Institutional Review Board (IRB)

Jinnah Post Graduate Medical Center
Rafiqui Shaheed Road, Karachi.
Email: jpmc.edu.pk

APPLICATION FORM

Checklist

Dear Applicant: This check list would help you to fill the application form and expedite the process of Institution Review Board, Jinnah Post Graduate Medical Center. Do not attach unnecessary document such as 'Guideline for Informed Consent' etc.

- ☐ Research Protocol with soft copy
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ Informed consent both in English and Urdu or any other local language of the population study with soft copies
- ☐ Questionnaire to be administered during the study (if applicable) with soft copies
- ☐ IRB Application form and soft copy
- ☐ I have made a copy of this entire application for my files.

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Signature: Principal Investigator Date

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Signature of Supervisor (if applicable) Date

Date
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Signature of Co-supervisor

Institutional Review Board
Jinnah Post Graduate Medical Center

How to complete this form and begin the IRB review process

1. This form must not be handwritten. Incompletely and inappropriately filled form will not be accepted for review and discussion in the committee.
2. Fill out all of the questions on this form completely. (If there are questions about using the text form fields or checkboxes with this form, please contact the Research Office, Jinnah Post Graduate Medical Center. Email: jpmc.edu.pk (Please wait 7 – 10 days for the appropriate response).
3. Students' research project has to be signed by supervisor.
4. Fill out and attach the appropriate appendices required by responses in this application.
5. Attach supporting documentation: consent form(s), protocol, survey instruments, interview schedules, advertisements, letters of permission, etc. Consent form and questionnaire should also be submitted in other languages where applicable.
6. Complete the checklist that accompanies this form to ensure all requirements for submission are completed so that review is not delayed.
7. Submit this application and appendices along with the supporting documentation to the Research Department Jinnah Post Graduate Medical Center, Rafiqui Shaheed Road Karachi Pakistan.
8. Please make sure that you submit your proposal between 1st and 15th day of every month to avoid delays in review

Principal Investigator Information:

Title:	Name:
Designation:	
Department or Unit:	
Mailing address:	
Phone (Res.) & Cell:	Email:
Signature:	Date:

Supervisor Information:

Title:	Name:
Designation:	
Department or Unit:	
Mailing address:	
Phone (Res.) & Cell:	Email:
Signature:	Date:

Co-supervisor Information:

Title:	Name:
Designation:	
Department or Unit:	
Mailing address:	
Phone (Res.) & Cell:	Email:
Signature:	Date:

If more than three authors, please write down only name and institution for other authors.

Name	**Institution**	**Email**

1.	**Title of the Project**
2.	**Select one of the categories from the following for your research project**
	a. Clinical trial on a medicine/drug b. Clinical trial on a medical device c. Experimental surgical procedures d. Study administering questionnaires/interviews for quantitative or mixed qualitative/quantitative methods. e. Study involving qualitative methods only f. Study limited to working with human tissue samples, other human biological samples and/or data g. Research data base (secondary data analysis only) h. Research involving animal subjects If any other category, then please write down in the space given below
	Note: Please provide details if study is related to Experimental drug(s) or Non-approved use or non-approved dose for approved drugs
3.	**Subject Information:** a) Study Population: b) Age Range: _____ d) Gender: ☐ Male ☐ Female ☐ Both
4.	**Do you plan to include any participants who are children, pregnant women, mentally retarded, or it is a foetal research?**
	Yes☐ No ☐ (If yes please justify why it is important to take this study population)

5.	**Please give a brief background and Rationale of the study (Max: 300 words)**
6.	**Objectives of the proposed research**
7.	**Methodology of Research**
	a) Study Design
	b) Study Sites
	c) Inclusion and Exclusion Criteria

	d) Sample Size and its justification (Number of IDIs and FGDs in case of Qualitative /studies)
	e) Sampling
	f) Data Collection Tool (Validity and Reliability)
	g) Data Collection methods

	h) Plan of Analysis
8.	**How long do you expect each participant to be in the study in total?**
9.	**Expected duration of the study period (to completion):**
10.	**Potential Risks to participants and their management**
	a) What are the potential risks and burden for research participants and how will you minimise them? (Describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimize risks and burdens as far as possible)
	b) What is the provision for managing the effect?
	c) Who will pay for this?

11.	**Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting?**
	Yes☐ No ☐ If Yes: Please explain how will you address the issue
12.	**Explain the Potential Benefit for:**
	a) Participants
	b) Institution where the research is being conducted
	c) Society as a whole
13.	**What arrangements have been made for persons who might not understand verbalexplanations or written information given in Urdu/English, or who have special communication needs? *(*E.g. translation, use of interpreters)**
14.	**How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality**

15.	**Compensation**
	a) To research participant Monetary Yes☐ No ☐ Amount: Other Yes☐ No ☐ Specify: Re-imbursement of expenses Yes☐ No ☐ Type & Amount:_____
	b) To investigator Yes ☐ No ☐ If yes: (Tick all that apply) Monetary ☐ Travel ☐ Gift ☐ Amount ☐
16.	**Who will have access to participants' personal data during the study?**
17.	**Laboratory and Radiological Studies**
	a) Will any tests be performed which are not routinely included as part of the work-up for these types of patients? Yes ☐ No ☐
	b) Who or what agency will pay for these tests?
18.	**Please give details of how you will inform the participants about the results of the study or justify if not doing so**

19.	**Funding of the Study**
	☐ Funding secured from one or more funders ☐ Funding application to one or more funders in progress ☐ No application for external funding will be made If Yes: Name the funding agency
20.	**Has this or a similar application been previously rejected by a Research Ethics Committee in Pakistan or another country?**
	Yes ☐ No ☐
21.	**Discuss Ethical issues involved in this study**
22.	**Any other information relevant to the study in context of Pakistan**
23.	**Provide references for similar studies conducted in Pakistan and other countries**

Declaration by Principal Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the Ethical Review Board before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the subjects' data.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

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Signature: Principal Investigator Date