Ethical Review Consideration Form

Principal Investigator Information:

Title:	Name:
Designation:	Department or Unit:
Mailing address (Office):	
Phone:	Email:
Signature of PI:	Date:

Co-Investigators Information:

1.

Title:	Name:
Designation:	Department or Unit:
Mailing address (Office):	
Phone:	Email:
Signature of Co-Investigator:	Date:

2.

Title:	Name:
Designation:	Department or Unit:
Mailing address:	
Phone:	Email:
Signature of Co-Investigator:	Date:

If, there are more than three authors, please write down only the names and institution for of remaining other authors.

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1. Title of Research/Project: _____
2. Select the category/ies that align with your research project.

    a. Clinical trial on a medicine/drug
    b. Clinical trial on a medical device
    c. Experimental/ surgical procedure/s
    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 database (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 the study is related to Experimental drug(s), non-approved use, or non-approved dosage for approved drugs.

3. Do you plan to include any participants who are children or pregnant women?

    Yes ☐ No ☐

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

4. Please provide a one-page summary of the research project, including details of research methodology (use simple language but give details of how the study will take place).
5. Aims & Objectives of the proposed research.
6. What is the scientific justification for this research?
7. Please enlist the principal inclusion criteria
8. Please enlist the principal exclusion criteria
9. Please describe the methodology and procedures involved in this study.
10. How long do you expect each participant to be in the study?
11. Please complete the columns for each intervention/procedure as follows:

    a. Total number of interventions/procedures to be received by each participant as part of the research protocol.
    b. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
    c. Average time taken per intervention/procedure (minutes, hours or days)

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d. Who will conduct the intervention/procedure, and where, it would take place?

12. What are the potential risks 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)
13. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing, or upsetting?

    Yes ☐ No ☐

If yes give details.

14. What are the potential benefits for the research participants?
15. How and by whom will potential participants first be approached?
16. How long will you allow potential participants to decide whether or not to take part?
17. 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)
18. Please describe the physical security arrangements for storage of personal data during the study.
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. Who will have access to participants' personal data during the study?
21. Ownership of the data.
22. Laboratory and Radiological studies:
23. Will any tests be performed which are not routinely included as part of the work-up for these types of patients?
24. Who or what agency will pay for these tests?
25. How do you intend to report and disseminate the results of the study?
26. 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.

27. What is the primary outcome measure for the study?

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28. What is the sample size for the research? How many participants/samples/data records do you plan to study in total?
29. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.
30. 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
    - ☐ Give details.
31. Has this or a similar application been previously rejected by a Research Ethics Committee in Pakistan or another country?

    Yes ☐ No ☐
32. How long do you expect the study to last in Pakistan?
33. Is this study?
    - ☐ Single centre
    - ☐ Multicentre
    - ☐ Did you acquire any permissions from the in-charge of centre/s for this study?

31. Where will the research take place?

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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

ATTACHMENTS REQUIRED:

1. Consent Form
2. Research Proposal/Synopsis
3. Research Instrument/Questionnaire

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