



**FAZAIA MEDICAL COLLEGE – INSTITUTIONAL REVIEW BOARD
(FMC – IRB)**

AIR UNIVERSITY ISLAMABAD

**FMC – IRB RESEARCH ETHICS
APPLICATION FORM**

ADAPTED & USED WITH THANKS & PERMISSION OF NBC PAKISTAN AND MSF

Fazaia Medical College - Institutional Review Board (FMC - IRB)

Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help Fazaia Medical College - Institutional Review Board (FMC - IRB) for review.
Your cooperation in completing it will be highly appreciated.

- ☐ FMC - IRB Application Form with checklist
- ☐ Research Protocol in standard format
- ☐ Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ Informed consent in English and if applicable Urdu or any other local language of the population study
- ☐ Questionnaire in English and Urdu administered during the study (if applicable).
- ☐ Please make four hard copies for IRB submission and a copy of this entire application for your files.
- ☐ I have submitted the application form, research protocol and informed consent electronically by e-mail. (fmc.irb@mail.au.edu.pk)

Signature of Principal Investigator

Date

Signature of Supervisor (if applicable)

Date

Signature of Chairperson of the Department

Date

Fazaia Medical College – Institutional Review Board (FMC – IRB)

Instructions / Guidelines for Researchers

1. Form to be filled out and submitted with the research protocol when requesting IRB review.
2. Please use the FMC-IRB Research Ethics Framework - Guidance document to help answer the questions below. If appropriate, you may directly copy-paste text from the research protocol sections in the protocol.
3. Please answer all questions. It is the responsibility of researcher to fill the application form appropriately. Incompletely and inappropriately filled form will not be accepted/ considered for review and discussion in the meeting. This may result in delay in approval of the proposal.
4. The review process takes minimum 6 weeks in granting approval.
5. Application must be signed by Principal Investigator. In case of student's/ resident's application, it should also be signed by the supervisor/Head of the department.

Introductory Questionnaire

Research Proposal
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 other institutional ethics review committee(s)? If yes, name the ERC and attach the relevant document. If not yet submitted, please indicate when and to which committee the protocol will be submitted.

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? The protocol must include details (if applicable) about <u>existing and planned community engagement and collaborative partnerships</u> 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 be in conflict?
(1.5) Are all relevant resources and protections for the research secured?
(1.6) Do the research staff have the relevant training and protections?
2. Respecting and Protecting Research Participants and Communities
(2.1) What are the anticipated:- a. Harms b. Benefits
(2.2) What are your plans for obtaining consent?
(2.3) How do you plan to protect confidentiality?
(2.4) Financial considerations a. Any financial compensation involved has been explained b. Any additional costs to the subject c. Financial benefits to the subjects

(2.5) How do you plan to access, store and distribute any collected human biological material? Guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available at <http://www.au.edu.pk/fmc/>

3. Implications and Implementation of the Research Findings

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

(3.2) How will the findings be disseminated?

Declaration of originality of work:-

I am aware of and understand the University's policy on plagiarism and I certify that this assignment is my own work, except where indicated by referencing and that I have followed the good academic practices.

In addition, I understand that any false claim in respect of this work will result in disciplinary action in accordance with University regulations.

Signature: _____