

Checklist for IEC submission (all in 11 copies)

- 1. Written application (address to member secretary/coordinator) along with details of documents submitted with their version number, date from the principal investigator**
- 2. Final protocol with all amendments with version, date and number etc.**
- 3. Case record form (CRF) with version, date, and number.**
- 4. Patient informed consent form and Patient information sheet in English and translated in Gujarati and Hindi with appropriate translation certificates with version, date, and number.**
- 5. Investigator's Brochure, safety related information and published reports of earlier investigation, if any.**
- 6. Clinical trial insurance policy with proposed compensation (covering the subjects, investigators and hospital), (To be signed and dated).**
- 7. Copy of the notification of any payments proposed to be made to study subjects towards reimbursements of incidental/travel expense.**
- 8. Copy of permission from regulatory authorities (DCGI) with version, date, and number.**
- 9. Undertaking by sponsor for free medical management for as long as required and financial compensation in case of serious adverse event or injury related to trial**
- 10. Certificate of GCP training by investigator**
- 11. Clinical trial agreement tri-partite or four-party (To be signed and dated)**
- 12. Investigator's undertaking to comply with national and international GCP protocols for clinical trials (To be signed and dated).**
- 13. CV of principal investigator**
- 14. Details of the funding agency / sponsors and fund allocation for the proposed work.**
- 15. Private sponsor's Rs. 30,000/- deposit in Rogikalyan Samitee (cheque / D.D. in the name of Rogikalyan Samitee, CHA).
Original receipt to be attached with the application.**