PROTOCOL FOR SUBMISSION OF RESEARCH PROJECT FOR ETHICAL REVIEW BOARD

Title of Project:

Name of Principal Investigator:

Designation:

Qualification:

Department:

Institute:

Cell No:

Email:

Name of Supervisor and department:

Type of Project: Observational / Experimental

Check List for submission of Research Project for Ethical Review:

Sr #	Documents to be attached in one set	Yes	No
1.	ERB Scrutiny Form (including signs on undertaking and permission from concerned authority for data collection)		
2.	Summary of Research Project (One Page)		
3.	Complete Synopsis		
4.	Consent Form in Urdu & English (as per ERB form)		
5.	Data Collection Proforma / Questionnaire		
6.	4 sets submitted to ERB secretariat in hard copy for observational and 6 sets for experimental project		
7.	Email 5 min PowerPoint presentation to erb@aimc.edu.pk		

ETHICAL REVIEW BOARD AIMC/ JHL

MEMBER'S REMARKS FORM

TO BE FILLED BY CANDIDATE:

Name: | | Department: | |

Project title: | |

TO BE FILLED BY ERB COMMITTEE MEMBER

MEMBER NAME

MEMBER'S COMMENTS:

PLEASE TICK

APPROVED ◯ REJECTED ◯ PENDING ◯

MEMBER SIGNATURE
DATED

DETAILS OF ETHICAL ASPECTS RELATED TO PROJECT

TIME-LINE OF PROJECT:

a. **Total expected duration with dates: _____**

b. **Period of data collection: _____**

c. **Period of follow-up (if applicable): _____**

Source of data collection: Primary data collection ☐ Secondary data (based on record) ☐

How will confidentiality of research subjects be ensured?

Likely benefit / Applicable of project:

Is your research sponsored: **Yes** ☐ **No** ☐

If Yes, give the following details:

Name of the Sponsor: _____

How is it being sponsored (select the appropriate option)

a. Remuneration to research subjects

b. Remuneration to principal investigator

c. Remuneration to other investigator

d. Instruments provided by sponsor

e. Any other (plz specify)

Has the study been conducted before? Kindly provide reference (s) in Vancouver style:

_____

_____

PART B- (This part needs to be filled for experimental study design only)

Any Vulnerable Subjects involved (children, pregnant women, mentally retarded, prisoners, or if it includes fetal research)? Kindly give brief explanation of need to use these particular individuals

Kindly state if your project involves use of (tick as appropriate)

a) ☐ Experimental drug(s) b) ☐ Radioactive agents c) ☐ Non-therapeutic research

d) ☐ Non-approved use or non-approved dose for approved drugs e) ☐ Fetal research

f) ☐ Experimental surgical procedures or other interventions g) ☐ Behavioral research

h) ☐ Gene molecular cloning ☐ Other (Please specify)

Provide reference to the literature regarding safety of both intervention/s:

Potential harm to subjects (including expected drug reactions)

What measures will you take to minimize harm

What measures will you take if such harm occurs

Note:

- Submission of Synopsis does not mean approval. Candidates will be informed via SMS for Presentation / Discussion of submitted synopsis in Ethical Review Board Meeting.
- Candidates will be required to attend the meeting physically at the given date and time and bring along one set of the project submitted to ERB in hard copy and their presentation in pen drive.
- The time-period to resolve the objections raised during the meeting is one week. Failure to submit the corrected copy within this time will result in rejection/resubmission of the synopsis.

UNDERTAKING FOR RESEARCH PROJECT

"I solemnly declare that:

- I have read, understood, and agree to abide by all the principles derived from the Declaration of Helsinki regarding medical research involving human subjects.
- I will obtain informed consent from the subject or their legally authorized representative before including them in the study.
- I will fully inform patients which aspects of their care related to research and acknowledge that refusal or withdrawal from a study will not interfere with the patient-physician relationship.
- I will ensure that the results of research, whether positive, negative, or inconclusive, are made publicly available and reported accurately and completely, following accepted ethical reporting guidelines.
- I have not willfully withheld any information about the research project that is likely to result in harm to the humans involved (both research subjects and investigators) and environment.
- There will be no financial burden of any sort on the subjects. All the expenses involved in the research (cost of medicine/ procedure/ investigation) will be incurred by the researcher.
- If approved, I will follow the project exactly as approved and will follow any bindings (submission of progress of project, any amendments etc.) Suggested by Ethical Review Board and agreed by me.
- In case of any harm during the research project, I will inform immediately the ERB office in writing and steps taken to manage the adverse event.
- At the conclusion of the study, I will inform participants about the study outcome and provide access to any beneficial interventions or appropriate care resulting from the research.
- All information provided by me regarding this research project in this form is correct.
- The Board reserves the right to cancel the project at any time and at any stage in case of any deviation from approved project"

Date: _____ **Principal Investigator signature**

Supervisor Signature and Stamp

LETTER FROM CONCERNED AUTHORITY FOR PERMISSION OF DATA COLLECTION IN THEIR SETTINGS

RESEARCH TITLE:

_____

_____

NAME OF PRINCIPAL INVESTIGATOR: _____

NATURE OF DATA REQUIRED FROM WARD (tick all the relevant):

- ☐ INFORMATION (QUESTIONNAIRE)
- ☐ Observation (CHECKLIST)
- ☐ Sample of patient (plz specify)_____
- ☐ Procedure/ medication administered (plz Specify) _____
- ☐ Any other (plz Specify)_____

I have read the above said research project and all the necessary documentation related to the project. I will allow the researcher to collect the data from my department, provided the researcher is able to satisfy the Ethical review board of AIMC and obtain the ERB letter.

Name of Concerned Authority: _____

Signature: _____

Stamp of Authority: _____

Date: _____

Guideline for Writing Patient Information Leaflet and Consent Form

- Please note that all these points must be **mentioned with headings in both Urdu and English** in the consent form and that need to be attached before the start of questionnaire.
- Also ensure that the language is easy to understand by lay person and all medical and scientific terms where used are explained easily in simple words.
- In case of experimental study, clearly mention the method of group allocation.
- Mention properly all the possible side effects/complications related to drugs/ procedure/intervention/investigation if any in both consent form.
- You can include any other point that you feel is necessary

Sr. no.	Headings to be added
1.	Research Title, Principal investigator, Location of study, Contact number of investigators included
2.	Topic of study is highlighted
3.	Purpose of the research is explained
4.	Methods and procedures described
5.	Possible risks to the study subjects indicated (mention clearly if there)
6.	Possible benefits to the study subjects explained
7.	Financial burden on the study subjects indicated
8.	Available treatments for adverse experiences mentioned
9.	Confidentiality aspect highlighted
10.	Option of leaving the study by the study subject included
11.	Available sources of information explained

Authorization

This consent has been fully explained to me by **Dr**. (name of researcher) ___and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away legal rights in the case of negligence and other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form intended to replace any applicable federal, state, or local laws.

Participant Name:_____ **Participant's Signature/Thumb Impression**_____

Researcher Name: _____ **Signature:**_____