INSTITUTIONAL ETHICS COMMITTEE (IEC)

RESEARCH PROTOCOL FORMAT

TITLE PAGE

1. Title of the study
2. Details of the principal investigator and co-investigator(s) (name, present designation, department and contact no., e-mail address)
3. Signature of the principal investigator and co-investigator(s)
4. Signature of the head of department

PROTOCOL

[All of the following points are mandatory. Wherever not applicable, please mention: "Not Applicable".]

1. Rationale for undertaking the project:
2. Objectives of the study
3. Methodology of study:
   (a) Type of study design (observational, experimental, pilot, randomized, blinded etc.)
   (b) Precise description of methodology of the proposed research, including
      a. Sample size (with justification),
      b. Participant recruitment procedures in detail
      c. Inclusion and exclusion criteria for entry of participants
      d. Details on how randomization and blinding will be carried out
      e. Intended intervention (mention procedure of intervention in detail)
      f. Dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any.
      g. Monograph on drugs used in the study for intervention; if applicable
      h. Safety of proposed intervention (e.g. drug, vaccine, surgical procedure) to be tested, including results of relevant laboratory and animal research
      i. Outcome measures for the study in detail
   (c) Plan to withdraw or withhold standard therapies in the course of research
   (d) Plan for statistical analysis of the study

4. A statement on probable ethical issues, confidentiality, protection of vulnerable participants and steps taken to tackle the same.

5. Plan to provide medical therapy for any risk, injury or toxicity due to overdose during the study duration and policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.

6. Agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.

7. Details of funding agency or sponsor & fund allocation for proposed work

8. Contribution of research project to hospital, state and country

9. Regulatory clearances pertaining to trial on drugs/ devices/ vaccines/ herbal remedies as applicable.

10. For studies involving multiple institutes / centers / authorities a MoU / agreement / letter of permission between the collaborating partners is mandatory.

11. A statement on conflict-of-interest (COI), if any.

12. References.