MSF ERB Ethics Review Research Template

Template to be filled out and submitted with the research protocol when requesting ERB review

<u>Please use the appended MSF Research Ethics Framework Guidance document (version 2, November 2016)</u> to answer the questions below. If appropriate, you may directly copy-paste text from the research protocol or refer to relevant sections in the protocol.

Research Protocol
Title:
Version number:
Date created:
Duration of proposed study (one year, two years, more than two years):
Name of Principal Investigator (PI):
PI Institute/Organization:
Address of PI Institute/Organization:
Country of PI Institute/Organization:
Collaborating Institutions: *(Please provide information about all Institutions/Organizations collaborating in this research)*
Has the protocol been submitted to or approved by National/ Local Ethics Review Committee(s)? ***If not yet submitted, please indicate when and to which committee the protocol will be submitted.*** *Please name the various ERCs.*

1. Research Question and Methodology
(1.1) What is the research question? Why is it important?
(1.2) How is the methodology and proposed analysis appropriate given the research question(s)?
(1.3) What is the context in which the research will be conducted? How has this influenced the research design? Please include in the protocol any details about existing and planned community engagement and collaborative partnerships and how they have influenced or shaped the proposed research.
(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?
(1.5) What relevant resources have been secured for this study?
(1.6) Do the research staff have the relevant expertise, training and protections?
2. Respecting and Protecting Research Participants and Communities
(2.1) What are the anticipated harms and benefits?
(2.2) What are your plans for obtaining consent?
(2.3) How do you plan to protect confidentiality?
(2.4) How do you plan to access, store and distribute any collected biological material?
3. Implications and Implementation of the Research Findings
(3.1) What will happen when the research is stopped prematurely or has been completed?
(3.2) How will the findings be disseminated?
(3.3) How will the findings be implemented?

MSF ERB Ethics Framework for Review Guidance Document

Version 2, November 2016

The 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 main 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 sub-questions. *The latter sub-questions are for illustration only and are not supposed to be an exhaustive list of relevant considerations*. The relevance of these sub-questions will depend upon the detail of the proposed protocol's research question and methods. All relevant sub-questions should be considered and used to shape the answers to the main 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[1] and collaborative partnerships and how they have influenced or shaped the proposed research[2].

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

[1] Community engagement should be contextualised to the research that is proposed. Certain studies may not require community engagement; if so, please state this explicitly and give the reasons why.

[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.

(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) What relevant resources have been secured for this study?

a. What is the budget for the research? Is it secured? Who will finance the research?

b. What additional infrastructure is required? Is it secured?

c. How will human resources for the project be secured? Will pre-existing field staff be utilised? Will new staff be recruited and trained?

d. What possible changes might occur in the field during the course of the research? What plans are in place to respond to such alterations?

e. Is there an operational commitment for the expected time of the study?

(1.6) Do the research staff have the relevant expertise, training and protections?

a. Do the research staff have the required expertise to carry out the research? *Please provide short (maximum two pages) CVs of the investigators*

b. What research-related training has been conducted with the research staff, or how will this be provided?

c. What risks and/or harm might researchers be exposed to? How can this be minimised/mitigated?

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 subgroups. 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 and/or 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; how the potential participant was selected to be asked to be involved; details about what any intervention might involve and any on-going commitments of participation; details about anticipated risks, harms, and benefits; details on plans for use of data and/or samples beyond the study; the fact that participants are free to refuse or withdraw at any time; 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 will information be provided at an appropriate linguistic level, without jargon or technical terms, and appropriate to the local language and culture?

c. Will 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 secure the 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?

   How will the act of consent be documented (e.g. signature, thumb print etc.)?

   Prior engagement with communities can be a useful way to ensure that the consent process meets local expectations and sensitivities.

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 be taken to? Who will be responsible for the protection of stored data?

c. Will data and samples be anonymous[3] anonymised[4] or coded[5]? Will it be linked, or could it be linked, to other data sets and/or to biological materials? If so, what protections are in place?

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[3] Data and samples are anonymous if no one, not even the researcher, can connect these to the individual who provided it. They are never labelled with personal identifiers when originally collected; no identifying information is collected from the individual, including direct identifiers such as name, address or identification number (national ID, social security, hospital patient ID, etc); neither is a coding key generated. Researchers should be aware that collection of indirect identifiers (i.e., information regarding other unique individual characteristics) might make it possible to identify an individual from a pool of subjects. For example, a study participant who is a member of a minority ethnic group might be identifiable from even a large data pool.

[4] Anonymised data and samples are often initially coded but where the link between the study participants' identifiers and the unique code(s) or the data between the study participants' identifiers and the samples is subsequently deleted. Once the link has been deleted, it is no longer possible to trace the data and samples back to individual subjects through the coding key(s). Anonymisation is intended to prevent study participant re-identification. As anonymised samples and associated data are not traceable back to the study participant, it is not possible to undertake actions such as sample withdrawal, or the return of individual results, even at the study participant's request.

[5] Coded data and samples are labelled with at least one specific code and do not carry any personal identifiers. It is possible to trace the data or samples back to a given individual with the use of coding keys. Samples and/or data are indirectly traceable back to a study participant via his/her unique coding key. It is possible to undertake actions such as sample withdrawal, or the return of individual results in accordance with the study participant's request.

Definitions available from http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E15/Step4/E15_Guideline.pdf [accessed 25 Nov 2016]
Additional definition of anonymous data taken from http://research-compliance.umich.edu/data-security-guidelines [accessed 25 November 2016]

d. Will data be placed in the public domain (in line with the MSF data sharing policy) or be shared? How will confidentiality be protected? Where data will be shared, there should be a Data Sharing Agreement in place. Please submit a copy.

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

a. Will biological material be collected, retained, stored, shared, exported or destroyed? If so, how will collection, retention, storage, sharing, transport, destruction be conducted? If collected for one purpose, could it be used for another purpose?

b. Where transfer of material is planned: What national or international regulations are relevant? Have the necessary authorisations been sought? Please submit a copy of the Material Transfer Agreement.

c. Have these plans been communicated to the participants in the information sheet? Is the relevant consent obtained?

3. Implications and Implementation of the Research Findings

(3.1) What will happen when the research is either stopped prematurely or has been completed?

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 the data and biological materials collected if the project is stopped prematurely? How shall the study participants be informed?

c. What will happen to investments in infrastructure, equipment, human and other resources, when the research is complete or ends prematurely?

(3.2) How will the findings be disseminated?

a. How will the results be disseminated? Through publication(s) and/or oral/poster presentation(s)? Where? Will the published articles be available through open access or on the MSF website? Will copies of presentations or research reports be available on the MSF website?

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).