



## **INSTITUTIONAL ETHICS COMMITTEE** **SMT. NHL MUNICIPAL MEDICAL COLLEGE, AHMEDABAD**

### **CHECKLIST OF DOCUMENTS TO BE SUBMITTED BY THE INVESTIGATOR AT THE MINIMUM:**

The applicant of the proposal generally the principal investigator is required to submit his/her application letter and 12 copies of a dossier comprising of following documents, at least 15-20 days before a scheduled meeting:

- The PI will submit the application for the proposed Clinical Trial.[1 copy only]
- Research protocol.
- Protocol Amendment, if any.
- Investigator's Brochure.
- Case Report Form
- Informed consent form, [English]
- Informed consent form, [English to Gujarati translation].
- Informed consent form, [Gujarati to English back translation].including translation certificate [1 copy]
- Informed consent form, [English to Hindi translation].
- Informed consent form, [Hindi to English back translation].including translation certificate [1 copy]
- Patient/ volunteer information Leaflet [English]
- Patient/ volunteer information Leaflet [English to Gujarati translation].
- Patient/ volunteer information Leaflet [Gujarati to English back translation].including translation certificate [1 copy]
- Patient/ volunteer information Leaflet [English to Hindi translation].
- Patient/ volunteer information Leaflet [Hindi to English back translation].including translation certificate [1 copy]
- Safety Reports[where required]
- DCGI Approval Letter [1 copy]
- Insurance Policy [1 copy]
- Import license, where applicable[1 copy]
- Investigator's undertaking[1 copy]
- Registration number with Clinical Trial Registry of India (CTRI)
- Curriculum vitae of Principal Investigator
- Copy of Medical Council Registration certificate & "Good Clinical Practices" training certificate of Principal Investigator
- Clinical trial Agreement (CTA) as per existing rules of the Institution, as on the date of submission of the protocol. A tri-partite or four-party clinical trial agreement [CTA] will be done, including "Institutional Head/ Dean, Smt NHL Municipal Medical College" as one of the party. The Financial distribution pattern shall be decided as per the resolution of the governing body of the AMC Medical Education Trust. All payments proposed to be made to the Principal Investigator by the sponsor, for the study shall be made to the institution directly and shall be then disbursed by the institution with the consent of the Dean/Institutional Head and the Principal Investigator.*
- The NHLIEC is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.*
- The total fees for consideration of the protocol/clinical study in question which includes Ethics Committee Members Conveyance Allowance will be Rs.50,000. The fees for any protocol &/or other amendment/s as well as for serious adverse event (SAE) review meeting in the study shall also be Rs.50,000 and should be in the form of a cheque addressed to "Institutional Ethics Committee, Smt. NHL Municipal Medical College"*
- It will be a responsibility of the PI & SPONSOR/CRO/SMO (Whatever applicable) to acknowledge the Institute Head & NHLIEC regarding any changes in the Financial Transactions from the SPONSOR/CRO/SMO (Whatever applicable) within 15 working days.*

**Member Secretary, NHLIEC**

**Date:**