

Médecins Sans Frontières - Research Ethics Framework

Guidance document

Introduction

Médecins Sans Frontières (MSF) is one of the leading humanitarian medical organizations. The foundational and animating values of MSF as a humanitarian medical organization are rooted in ethics. It has a well-deserved reputation for its work in responding to humanitarian needs created by a variety of health emergencies around the world. It is respected as an organization for its leadership and moral authority in humanitarian affairs.

Historically, research was not seen as core to the mission of MSF. However, it now initiates, sponsors or participates in numerous research projects in multiple field sites. The results of MSF research have had substantial impact on global health policy and provided benefits to populations served by MSF and elsewhere. MSF has also shown leadership in operational research initiatives in the humanitarian NGO sector. As a result, research has become increasingly integral to MSF activities, both in the field and in global health advocacy.

MSF has paid particular attention to ethical issues related to the research in which they engage. This is manifested by the creation of an independent ethics review board (ERB) that evaluates all research proposals involving MSF. This board chose to use an explicit framework to assess the ethical dimensions of the research¹. Since its adoption in 2003, the research ethics framework has served well, as it has brought greater clarity to the expectations of both the ERB and MSF staff engaged in research. The quality of the proposals submitted to the board has improved considerably over the past decade.

However, it seems an opportune time to revise the existing ethical framework. First, the research undertaken by MSF and the general culture of MSF as an organization has gradually changed. We are now entering a new era where MSF sees research as being more central to its mission and has taken great strides to internalize ethical standards related to research into its field activities. Second, ERB members reflecting upon their practice and use of the framework feel that it is not attuned as well as it could be to the kinds of research undertaken by MSF. Any framework must cover the full range of MSF's research activities. Third, since the formulation of the framework, there has been a rapid expansion of the literature on research ethics, particularly relating to global health ethics research. A revision of the framework allows new ideas to be incorporated into MSF's approach to maintaining high standards in ethical review.

¹ In 2003, in order to provide structured advice to field researchers and to facilitate standardized reviews, the ERB decided to adapt a draft framework for clinical research in the developing world developed by the National Institute of Health in the United States. (Emanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *JID* 2004;189:930-7.)

Based on the experience of the past ten years, it was decided to move away from the Emanuel framework in form and in content. While most of the benchmarks of the Emanuel framework are retained in some form, the framework is more practical by formulating explicit questions following a temporal logic of research development. An alternative format focused on principles or statements has been avoided, as it can suggest that ethics is a series of inflexible and absolute rules, and it can be unclear how the different elements relate to each other. In contrast, a series of questions are open-ended and invite discussion and engagement. They seek to encourage researchers to think critically about their proposed protocols and justify their methods, think about possible harms and benefits, and consider what the implications of their research might be. Additional considerations particularly relevant to MSF's research were added, such as conflict of interest, securing resources for research, use of biological material, dissemination of research findings.

In light of these considerations, and based on discussions during several ERB meetings a new ethical framework was drafted and finally adopted in September 2013. This new framework will be used during a pilot phase November-December 2013. Its use will become mandatory in January 2014.

What should be submitted to the ERB for ethics review?

MSF seeks to carry out research according to the highest possible ethical standards, and there is clear congruence between the ethical conduct of research and the aims of humanitarian medicine. Preserving and enhancing the well-being of the participants served by MSF must be the overarching imperative of any engagement in research. Independent ethical review by the ERB is essential to achieving this aim, as well as protecting the reputation of MSF, and ensuring that only persons possessing the requisite skills, qualifications and expertise are permitted to conduct legitimate and worthwhile research. All research involving human subjects must be submitted to ethics review. The ERB will not retrospectively review any research that has been started or taken place without ERB submission and approval.

In case of emergency research (research that is more than minimal risk in nature but which is urgent and time-sensitive), the ERB is willing to pre-approve generic proposals. The details will then be filled in for rapid expedited review (chair plus 2 reviewers, with a turn-around time of 48 hours) when operationalizing the protocol in a specific setting.

In few instances research can be exempted from ERB review under certain conditions.

A posteriori analyses of routinely collected clinical data do not require ERB review, if the medical directors take responsibility for addressing the ethics issues. The following criteria must be fulfilled to qualify for exemption from ERB review:

- ✓ Studies/articles are based on routinely-collected program data.
- ✓ They are either descriptive/evaluative or targeted evaluations.
- ✓ Confidentiality is respected; no individual patient identifiers are revealed.
- ✓ Harm is minimal but acknowledged where relevant.

