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| **Guidelines for Submitting a Synopsis to the Ethics Review Board (ERB)RMU** | **RMU -R&D -SOP-01** | **Rev: 0**  **Dated: 24.06.2024**  **Pages:** |

**Purpose:**

To establish a clear and systematic process for obtaining approval from the Ethics Review Board (ERB) for research proposals.

**Scope:**

This SOP applies to all researchers intending to submit research proposals for IRF-ERB approval within and outside the institution.

**Procedure:**

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| **1. Preparation of Research Proposal Synopsis** | **Responsibilities** |
| 1. Researchers must prepare a research synopsis according to standard guidelines in coordination with the supervisor and co-supervisors and submit the hard copy duly signed and indicating date of submission. 2. Resident researcher should finalize the title of the study in coordination with R&D RMU before getting approval from DRB and document feedback on the synopsis in their research logbooks 3. The title should be specific enough to indicate the scope and nature of the study. It should reflect the key aspects of the research question or hypothesis along with study design and setting 4. This document should clearly outline the proposed study's objectives, methodology, significance, and ethical considerations as per the R&D research guide. (annex -a) 5. The researcher conducting RCTs will be required to follow DRAP guidelines for registering RCTs as per RMU policy | Researcher, Supervisor  Departmental Review Board |
| **2. Submission of Hard Copy** |  |
| It is recommended to line in the submission 15 days before the ERB meeting to ensure enough time for internal review and processing. | Mr. Jaber |
| **3. Initial Review and Scrutiny Process** |  |
| a. The R&D Department team will conduct an initial review of the submitted synopsis. | Dr Abdul Qadoos  Dr. Sarah Rafi  Mr Aamir Afzal  Dr Farrah Pervaiz |
| b. Any feedback, comments, or required changes will be communicated back to the researcher within a week and will be documented in the synopsis feedback register (No.----) and residents research log book | Dr Abdul Qadoos  Dr. Sarah Rafi  Mr. Aamir Afzal  Dr Farrah Pervaiz |
| c. The researcher must make all the necessary changes and revisions to the synopsis as suggested by the R&D. | Researcher and Supervisor |
| d. Revised documents must be communicated back to the ERB office 5 days before the scheduled ERB meeting. | Jaber  Dr Haq Nawaz |
| **5. Submission of Final Documents** |  |
| a. A final hard copy of the revised synopsis, along with the checklist (annex – b) and presentation materials, must be submitted a minimum of 3 days before the scheduled ERB meeting. | Researcher and Supervisor |
| b. A Director / Additional Director / should countersign the final documents as a sign-off on the documents' completeness and accuracy. | Dr Shagufta  Dr Farrah Pervaiz  Dr Sarah Rafi |
| **6. Guidance on Proposal Submission** |  |
| a. No synopsis or research proposal will be entertained without following the guidance for submission |  |
| **7. Feedback and Documentation** |  |
| 1. The supervisor should be present in the ERB meeting at the time of the synopsis presentation 2. Researchers are responsible for noting down all the suggested changes and incorporating this feedback and for maintaining records of all communications with the IRF & ERB. 3. After the ERB meeting, the outcome, along with the feedback given by the IRF, will be documented regularly in minutes of the meeting to the relevant participants | Researcher and Supervisor  Jaber  Dr Sarah Rafi  Dr Haq Nawaz |
| **9.** **Issuance of ERB Letter** signed by the competent authority within 2-3 weeks | Jaber  Dr Sarah Rafi  Dr Farrah Pervaiz |
| **10. Documentation:** |  |
| All documents, communications, and revisions must be properly filed and stored in the corresponding research project file. | Jaber  Dr Haq Nawaz |
| **11. Compliance:** |  |
| Failure to comply with this SOP may result in delays or the non-acceptance of the research proposal. |  |
| **Revision History:** |  |
| This SOP is subject to review and revision as necessary. Any revisions must be approved by the ERB chairperson and communicated to all relevant parties. | Vice Chancellor  Chairperson ERB  Director R&D |
| This SOP has been created following the institution's policies and ethical guidelines for the conduct of research. |  |

**Research Synopsis Format**

**Annex-a**

1. **Title Page**

* Title: Clearly state the title of your research project mentioning the study design and site.
* Principal Investigator / Researcher: Include the principal investigator's/researcher's name, designation, contact details, and year of training.
* Co-Investigators / Supervisor: List the names, designations, and contact details of all co-investigators.
* Date: Date of Submission of synopsis
* Research ID:

**2. Introduction**

Background: Describe the context and significance of the study, including a brief literature review.

Rationale: Explain the need for the study and its potential contributions to the field.

**3. Objectives**

Clearly state the primary and secondary objectives of the research.

**4. Methodology**

* **Study Design**: Outline the design of the study, including type (e.g., observational, experimental), duration, and setting.
* **Participants:** Describe the study population, including inclusion and exclusion criteria.
* **Sampling and sample size estimation**
* **Data Collection:** Detail the methods for data collection, including tools, procedures, and timelines.
* **Data Analysis:** Explain the statistical methods and software that will be used for data analysis.

**5. Ethical Considerations**

* Informed Consent: Describe the process for obtaining informed consent from participants.
* Confidentiality: Explain how participant confidentiality will be maintained.
* Risk and Benefit: Assess the potential risks to participants and the measures taken to minimize these risks, as well as the expected benefits of the research.

**6. Budget and Funding**

Provide a detailed budget, including all anticipated expenses.

Mention any sources of funding or grants, if applicable.

**8. Timeline**

Present a realistic timeline for the completion of the study, including key milestones.

**9. References**

Include a list of all references cited in the synopsis, formatted according to the specified citation style.

**10. Appendices**

Attach any additional documents relevant to the study, such as survey instruments, consent forms, and letters of support.

**Checklist of documents to be submitted to R&D Annex-b**

1. Faculty / PGT/ Visitor research application
2. Letter of Collaboration (visitor researchers)
3. Updated ERB PowerPoint ppt according to the R&D RMU template
4. Approval from DRB/ parent institution
5. Consent form/ assent form in case of pediatric study population
6. Study budget
7. Data collection forms/ tools