Prescribed Application Form for Clearance of Research Project by IEC

a. Name of the Investigator/co-investigator with designation:
b. Name of the Department where research will be conducted:
c. Protocol of the proposed research involving human samples / participants:
d. Ethical issues in the study and plans to address these issues:
e. Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards, etc.:
f. Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language /English / Hindi:
g. For any drug / device trial, all relevant publications / pre-clinical data and clinical trial data from other institutions within the country / other countries, if available :
h. Curriculum Vitae of all the investigators with relevant publications during the last five years:
i. Regulatory clearances (other than IEC, NEIGRIHMS), if required:
j. Details of Funding agency/sponsors and fund allocation for the proposed work.
k. An agreement to report only Serious Adverse Events (SAE) to IEC:
l. Statement of conflicts of interest, if any:
m. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research:
n. Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants:
o. Agreement to comply with the relevant national guidelines for research in human genetic, transplantation etc, as and when applicable.
p. Any other information relevant to the study:

Signature of Principal Investigator (PI)
Place:
Date:

Signature of Co-investigator(s)
Place:
Date:

The protocols should include among other things of the following

a. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
b. Subject recruitment procedures.
c. Inclusion and exclusion criteria for entry of subjects in the study.
d. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedure, if any.
e. A description of plans to withdraw or withhold standard therapies in the course of research.
f. The plans for statistical analysis of the study.
g. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
h. Storage and maintenance of all data collected during the trial.
i. Agreement to comply with national and international GCP protocols for clinical trials.