

# Institutional Review Board (IRB)

Sindh Institute of Physical Medicine & Rehabilitation

Chand Bibi Rd, Deli Colony Ranchore Lane,

Karachi, Sindh

**APPLICATION FORM**

###### Checklist

Dear Applicant: This check list would help you to fill the application form and expedite the process of Institutional Review Board, SIPMR. Do not attach unnecessary document such as ‘Guideline for Informed Consent’ etc. Please submit:

* One printed and one soft copy for each of the following documents:

Research Protocol

Informed consent both in English and Urdu or any other local language of the population study with soft copies.

Questionnaire being administered during the study (if applicable)

IRB Application.

Drug Brochure or any supplementary information enclosed (if applicable).

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

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Signature of Chairman of the Department Date

Institutional Review Board

**Sindh Institute of Physical Medicine & Rehabilitation**

#### 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 Institutional Review Committee, Sindh Institute of Physical Medicine & Rehabilitation irb@sipmr.edu.pk. (Please wait 7 – 10 days for the appropriate response).
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.

Date:

 Day Month Year

1. Title of Research Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Principal Investigator Information:**

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| Name: Title …… First……………….. Middle …………. Last ……………….  |
| Department or Unit: |
| Institution: |
| Designation: |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email:  |
| Signature of PI:  | Date:  |

**Co Investigators Information:**

**1.**

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| --- |
| Name: Title …… First……………….. Middle …………. Last ……………… |
| Designation:  | Department or Unit:  |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email:  |
| Signature of Co-Investigator:  | Date:  |

**2.**

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| --- |
| Name: Title …… First……………….. Middle …………. Last ……………… |
| Designation:  | Designation:  |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email: |
| Signature of Co-Investigator:  | Date: |

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

1. Please indicate whether you are applying for ERC exemption, fast track or full committee review?

Exempted Fast Track Full review

1. Select one of the categories for your research project.

Behavioral research

Clinical Trial

Experimental drug(s)

Experimental surgical procedures

Fetal research

Gene molecular cloning

Non-approved use or non-approved dose for approved drugs

Non-therapeutic research

Observational research

Radioactive agents

Registry

Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is this study a part of students/resident synopsis?

Yes No

1. If ‘yes’ then: Undergraduate Resident MPhil/PhD
2. Is the study: Funded Non-Funded

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| Note: Please provide details if study is related to Experimental drug(s) or Non-approved use or non-approved dose for approved drugs |

1. Do you plan to include any participants who are children, pregnant women, mentally retarded, or prisoners or it is a foetal research?

Yes 🞏 No 🞏

(If yes please justify why it is important to take this study population)

1. Give a brief background and rational of the study

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1. Objectives of the proposed research.

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1. List the principal inclusion and exclusion criteria,

7. Subject Information:

1. Write down a brief methodology and procedures involved in this study (<100 words).

 a) Group: Patient Student Others

 b) Records: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 c) Age Range: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 d) Gender: Male Female Both

1. How long do you expect each participant to be in the study in total?
2. Expected duration of the study period (to completion):

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| From: To: |

15. (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?

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c. Who will pay for this?

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16. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting?

 Yes No

17. What are the potential benefits for the research?

a) To the investigator (s)

b) To the participants

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| c) To the Society  |
| d) To the funding agency  |
| e). To the institution: |

18. 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)

19. 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.

20. Compensation:

To research subject:

Monetary Yes NoAmount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other Yes NoSpecify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Re-imbursement of expenses: Yes NoType Amount:\_\_\_\_\_\_\_\_\_\_\_

To investigation Yes No

if yes: Monetary Travel Gift  Amount **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

21. Who will have access to participants' personal data during the study?

22. Laboratory and Radiological studies:

1. Will any tests be performed which are not routinely included as part of the work-up for these types of patients? Give detail:

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

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23. Will you inform participants of the results of the study?

Yes No

Please give details of how you will inform the participants or justify if not doing so.

24. (a) What is the sample size for the research?

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(b) How many participants/samples/data records do you plan to study in total?

(c) How as the sample size decided?

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25. Has funding for the research been secured?

* Funding secured from one or more funders
* Funding application to one or more funders in progress
* No application for external funding will be made

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

Yes No

27. Is this study?

* Single centre
* Multicentre in same city
* Multicentre in different cities/country

28. Where will the research take place?

29. Discuss ETHICAL ISSUES involve in the study?

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30. Any other information relevant to the study in context to Pakistan?

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 31. Has the study conducted elsewhere earlier?

if yes Where? Mention the references:

**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 Institutional 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