

30. RESEARCH PROTOCOL PROFORMA:



INSTITUTIONAL ETHICS REVIEW BOARD

Jawaharlal Nehru University

New Delhi-110067

Name of the Principal Investigator/Supervisor:

Center of..... and School of

Detailed Information of the Study:

I.

- 1) Introduction
 - 1.1 Purpose
 - 1.2 Background & Justification
- 2) Methodology
 - 2.1 Study Design
 - 2.2 Study Objectives
 - 2.3. Study Setting (Exact place where the study will be conducted):
 - 2.4 Number of Subjects (with rationale)
 - 2.5 Minimizing Study Bias
 - 2.6 Subject Selection
 - 2.7 Inclusion/Exclusion Criteria (detail in bulleted points)
- 3) Procedure
 - 3.1 Center Readiness (Faculties available)
 - 3.2 Informed Consent
 - 3.3 Enrollment
 - 3.4 General Data Collection Requirement
 - 3.5 Specific Case Study: Longitudinal /Cross-sectional
 - 3.6 Status of withdrawal and the Plan in such a situation
 - 3.7 Conflict of interest for any other investigator(s)
- 4) Statistical Methods & Data Analysis
- 5) Data Management
- 6) Risk Analysis
 - 6.1 Potential Risk
 - 6.2 Risk Minimization
 - 6.3 Potential Benefits
- 7) Warranty
 - 7.1 Insurance
- 8) Monitoring and Auditing

8.1 Procedures and Responsibilities

8.2 Source of Funding (Name and details of funding agency; attach a copy of the sanction letter)

9) Records and Reports

10) Preliminary Publication Plan

10.1 Expected Outcome

10.2 Authorship Selection Criteria

10.3 Printing and Ancillary Publication

II. Investigator's Brochure Including Report of Prior Investigations

III. Informed Consent

IV. Insurance Statement (Wherever required):

For example, Appropriate insurance/indemnity provisions have been made to cover research-related injury or harm to participants, as per applicable regulatory guidelines. In case of any adverse event, necessary medical management and compensation will be provided in accordance with institutional policy and national regulations.

P.S. *The students are required to enclose a copy of the registration certificate and synopsis of their M.Sc./M.A./Ph.D. Research Proposal as approved by the Faculty/Supervisor/BoS.*

DECLARATION BY THE INVESTIGATOR(S)

- 1) I certify that the research proposal submitted herein is original and is not a duplication of any previously conducted or reported study, except where appropriately cited.
- 2) I undertake to obtain approval from the Institutional Ethics Review Board (IERB), Jawaharlal Nehru University, New Delhi, prior to the initiation of the research study.
- 3) I further undertake to seek prior approval from the IERB, JNU, New Delhi, for any protocol amendments or significant changes in the study design, methodology, or conduct.
- 4) I undertake to maintain complete and accurate records of all research activities and to make them available for review, audit, or inspection by the IERB or other authorized authorities, as and when required.

Signature and Name of the Research Scholar

Signature and Name of the PI

Signature and Name of the Co-PI's

Date:

Place: