Government of Pakistan

National Institutes of Health

Health Research Institute

National Bioethics Committee (NBC) Pakistan

RESEARCH ETHICS -GUIDANCE DOCUMENT TO HELP RESEARCHER FILL THE ERC APPLICATION FORM

Secretariat

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(Adapted & used with thanks & permission of MSF Ethics Review Board)

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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.

The framework consists of twelve questions, structured into three broad sections following a temporal logic.

Section 1 Research Question & Methodology

Addresses issues to be considered in defining the research and developing the methodology. It has 6 main questions

Section 2 Respecting and Protecting Research Participants and Communities

Asks questions related to the implementation phase of the research. It has 4 main questions.

Section 3 Implications and Implementation of the Research Findings

Is concerned with what will occur once research has been completed or stopped.

The format of using questions is adopted as a way to help researchers and NBC-REC 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?

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(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 research[1].

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 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 be in conflict?

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 Pakistan 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?

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(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 minimized?

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.

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

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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? 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 authorizations 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 a web site?

b. How will researcher 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?

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(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 researcher's obligation to the research participants?

b. What is researcher's obligation to others in the immediate programme or community where the research occurred?

c. What is researcher's obligation to others in the same situation elsewhere?

d. How will researcher 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).

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