ICMR GUIDELINES

SUBMISSION OF APPLICATION

The researcher should submit an appropriate application in a prescribed format along with the study protocol. The protocol should include the following:

1. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
2. Recent curriculum vitae of the investigator indicating qualification and experience.
3. Subject recruitment procedures.
4. Inclusion & exclusion criteria for entry of subjects in the study.
5. Precise description of methodology of the proposed research including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
6. A description of plans to withdraw or withhold standard therapies in the course of research.
7. The plans for statistical analysis of the study.
8. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and vernacular languages.
9. Safety of prepared intervention and any drug or vaccine to be tested, including results of relevant laboratory & animal research.
10. For research carrying more than minimal risk, on account of plans to provide nominal therapy for such risk or injury or toxicity due to over dosage should be included.
11. Proposed compensation and reimbursement of incidental expenses.
12. Storage and maintenance of all records collected during the trial.
13. A statement on probable ethical issues and steps taken to tackle the same.
14. All other relevant documents related to the study protocol including regulatory claim.
15. Agreement to comply with national and international GCP protocol for clinical trials.
16. Details of funding agency/sponsors and fund allocation for the proposed work.