

INSTITUTIONAL ETHICAL COMMITTEE, NDCH (IEC, NDCH) PROFORMA II

(RESEARCH UNDER OTHER REGULATORY BODY)

- 1. Title
- 2. Background & Justification
- 3. Brief Review Of Literature
- 4. Research Question
- 5. Formulate The Question In Pico Analysis Format:
  - a) Patient/Population/Problem:
  - b) Intervention:
  - c) Comparison:
  - d) Outcome:
- 6. Aims & Objectives & Hypothesis
- 7. Primary Outcome Of The Study:
- 8. Secondary Outcome Of The Study:
- 9. Detailed Methodology
  - a) Study design: Prospective/Retrospective/Observational/Interventional/etc
  - b) Sample size: (with justification)
  - c) Sampling technique
  - d) Randomization (if any)
  - e) Details of clinical examination (if any) (attach one proforma)
  - f) Details of questionnaire (if any) (attach one sample questionnaire)
  - g) Details of investigations (if any) and how the sample will be obtained and processed
  - h) Details of data tabulation and statistical methods to be employed
- 10. Timeline
- 11. Budget/Expenditure And How The Finances Will Be Met
- 12. Expected Outcome/Benefit To Institution/Society
- 13. Area Of The Project
- 14. Collaboration Details
- 15. Regulatory Body To Be Submitted To
- 16. If Yes Details Of The Body

Professor & Head, Dept of .....