The IBN-E-SINA UNIVERSITY MIRPURKHAS SINDH PAKISTAN

Ethical Review Board [ERB]

Email: ISU.EDU.PK

APPLICATION FORM

Instructions / guidelines for researchers

1. Form to be filled out and submitted with the research protocol when requesting IRB review.
2. Please use the IRB 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 take 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.
6. Please attach the separate sheet where necessary.

Note: The PI will be the supervisor of the enrolled postgraduate for the submission of the synopsis.

Name of Principal Investigator:

Desgination:

Department:

Contact No: Email ID:

- Research Protocol soft copy and one hard copy
- Informed consent both in English and Urdu or any other local language of the population study with soft copies & Hard copy
- Questionnaire being administered during the study (if applicable)
- ERB Application.Form (one copy)
- Drug Brochure or any supplementary information enclosed (if applicable).
- I have made a copy of this entire application for my files.

Roll in research	Name & Signature	Date
Principal Investigator		
Supervisor		
Co-Supervisor		
Chairman of Department		

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 Ethical Review Committee,
3. Students' research project has to be sign 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 assure 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 Institutional Review Committee, Sindh Institute of Physical Medicine & Rehabilitation.

Principal Investigator Information:

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

Co Investigators Information:

Title:	**Name:**
Designation:	
Department:	
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 Research Project :** ----------
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2. **Project involves the use of:** *(Check relevant boxes)*

   a) Experimental drug(s)
   b) Radioactive agent(s)
   c) Non-therapeutic research
   d) Non-approved use or non-approved dose for approve drugs
   e) Experimental innovative or new surgical procedures
   f) Fetal Research
   g) Behavioral research
   h) Stem cell research / somatic cell nuclear transfer (cloning)
   i) Observation only
   j) Other (Please specify)

3. **Please provide details in case a, d, e, h or i are checked**.

4. Do you Plan to include any participants who are children, pregnant women, mentally retarated, 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 study

7. Methodology of Research

Study setting	
Study design	
Inclusion and Exclusion Criteria	
Sampling Technique:	
Sample size and its justification	
Data collection tool (validity and reliability)	
Data collection method	
Plan of Analysis (Statistical Analysis)	
Expected Duration of study periods (to completion)	

8. **Potential Risks to participants and their management**

8.1	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)
8.2	What is the provision for managing the effect?
8.3	Who will pay for this?

9. Subject Information:

Group	Patients	Students	Others
Scrutiny of records	Yes	No	
Gender	**Male**	**Female**	**Both**
Age Range: ---------- ----------			
If subjects are children, pregnant women, mentally handicapped persons, prisioners or If is includes foetal research, please provide justification for the need to use these particular subjects ---------- ---------- ----------			

10. . **Potential Risks to participants and their management**

8.1	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)
8.2	What is the provision for managing the effect?
8.3	Who will pay for this?

11. **Will you be providing any compensation to the research subjects?**

Monetary	No	Yes	Amount
Others	No	Yes	Specify
Reimbursement of Expenses	No	Yes	

12. **Will you be providing any compensation to the co-investigations ?**

Monetary Travel Gift Other (Please specify ----------)

13. **Name of the funding Agency (if any):**

14**. Describe possible adverse outcomes/ risks that may affect the subjects?**

15**. What is the provision for the mananging any adverse outcomes as a result of this research?**

16. **Who will pay for these adverse outcomes?**

17. **In case research subjects are patients, will any additional study related tests beperformed which are not routinely required as part of the workup for the patient?**

Yes No

Specify (if marked yes) ----------

18**. Who will pay for these additional tests?**

19. **What are actual potential benefits, if any, to be obtained as a result of this study by:**

18.1 Participants	
18.2 Society	
18.3 Funding agency or sponsors.	
18.4 Institution where the research conducted?	

20. **How will you ensure confidentiality of your subjects?**

21**. What arrangement have been made for persons who might not understand verbal explanations or written information given in Urdu/English, or who have special communication needs?(e.g. translation, use of interpreters)**

22. **How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.**

23. How do you plan to access, store and distribute any collected biological material? Guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available on National Bioethics Committee website: http://nbcpakistan.org.pk/guidelines.html

24. Who will have access to participants personel data during the study?

25. **Please give details of how you will inform the participants about the results of the study or justify if not doing so**

26. **Funding of the study**

- ☐ Funding 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?

27. **Has this or a similar application been previously rejected by a Research Ethics Committee in Pakistan or another country?**

Yes ☐ No ☐

28. **Discuss ETHICAL ISSUES involve in the study?**

29 **Any other information relevant to the study in context to Pakistan?**

30. **Provide references for similar studies conducted in Pakistan and other countries?**

Declaration Statement

I, ---------- am the principal investigator of the research proposal titled "----------
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Declared that I have neither started the data collection for this study nor planned to do so until I recveive approval from Ethical Review Board ISU.

Signiture of Principal Investigator

Name:

Discipline/ Designation/ Department:

Signiture of enrolled postgraduate

Date ----------