberative thinking, and proactive response to ethical issues that arise in developing protocols, reviewing proposals and conducting humanitarian health research.
3. The framework should not be clustered around specific groups of ethical challenges, nor have arbitrary hierarchies. Rather, it should have interconnected, overlapping and repeated opportunities for reflection on ethical challenges based on an assumption that these reflections are guided by context-specific factors.
4. The framework should be firmly grounded in the belief that reflection on ethical issues should be done throughout research projects, including before, during and after the research.
5. The framework should be a user-friendly, stand-alone tool, easily detachable from other accompanying literature.

Using these points as guiding principles, we have developed the new version of the R2HC Ethics Framework, which is graphically presented as a series of 'steps'. An explanatory document precedes the graphical framework, which will act as guidance for understanding its usage and formative structure.

R2HC Ethics Framework 2.0

1. Introduction

Funded by the UK Department for International Development (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 tool[1] 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 aftermath[2]. 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 phrase 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

[1] Suggested citation: Chesmal Siriwardhana, Sapfo Lignou, Shannon Doherty and Dónal O'Mathúna. 2017. R2HC Ethics Framework 2.0.
[2] For more information, see the following links –
http://www.alnap.org/resource/10441
http://www.elrha.org/wp-content/uploads/2015/01/Evidence-Review-22.10.15.pdf

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 categorizations 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 deliberatively 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 marginalized or disenfranchised within the communities where the research will be conducted.

R2HC Ethics Framework 2.0

2
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?
3
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 all 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?

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Appendix A – Online survey questions

Section 1 - General questions

1. Please indicate your gender
2. Please indicate whether you have used the R2HC Ethical Framework in preparing research proposals for: R2HC-funded research, Non-R2HC-funded research, Both, Neither
3. Please indicate where you are currently based for the majority of your work time (Please choose only one): Sub-Saharan Africa, East Asia and Pacific, Central Asia, Latin America and the Caribbean, Middle East and North America, South Asia, Europe, Prefer not to say, Other
4. Please indicate which professional setting(s) best describes where you currently work (Please choose all that apply): Higher education institution, NGO, Not-for-profit institution, Research institution, Think tank, Humanitarian agency, UN or affiliated agency, Charity, Hospital, Other health service provider, Prefer not to say, Other. How many years have you worked in this setting/each of these settings?
5. What type of humanitarian setting do you primarily conduct research in? Current conflict, Protracted refugee situation, Post-conflict, Natural disaster, Other complex emergency, Prefer not to say, Other
6. How long have you been working in this/these settings? (Please choose only one): Under 1 year, 1-5 years, 5-10 years, Over 10 years, Prefer not to say, Other
7. Would you describe your involvement in research to be any or all of the following? (Please select all that apply): Task-driven (i.e. operational personnel doing research), Context-driven (i.e. academic research) Clinical research involving direct contact with human participants, Non-clinical research involving direct contact with human participants, Prefer not to say, Other
8. In what areas would you classify the research you are involved in? (Please select all that apply): Biomedical, Physical health, Public health, Mental health, Prefer not to say, Other
9. Please select any and all subcategories that apply to your research: Communicable disease, Non-communicable disease, WASH (Water, Sanitation and Hygiene), Sexual and reproductive health, Maternal and child health, Mental health/psychosocial Support, Injury and rehabilitation, Health systems, Ethics, Nutrition, Prefer not to say, Other
10. How would you classify the types of research that you are involved in? (Please select all that apply): Interventional, Epidemiological, Health systems research, Other (i.e. case studies, policy analysis, ethnographic reviews, etc.), All of the above, Prefer not to say. If intervention (e.g. RCT/monitoring & evaluation) or epidemiological (e.g. cross-sectional or cohort), please specify study design
11. Please indicate if your research methods include any of the following (Please select all that apply): Interventional-experimental design, interventional-quasi-experimental design, Descriptive (e.g. cross-sectional design), Using standardized tools (e.g. Harvard Trauma Questionnaire, Patient Health Questionnaire), Self-developed tools, Structured interviews (i.e. using free text answers), Semi-structured interviews, Unstructured interviews, Focus groups, Participatory methods, All of the above, Prefer not to say, Not applicable, Other
12. What type of population do you work with? (Please select all that apply): Refugees, Internally displaced populations, Mixed populations with host communities, Urban populations, Rural populations, Prefer not to say, Other.
13. Does your population involve any or all of the following categories? (Please select all that

apply): Elderly populations, Women, Refugees/IDP, Former child soldiers, Torture victims, Survivors of gender based violence, Asylum seekers, Children and adolescents (under 18 years), Prefer not to say, Other

14. Please indicate in which regions of the world you work with the populations selected for the previous question only (Please select all that apply): Sub-Saharan Africa, East Asia and Pacific, Europe and Central Asia, Latin America and the Caribbean, Middle East and North Africa, South Asia, Prefer not to say
15. Which of the following stakeholder group best describes you: Applicant to R2HC programme, Current or previous recipient of R2HC grant, R2HC funding committee member, Ethics review for R2HC funded projects (i.e. ethics committee member or Ministry of Health official)

