Ethics Committee CMU (HIV/AIDS, TB & Malaria)

Ministry of National Health Services Regulations & Coordination, Islamabad

RESEARCH ETHICS APPLICATION FORM

Instructions / guidelines for researchers

1. Form to be filled out and submitted with the research protocol, cover letter, budget, questionnaire and consent form in English and Urdu.
2. Incomplete and inappropriately filled form will not be accepted/ considered for review and discussion in the meeting.
3. The review process takes 4 weeks in granting approval.
4. Application must be signed by Principal Investigator. In case of student's application, it should also be signed by the supervisor.

Note: All duly filled research projects in hard copy must be submitted to:

IRB ETHICS COMMITTEE CMU-ATM
Block F, EPI Building, Near National Institute of Health (NIH) (Prime Minister's National Health Complex), Park Road, Islamabad, Pakistan.

Scanned soft copy may be submitted to the following email addresses:

1. drrazia@ntp.gov.pk
2. aashifa.yaqoob@ntp.gov.pk

Project Title

_____

Principal Investigator (PI) (Full Name and Contact Information)

First: _____ **Middle:** _____ **Last:** _____

Mailing Address or Campus Mail Address:

Phone: _____ **Email:** _____

Health program/ Institution name: _____

Highest Education Level: _____

Co - Investigator (PI) (Full Name and Contact Information)

First: _____ **Middle:** _____ **Last:** _____

Mailing Address or Campus Mail Address:

Phone: _____ **Email:** _____

Health program/ Institution name: _____

Highest Education Level: _____

1. **Project Title and Identification**

As Principal Investigator of this study, I assure the IRB that the following statements are true:

- ☐ The information provided in this form is correct.
- ☐ I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.
- ☐ I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- ☐ I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- ☐ I will not begin my research until I have received written notification of final IRB approval.
- ☐ I will maintain records of this research according to IRB guidelines.
- ☐ If these conditions are not met, I understand that approval of this research could be suspended or terminated.

I Agree _____ (Initial)

2. Funding

Is this research funded by national or international organization?

1) Yes 2) No

If Yes, indicate the source of funding:

_____

If no, please explain how costs of research will be covered:

_____

3. Conflict of Interest

Belmont guidelines encourage Institutions to assure there are no conflicts of interest in research projects that could adversely affect the rights and welfare of human subjects. If this proposed research study involves a potential conflict of interest, additional information will need to be provided to the IRB ethic committee.

Do any of the Investigators or personnel listed on this research have a potential conflict of interest associated with this study? 1) Yes 2) No

Payment or Other Compensation for Research Subjects

Will you give subjects gifts, payments, compensation, reimbursement, services without charge? 1) Yes 2) No

If Yes, please explain:

_____

4. **Protocol Description and Other Detail**

Describe the objective(s) of the proposed research including purpose, research question, hypothesis, method, data analysis, research design and relevant background information etc. (Max: 1000 words)

Note: ***Attach surveys, instruments, interview questions, focus group questions etc.***

5. **How many months do you anticipate this research study will last from the time final approval is granted?** _____

6. Participant (Subject) Population

7. Expected number of participants (sample size)

8. **Expected Age Range**

- ☐ 0-15 (Attach parental permission form)
- ☐ 15 and older (Attach consent form)

9 Populations to be Included in this Research

Inclusion and Exclusion of Subjects in this Research Study (Describe criteria for inclusion and exclusion of subjects in this study)

Inclusion Criteria:

_____

Exclusion Criteria:

_____

10. Location of subjects during research activity or location of records to be accessed for research

Describe the rationale for selected location

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11. Sampling methodology:

Describe sampling methodology for selection of research subjects

12. Risks and Benefits

- ☐ Does the research involve any of these possible risks or harms to subjects?
- ☐ Are there any other parties involved in the research? What potential interests of these parties might be in conflict?
- ☐ Are all relevant resources and protections for the research secured?
- ☐ Have the research staff the relevant training and protections?

13. Respecting and Protecting Research Participants and Communities

- ☐ What are the anticipated harms and benefits?
- ☐ What are your plans for obtaining consent?
- ☐ How do you plan to protect confidentiality?
- ☐ How do you plan to access, store and distribute any collected biological material?

14. Implications and Implementation of the Research Findings

- ☐ What will happen when the research is either stopped or is complete?
- ☐ How will the findings be disseminated?

Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help Ethical Committee CMU for expedited review. Your cooperation in completing it will be highly appreciated.

- ☐ One copy of Application form with checklist
- ☐ One copy of Research Protocol in standard format
- ☐ One copy of informed consent in English and Urdu or any other local language of the population study.
- ☐ One copy of Questionnaire in English and Urdu administered during the study (if applicable).

_____ _____

Signature: Principal Investigator **Date**

_____ _____

Signature of supervisor (if applicable) **Date**

_____ _____

Signature of Chairman of the Department **Date**