

PUIEC Proposal Submission Template

1. Cover Letter: addressed to Member secretary, Panjab University Institutional Ethics Committee Panjab University Chandigarh

2. RDC approval letter

3. Title Page - Study Title: - Principal Investigator (PI): - Co-Investigators: - Department / Institution: - Date of Submission:

4. Letter of Institutional/Departmental Support: To certify that the department/ institution has the necessary infrastructure, equipment, and facilities to conduct the proposed research safely and effectively.

5. Synopsis / Summary –

i) Brief Study Rationale: -

ii) Aims & Objectives (Primary & Secondary): -

6. Materials / Equipment / Investigational Products –

7. Material & Methods:

i) Study Design - Type of Study (Observational / Interventional / In Vitro / Other):

ii) Duration

iii) Sample Size Calculation & Justification:

iv) Inclusion/ Exclusion Criteria

v) Study Setting: Recruitment Method, Intervention Details, Outcome Measures

vi) Methodology

8. Data Collection and Management - Data Source(s): - Case Report Forms (CRFs) / EMR Usage: - Data Confidentiality Measures: - Data Storage and Retention:

9. Statistical Analysis - Planned Statistical Tests, Significance Levels, Software to be used, Handling Missing Data

10. Ethical Considerations -

11. References - List relevant references here

12. Annexures – i) Participant Information Sheet (English / Hindi/Punjabi)

ii) Informed Consent Forms (English / Hindi/Punjabi)

iii) Questionnaires / SOPs / Additional Documents

iv) CVs of investigators/co-investigators