Section 2 - Funding applicants

16. Please choose the option that best describes the funding you received from R2HC: Seed funding only, Full funding (can include seed funding at shortlisted stage), Rapid response grant, Ebola special call grant
17. Are you aware of the R2HC ethics framework (2014)? Yes, No, Not sure, Prefer not to say
18. If yes, did you use the R2HC Ethics Framework (2014) at any application stage? Yes, No, Not applicable, Prefer not to say
19. Please consider your R2HC funded study and indicate approvals gathered (Please select all that apply): Ethical approval by an international body, Ethical approval from only the sponsor country, Both local and international ethical approval, Approval by representatives of the community, Approval by local/regional government, Approval by University/academic institution, Approval by humanitarian organization, Approval by authorities running the camp/humanitarian setting, None, Prefer not to say, Other
20. Did you use the R2HC ethics framework (2014) for guidance when seeking ethical approval? (Applies to both in- country and in-house): Yes, No, Prefer not to say. If yes, in what ways did you use the framework?
21. If you obtained in-country ethical approval, in the process of gaining this approval did you encounter any of the following challenges? (Please choose all that apply): Difficulties finding a structure for approval process (i.e. no national ethics board, disrupted infrastructure), Cultural differences in understanding ethical requirements of research (i.e. coercion, undue inducement), Cultural differences in consent procedures and types (i.e. community vs. individual; oral vs. written), Bureaucracy related challenges (i.e. frequency of ethics committee meetings, timing of feedback, paperwork), Collaboration difficulties (i.e. different health priorities, lack of familiarity with research), Conflict of interest (i.e. corruption, power dynamics), Other.
22. Please consider your study and describe how you managed the challenges of securing in-country approval
23. During the process of research, please indicate if any of the factors below created ethical challenges (Please select all that apply): Type of humanitarian crisis, Language, Cultural variations (i.e. between researcher and research cultures), Cultural variations (i.e. multiple cultures in one setting), Severity of crisis, Expertise and knowledge of researchers, Availability of ethical oversight, Local ethics approval at country level, Support at field level, Prefer not to say, Other

24. If you used the R2HC ethics framework (2014) at any point in the application and/or ethics approval process, did you find any of the following to be applicable? It was easy to find, It was difficult to find, It was easy to understand, It was difficult to understand, It was applicable to my research project, It was not applicable to my research project, It helped me anticipate potential ethical challenges/practical difficulties related to my project, It did not help me anticipate potential ethical challenges/practical difficulties related to my project, Prefer not to say, Other
25. Please provide suggestions on how the R2HC ethics framework (2014) can be improved
26. We would like to ask some questions from the ethics review boards or other organizations that you obtained ethics approvals from for your R2HC funded project. Would you be willing to provide the contact details of relevant ethics committees or organizations? If yes, please provide details of a contact person, email, telephone or postal address and any reference details of your proposal

Section 3 – Funding committee members

27. Please indicate your expert areas
28. How long have you been a member of the R2HC funding committee?
29. How many proposals do you review, on average, per funding call?
30. Are you aware of the R2HC ethics framework (2014)?
31. If yes, did you use the R2HC ethics framework (2014) at any point when reviewing the ethics related aspects of research proposals?
32. If you used the R2HC ethics framework (2014) during your review of proposals, did you find any of the following to be applicable? It was easy to find, It was difficult to find, It was easy to understand, It was difficult to understand, It was applicable to the proposal being reviewed, It was not applicable to the proposal being reviewed, It helped me anticipate potential ethical challenges/practical difficulties related to the proposal being reviewed, It did not help me anticipate potential ethical challenges/practical difficulties related to the proposal being reviewed, Prefer not to say, Other
33. Please provide any suggestions you may have on areas where the framework might be strengthened to make it more useful for R2HC funding committee members when conducting reviews, and how this could be done

Section 4 – Ethics review committee members

34. What is your role in the ethics committee/other regulatory body?
35. How long have you been a member of this ethics committee/regulatory body?
36. Have you been a member of an ethics committee/regulatory body previously? If yes, for how long?
37. Are you aware of the R2HC ethics framework (2014)? Yes, No, Not sure, Prefer not to say
38. If yes, did you use the R2HC ethics framework (2014) at any point when reviewing the ethics application of the R2HC funded project? Yes, No, Not applicable, Prefer not to say
39. If you used the R2HC ethics framework (2014) during your review of proposals, did you find any of the following to be applicable? It was easy to find, It was difficult to find, It was easy to understand, It was difficult to understand, It was applicable to the proposal being reviewed, It was not applicable to the proposal being reviewed, It helped me anticipate potential ethical

challenges/practical difficulties related to the proposal being reviewed, It did not help me anticipate potential ethical challenges/practical difficulties related to the proposal being reviewed, Prefer not to say, Other

40. Please provide any suggestions you may have on areas where R2HC ethics framework (2014) might be strengthened, and how this could be done
41. If you would like to take part in the qualitative interview, please indicate your preference AND provide us your email address in the box below. If you agree to take part, an information sheet and consent form will be provided to you at a later date. If yes, please provide your email address

Appendix B. Literature review bibliography by publication year

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Appendix B. List of reviewers of the R2HC Ethics Framework 2.0

Reviewer	Affiliation
Anna Chiumento	University of Liverpool, UK
Angus Dawson	University of Sydney, Australia
Bayard Roberts	London School of Hygiene & Tropical Medicine, UK
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Ayesha Ahmad	St George's University of London, UK and COST Action IS1201: Disaster Bioethics
Saskia Heijnen and others	Wellcome Trust, UK
Anne Harmer, Josiah Kaplan & Maysoon Dahab	Elrha, UK