

Submission Format for Review of Investigator Initiated Research Proposal
INSTITUTIONAL ETHICS COMMITTEE - 2
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

Instructions:

- None of the following headings should be omitted or changed
- Use 11/ 12pt Times New Roman/ Calibri, 1.5 spacing
- Write continuous text [except for aims, inclusion or exclusion criteria]
- Use both sides of page to avoid paper wastage
- Only 1 hard copy to be submitted
- Upload the .doc/ .docx file in eEC Software under respective heading
- Highlight changes in '**red**' on resubmissions after IEC review
- Submit the hard copy along with application for research proposal as per Annexure 4

----- X -----

1. Brief summary of intended work:

1.1 Need for the study [including operational definition of variables]

1.2 Review of literature

1.3 Objectives of the present study

2. Material and method:

2.1 Source of data [area or institute from where samples will be collected]

2.2 Methodology [brief description]

- consider feasibility of method in context of resources

- inclusion & exclusion criteria, sampling procedures etc.

- requirement of any investigations or interventions to be conducted on participants

2.3 Plan of statistical analysis [Details of tables, tests and other statistical analysis]

3. Ethical issues:

3.1 Informed consent process [justify, if asked for waiver]

3.2 Steps proposed for protection of participants from unanticipated harm arising out of the study

[Including privacy and confidentiality]

3.3 Plan of publication at the end of study

3.4 Declaration about amount of funds required and its source

4. Contribution of the research project

[How the research will benefit the community at large; measures to be undertaken to address the identified problem]

5. References [to include only those references that are cited in the proposal]

(Refer to http://www.nlm.nih.gov/bsd/uniform_requirements.html for guidance to referencing standards)

Title of project:

Proposals not in format would not be accepted. Kindly print on both sides of the page, Save Paper.