- ✓ Potential benefits to both the programme and the community are described. Since the goal is publication, the relevance to a wider audience is described.
- ✓ Collaborative involvement and, if applicable, authorship from a local authority or partner (Ministry of Health, DHO, other NGO) is encouraged. If relevant and possible, consultation with a body representing the community is desirable.
- ✓ If the decision for exemption from review is taken by the medical directors, the responsibility to ensure that ethical requirements are met lies with MSF. This, however, does not exempt MSF to comply with regulatory requirements in the country from where the data originate. In some countries, local ethical review may still be required.

Standardized surveys (mainly nutrition survey, immunization survey, mortality survey) are not exempted from review a priori. However, if a standard protocol has been pre-approved by the ERB, if no changes are made to this protocol and if certain criteria are met (still to be defined), standardized surveys may be exempted from review. Sensitive surveys (e.g. mental health, sexual violence) always have to undergo ERB review.

Other studies that may also be exempt from review are:

- Routine programme implementation and assessment related work
- Monitoring and evaluation as part of normal implementation of projects

Any MSF research not exempt from review should be submitted to the ERB.

The Ethics Framework

The proposed framework is based on accepted ethical principles for research involving humans and builds upon the most influential international guidelines. It attempts to capture the diversity of research carried out by MSF.

The framework consists of twelve questions, structured into three broad sections following a temporal logic. Section 1 addresses issues to be considered in defining the research and developing the methodology. Section 2 asks questions related to the implementation phase of the research. Finally, section 3 is concerned with what will occur once research has been completed or stopped.

Section 1. Research Question and Methodology (5 main questions)

Section 2. Respecting and Protecting Research Participants and Communities (4 main questions)

Section 3. Implications and Implementation of the Research Findings (3 main questions)

The format of using questions is adopted as a way to help MSF researchers and ERB members in their deliberations about ethical issues. Each main question is followed by a short explanatory statement and a further series of sub-questions. The latter sub-questions are for illustration only and are not supposed to be an exhaustive list of relevant considerations. Which of these questions are most relevant will depend upon the detail of the proposed protocol's research question and methods. All

relevant questions should be considered and used to shape the answers to the questions when filling out the ethics review research template.

1. Research Question and Methodology

(1.1) What is the research question? Why is it important?

The research question should be the central element in any protocol. Where there is more than one question they should be presented in a logical order.

- a. Why is the research question(s) scientifically important? What knowledge gap will it fill?
- b. Why is the research question(s) important to the community affected?
- c. If other alternative research questions are possible, why was the particular question selected?
- d. What potential harms might arise if the research is not conducted?

(1.2) How is the methodology and proposed analysis appropriate given the research question(s)?

It is important that the proposed method and analysis will not only allow the researchers to answer the question that they have set, but that it is the best way to do so.

- a. How will the research design and analysis provide the best means of answering the proposed question (e.g. sample size and method, selection of study population etc.)?
- b. What scientific/methodology review has been obtained prior to submission for ethical review?
- c. How have ethical considerations shaped the proposed methodology? For example, what justification exists for any standard of care in the proposed research?

(1.3) What is the context in which the research will be conducted? How has this influenced the research design? The protocol must include details about existing and planned community engagement and collaborative partnerships and how they have influenced or shaped the proposed research².

- a. How have the community's views about their needs and research priorities been taken into account? What is the researchers' strategy to engage the community as part of the research process?
- b. What collaborative research partnerships or agreements exist in relation to this project? What engagement has occurred with local or national health authorities?
- c. To what extent can partnerships be structured in a fair and equitable manner?
- d. How will the researchers enhance local research capacity with this project?

² The **concept of 'community'** can be used in a number of different ways. Most commonly, it is used in a descriptive sense to pick out a particular geographic, linguistic, functional or socio-cultural entity with characteristics such as shared interests and experiences, values, common fate or cultural affinity. Sometimes a community will have a pre-existing structure, such as a village committee, that may be used as a means of engagement. However, care needs to be taken to avoid assuming that such structures represent all relevant interests in the community; otherwise there is a danger of reflecting prior repressive or coercive structures, potentially interfering with the voluntariness of decisions about participation. In some conflict-ridden environments where MSF works, the social structure has been damaged or destroyed. In such contexts it is especially important to consider carefully who would best represent the interests of the relevant population.

- e. Has research ethics review been obtained by all appropriate ethics review boards at the local/regional/national level?

(1.4) Are there any other parties involved in the research? What potential interests of these parties might conflict with MSF's mission and values?

- a. Who may benefit directly and indirectly from the research?
- b. Where other parties (e.g. companies) benefit from the research, how will the interests of participants, community and MSF be protected?
- c. What are the potential benefits relating to spin-off interests or intellectual property etc? How will they be apportioned?

(1.5) Are all relevant resources for the research secured?

- a. What is the budget for the research? Is it secured?
- b. What additional infrastructure is required? Is it secured?
- c. What possible changes might occur in the field? What plans are in place to respond to such alterations?
- d. Is there an operational commitment for the expected time of the study?

