Fatima Jinnah Medical University Lahore

Checklist for IRB-ERC Application

This checklist is developed to aid investigators to prepare a complete application and to aid expedite the review process by the Institutional Review Board and Ethics Review Committee.

PRINCIPAL INVESTIGATOR NAME _____

DESIGNATION _____ **DEPARTMENT** _____

INSTITUTE _____

- ☐ A copy of IRB-ERC Application form with checklist.
- ☐ A copy of Research Protocol.
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ A copy of informed consent both in English and Urdu or any other local language of the study's population.
- ☐ A copy of Research / Project Questionnaire/ Tool (in English and Urdu or any other local language of the study's population) being administered during the study (if applicable).
- ☐ I have made a copy of this entire application for my files.
- ☐ I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail at irb@fjmu.edu.pk

_____ _____

Name and Signature: Principal Investigator **Date**

_____ _____

Name and Signature of Supervisor (if applicable) **Date**

_____ _____

Name and Signature of Chairman of the Department **Date**

Office of the Research & Publication
Fatima Jinnah Medical University
Sir Ganga Ram Hospital Lahore
Ph: *99200281* ***Fax****: 99203716*

No._____/IERB ***Dated:*** _____

INSTITUTIONAL REVIEW BOARD (IRB)
ETHICS REVIEW COMMITTEE (ERC)
APPLICATION FORM

Name of Principal Investigator (PI): _____

Designation _____ Department _____

Address for correspondence _____

Mobile/Land Line NO. _____ e-mail: _____

Title of Study _____

_____

If the Pl is a student provide the following information:

Discipline/Subject _____ Department _____

Name & e-mail Address of Faculty Advisor

_____

Proposed beginning date of study _____ Estimated duration of study _____

Type of Project (Check all that apply)

PhD Thesis ☐ Master's Thesis ☐ Study ☐ Dissertation ☐ Class project ☐
Faculty research ☐ Pilot ☐ Other (specify) _____

Please refer to instructions while completing this form.
The application may be typed (Calibri 12)

1. **Describe the purpose of study, including Rationale, Objectives, Research question, and/or Hypotheses.**

   _____

   _____

2. Study subjects/participants' Information (use additional paper if required)

a. Description of participants in study

b. Approximate number of participants

c. Vulnerable populations as participants (check all that apply)
Pregnant women ☐ Fetuses/neonates ☐ Minors ☐
Others ☐ (Please specify) _____

d. Age (or age range) of participants: _____
Provide the rationale for inclusion, exclusion on the basis of age
_____
_____

e. Gender of Participants Male ☐ Female ☐ Both ☐
Provide the Rationale for inclusion/exclusion on the basis of gender
_____

f. Participants will be excluded based on ethnicity Yes ☐ No ☐
If yes, provide a description of the exclusion criteria and the rationale for using these criteria:
_____
_____

g. List and provide rationale for any other inclusion/exclusion criteria
_____

3. Describe the recruitment process of study participants/subjects. Attach any recruitment materials or scripts.

_____
_____
_____

4. Describe in detail the research procedures under following heads (use additional paper)

a. Magnitude of problem and current local, national and international information available on the research topic
b. Rationale and objectives
c. Study design
d. Methodology
e. Statistical analysis
f. References (not older than 5 years, must include local or national study)

5. **Does study require follow up?** **Yes** ☐ **No** ☐
   If yes: Duration _____

6. **Location of study**
   Outpatients ☐ **Inpatients** ☐ **FJMU Department** ☐
   Other than FJMU (please specify location) _____
   If multi-institutional or multi-unit

Approval by the concerned head/in charge	
Name	**Designation**
Signature with stamp	

7. **POTENTIAL RISKS AND PROTECTION OF PARTICIPANTS**
   Explain the potential risks to the human participants involved in this research.
   All risks must be identified and listed on the consent form (If applicable).

RISK	STEPS TO MINIMIZE RISK
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(Use Continuation pages if necessary)

8. **Will participants be told about the intent of the study prior to participating?**
   Yes ☐ **No** ☐
   If "No", provide explanation of why such act/deception is necessary and the debriefing method to be used to fully inform the participants of the study's intent.
   _____
   _____

9. **Explain when and how the participants will be given the opportunity to ask Question.**
   _____

10. **Identifiable data:**
    Outline the steps to ensure the confidentiality of identifiable data. Identifiable data includes documents, audio and video recordings, electronic data, and blood or other human specimens.
    a. Explain what identifiable data, if any, will be collected.
    b. Where will identifiable data, if any, will be collected?
    c. Where will identifiable data be stored? (Specify precise location)
    d. Approximate date that identifiable data will be destroyed (dd/mm/yy) _____
    e. If identifiable data will be stored for an indefinite period of time, please explain:
    _____
    f. Identify specific ways that identifiable data will be destroyed at the end of this period of time:
    _____
    _____

BENEFITS/REMUNERATION

11. **What will the participant receive for taking part in the study?**
    (i.e. financial remuneration free services, access to information, and access to an intervention)?
    _____
12. **What are the generalizable benefits of this study?**
    (e.g contribution to knowledge in field).
    _____
13. **Explain when and how the participants will be provided with the result of the study.**
    _____
    _____

14. **Discuss ETHICAL ISSUES involved in the study.**

INFORMED CONSENT

15. **If you will use written informed consent, explain how that consent will be obtained and attach a copy of the consent form according to university guidelines.**

_____

_____

16. **If you will not use written informed consent, provide a detailed rationale and explain how informed consent will be obtained.**

_____

_____

_____

_____

17. Adverse effects:

a. Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

b. What is the provision for managing these effects?

c. Who will pay for them?

18. **In cases where therapeutic need of the research subject is identified during the course of the study:**

a. What is the provision for managing these cases?

b. Who will pay for them?

19. Laboratory and Radiological studies:

a. Will any laboratory/imaging tests be performed which are not routinely included as part of the work-up for these types of patients?

b. Who or what agency will pay for these tests?

20. Has this proposal been submitted to/approved by any other Institute?

Yes ☐ No ☐

If 'YES', Please attach the comments/approval form of the institute.

ASSURANCE

I, _____, from _____,
Principal Investigator for the Research titled
_____
_____
hereby declare that I have read and understood the information/terms/condition required in the application form and the information provided by me is correct.

Name _____ Date _____

Faculty Research Supervisor (for student research only) Signature certifies that the faculty member has read, reviewed, and approved the content of the research and is responsible for the supervision of this research.			
Supervisor Name	**Stamp**	**Signature**	**Date**