AAMC/IRB/Form_____/___

Application for Institutional Review Board

Title:

_____

_____

_____

Researcher Name: _____

Supervisor/ H.O.D: _____

For Administration:

Title:

_____

_____

_____

Principle Author Name: _____

Application #: _____

Proposal #: _____

Received On: _____

IRB Meeting Date: _____

Research Proposal Status

☐ Approved

☐ Not Approved

Checklist

Please ensure that the following documents (if applicable) are completed with this form.

☐ 1 copy of filled IRB application for along with the required documents.

The following documents, if applicable, will be attached with each form.

☐ 9 hard copies of research proposal written according to research proposal guidelines *(Appendix 1).*

☐ *Soft Copy (PDF & Word Document)*

☐ A copy of drug brochure or any supplementary information enclosed (if applicable).

☐ A copy of "informed consent" in English and/or Urdu or any other local language of the population study.

☐ A copy of the questionnaire in English and/or Urdu administered during the study (if applicable).

☐ A signed permission from the University and Supervisor to allow allotment of Co-Supervisor from Gulab Devi Teaching Hospital.

Note: Please make a copy of this entire application for your files

I have submitted the application form, research proposal and informed consent.

_____ _____

Principle Researcher Date

_____ _____

Supervisor Date

Instructions/Guidelines for the researcher

1. Form to be filled out and submitted with the research proposal when you request an IRB Review.
2. Please use AAMC-Research Proposal Guidelines (Appendix 1) to help answer the questions below. If appropriate, you may directly copy-paste text from the research proposal in the form.
3. Please answer ALL questions. It is the researcher's responsibility to fill the application form appropriately. An incomplete for will not be accepted/considered for review and discussion in the meeting. It may result in delay in approval of research.
4. Once the form has been submitted, it takes at least two weeks to schedule an IRB Meeting on which you will be summoned to answer any relevant questions. You will be informed of the meeting via a text message. Please make sure you acknowledge the message.
5. In case any observations are highlighted, the researcher is required to amend them on the IRB Feedback Form along with the amended research proposal (with amendments highlighted in the document) and submit it to IRB within two weeks. Failure to do so, the researcher will be required to reapply in the IRB Committee.
6. The Ethical Approval will be developed by the board consensus after the quorum requirements are fulfilled.
7. The IRB may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ratio.

Dear applicant,

You are required to submit a filled hard copy of the IRB form, along with 9 hard copies and soft copy (Duly Titled Pdf & Word Document) of your Research Proposal written as per the guidelines given in the form, to the Department of Medical Education - AAMC. Your proposal will not be considered in that particular month's IRB Meeting if the said documents are not submitted till the designated date, and will be considered in the following month's meeting.

Research Proposal	
Title	
Version number:	
Date created:	
Duration of proposed study	
Name of Principal Investigator (PI)	
Name 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) (ERC) or IRB? If not yet submitted, please indicate when and to which committee the protocol will be submitted. Please name the various ERCs.	

(Appendix 1)

Research Proposal Checklist

Please make a cover page and write your name, degree, institute's name, email address, contact number and name of supervisor on it.

1. Title Page:

1.1 Title: (Should not exceed 50 words)

1.2 Statement that this thesis is for partial fulfilment of FCPS/MS/M.Phil. programme.

1.3 Name and signature of Candidate

1.4 Name and signature of Supervisor

1.5 Name and signature of Co-Supervisor (s)

1.6 Name of Institute

1.7 Candidate's Program/Degree

1.8 Candidate's Email ID

1.9 Candidate's Contact Number

2. Introduction: (250-300 words)

2.1 Background

2.2 Problem Statement

2.3 Purpose of Study

2.4 Justification

2.5 Key Words

3. Objectives:

3.1 Objectives (objectives must be stated in measurable terms and starting with action verb)

3.1.1 General Objective

3.1.2 Specific objective (s)

3.2 Research Question (s)

3.2.1 Primary Question

3.2.2 Secondary Questions (s)

3.3 Hypothesis

4. Operational Definitions:

All variables of the study must be clearly defined in detectable terms.

5. Materials and Methods:

5.1 Study Design

5.2 Study Duration

5.3 Study Setting

5.4 Sampling Issues

5.4.1 Target Population

5.4.2 Study Population

5.4.3 Sample Size

a) How many subjects?
b) How did you calculate the sample?
c) What is the formula/method for sample size calculation?

5.4.4 Sampling Technique

5.4.5 Sample Selection

a) Inclusion Criteria

b) Exclusion Criteria

6. Methodology

(Clearly explain how the researcher will follow his date collection plan right from the follow-up subjects or material)

6.1 Ethical Approval

6.2 Participants

6.3 Study Variables

6.4 Data Collection Tools/ Instrumentation e.g. proforma/questionnaire (mention the reliability and validity)

6.5 Data Collection Procedure

6.6 Control of Biases

7. Data Analysis Procedure

Detailed description of:

7.1 Type of analysis plan according to type of variables and study design

7.2 Name of the software to be used

7.3 Statistical tests (if required)

7.4 Stratification of confounders (if any)

7.5 Presentation of results

8. References:

In Vancouver Style

9. Annexures:

9.1 Data Collection Tool / Instrument

9.2 Gantt Chart

9.3 Informed Consent Form (both in English and Urdu)

This must mention

a) Brief description of the study

b) Risks and discomfort involved

c) Potential benefits

d) Protection of confidentiality

e) Voluntary participation

f) Contact information

g) Signatures and date

9.4 Budget / Estimated Cost

9.4.1 Non-recurring

9.4.2 Recurring