(1.6) Have the research staff the relevant training and protections?

- a. Have the research staff the required expertise to carry out the research?
- b. What training has been conducted with the research staff, or how will this be provided?
- c. What risks of harm might researchers be exposed to? How can this be minimised?
- d. Have any of the research staff double allegiances (being both carer and researcher)? How will potential conflicts of interest be avoided?

2. Respecting and Protecting Research Participants and Communities

(2.1) What are the anticipated harms and benefits?

Considering all relevant harms and benefits is an essential part of assessing whether a proposed piece of research is ethical. As MSF works mostly with populations at risk, there are multiple opportunities for considerable harm.

- a. Given the best available evidence and any relevant experience what are the anticipated harms and benefits of the research? How likely and how significant are any harms and benefits to research participants?
- b. What are the potential wider social harms and benefits to communities?
- c. What protections will be put in place to avoid or mitigate anticipated harms?
- d. Benefits and burdens of research may be unequally distributed between sub-groups. How are harms and benefits distributed between participants and communities? Have researchers ensured that any proposed inclusion/exclusion criteria are fair?
- e. What is the process to monitor unknown harms/new information arising in the study? Will a data and safety monitoring committee be needed?

(2.2) What are your plans for obtaining consent?

A requirement to inform participants is often seen as being an important way to show respect and promote patient autonomy and welfare.

- a. What information ought to be provided? This will usually include the following elements: the reasons for doing research, details about who is doing the research, why the potential participant is being asked to be involved, details about what any intervention might involve and any on-going commitments of participation, details about anticipated risks and benefits, the fact that participants are free to refuse or withdraw, that any findings will be communicated back to the participants etc. The information given should be proportionate to any risks, but this does not mean that the higher the risk, the more information ought to be provided. Sometimes, calling attention clearly to a common or significant particular risk is more important than listing every possible remote risk.
- b. Providing information does not guarantee it has been understood. How can information be provided at an appropriate linguistic level, without jargon or technical terms, and appropriate to the local language and culture?
- c. Should information be provided in oral and/or written form?
- d. How will the consent process be conducted? You may want to consider issues such as: who will consent, where they will do so (is the place appropriate to allow a confidential discussion), will a witness to the consent be required, how much time will be offered to consider whether to be involved? Prior engagement with communities can be a useful way to ensure that the

consent process meets local expectations and sensitivities. How will the act of consent be recorded (e.g. signed and witnessed document, thumb print etc.)?

- e. Alternative or additional consent procedures may need to be developed where potential participants are minors, minor parents, or suffering from short or long-term incapacities etc.
- f. It should not be assumed that a long and complicated information sheet is always necessary and in exceptional cases it may be justifiable not to seek informed consent. Where researchers believe that this is appropriate, they should be careful to provide reasons for this in the protocol.

(2.3) How do you plan to protect confidentiality?

Data will include all information (medical and non-medical) about or derived from participants.

- a. What data security policies are in place?
- b. Where will data be gathered and stored? Who will have access to it? Where will it go?
- c. Will it be anonymised or coded? Will it be linked, or could it be linked, to other data sets? If so, are adequate protections in place?
- d. Will data be placed in the public domain (in line with the MSF data sharing policy)? How will confidentiality be protected?

(2.4) How do you plan to access, store and distribute any collected biological material?

- a. Will biological material be collected, retained, stored, exported or destroyed? If so, how will this be done? If collected for one purpose, could it be used for other purposes?
- b. Is the relevant consent obtained?
- c. Where transfer of material is planned what national or international regulations are relevant? Have the necessary authorisations been sought? Is there a material transfer agreement in place? If so, what does this say?

3. Implications and Implementation of the Research Findings

(3.1) What will happen when the research is either stopped or is complete?

Good planning for a project will consider how it will end.

- a. Under what conditions would you consider stopping the project earlier than planned?
- b. What will happen to investments in infrastructure, human and other resources, when the research is complete or ends early?

(3.2) How will the findings be disseminated?

- a. How will the results be disseminated? Through publication? Where? Will they be available through open access or on the MSF web site?
- b. How will MSF communicate the results of the research directly to the community/participants involved?
- c. What is the plan for dissemination if the research findings are negative?

(3.3) How will the findings be implemented?

It will not be possible, before results are known, to establish all the details about implementation. However, it is often possible to think about such issues in advance.

- a. What is MSF's obligation to the research participants?
- b. What is MSF's obligation to others in the immediate programme or community where the research occurred?
- c. What is MSF's obligation to others in the same situation elsewhere?
- d. How will MSF fulfil any post-research obligations entailed by the results of the research?
- e. Is there an (advocacy) plan in place to assure access to benefits of the study results if applicable? This is particularly important where individuals and communities are unable to access an intervention for some reasons (e.g. it is too expensive).