**Template II**

**INSTITUTIONAL ETHICS COMMITTEE**

**FACULTY OF SOCIAL SCIENCES**

**JAMIA MILLIA ISLAMIA**

**NEW DELHI**

**Ethics Review Application\***

**(***The text in parenthesis below the question serves as an indicative guide to frame responses to the question***)**

**1. Research Question and Methodology**

***(1.1) What is/are the research question(s)? Why is/are the research question(s) important to the community/society?***

(*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.)*

***(1.2) How have ethical considerations shaped the proposed methodology? For example, what justification exists for any standard of care in the proposed research?***

***(1.3) Are there any other parties involved in the research, directly or indirectly? How would the objectivity of the process be maintained?***

***(1.4) What possible changes might occur in the field? What plans are in place to respond to such alterations?***

***(1.5) Have the research staff the relevant training and protections?***

1. Have the research staff the required expertise to carry out the research?
2. What training has been conducted with the research staff, or how will this be provided?
3. What risks or harm might researchers be exposed to? How can this be minimised?
4. Have any of the research staff double allegiances (being both carer and researcher)? Yes/No
5. 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?***

1. Given the best available evidence and any relevant experience what are the anticipated harms and benefits of the research to the research participants?
2. What protections will be put in place to avoid or mitigate anticipated harms?
3. What is the process to monitor unknown harms/new information arising in the study?

***(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 participants autonomy and welfare*)

1. What information will be provided, while seeking consent?

(*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*)

1. How would you ensure that the information has been understood by the participant?

(*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*)

1. Will information be provided in oral and/or written form?
2. How will the consent process be conducted?

(*You may want to consider issues such as: who will consent, where will they 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.)*

1. What alternative or additional consent procedures will be developed in cases where potential participants are minors, minor parents, or suffering from short or long-term incapacities etc.

**Note: Please attach the informed assent/consent form (Template IV)**

***(2.3) How do you plan to protect data confidentiality?***

(*Data will include all information about or derived from participants. What data security policies are in place? Where will data be gathered and stored? Who will have access to it? Where will it go? Will it be anonymized or coded? Will it be linked, or could it be linked, to other data sets? If so, are adequate protections in place? Will data be placed in the public domain? How will confidentiality be protected?)*

**3. Implications and Implementation of the Research Findings**

***(3.2) How will the findings be disseminated?***

(*How will the results be disseminated? Through publication? Where? Will they be available through open access or otherwise? How will the Project team communicate the results of the research directly to the community/ participants involved? 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. What is the project team's/researcher’s obligation to the research participants? How will the project team fulfil any post-research obligations entailed by the results of the research? 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*)

**\*This Institutional Ethics Committee (IEC) proforma is based on and adapted from the proforma developed by the Tata Institute of Social Sciences (TISS), Mumbai and is used with appreciation and acknowledgement of their expertise.**