INSTITUTIONAL ETHICS COMMITTEE
Smt. NHL MUNICIPAL MEDICAL COLLEGE, AHMEDABAD

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

The PI will submit the application for the proposed Clinical Trial in a particular format as given on website. [1 copy only]

Research protocol. [12 copies of each]

Protocol Amendment, if any, [12 copies of each]

Investigator’s Brochure. [12 copies of each]

Case Report Form [12 copies of each]

Informed consent form, [English] [12 copies of each]

Informed consent form, [English to Gujarati translation], [12 copies of each]

Informed consent form, [Gujarati to English back translation]. [12 copies of each] including translation certificate

Informed consent form, [English to Hindi translation]. [12 copies of each]

Informed consent form, [Hindi to English back translation], [12 copies of each] including translation certificate [1 copy]

Patient/ volunteer information Leaflet [English] [12 copies of each]

Patient/ volunteer information Leaflet [English to Gujarati translation]. [12 copies each]

Patient/ volunteer information Leaflet [Gujarati to English back translation]. [12 copies of each] including translation certificate

Patient/ volunteer information Leaflet [English to Hindi translation]. [12 copies each]

Patient/ volunteer information Leaflet [Hindi to English back translation]. [12 copies of each] including translation certificate [1 copy]

Safety Reports [1 copy]

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)

Clinical trial Agreement (CTA) - A tri-partite or four-party clinical trial agreement as per the new financial distribution pattern, will be done by the parties involved, including “Institutional Head/Dean, Smt NHL Municipal Medical College” of AMC Medical Education Trust, as one of the party. A copy of the draft CTA should be approved by the undersigned before finalizing.

The NHLIEC is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.

The PI will also sign a “Financial Disclosure Statement” as given on website.
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 workings days.

Latest resume, Certificate of Medical Registration and Good Clinical Practices (GCP) training Certificate of Principal Investigator

The fees for the consideration of the protocol/clinical study in question will be Rs.20,000(INR). The fees for any protocol &/or other amendment/s in the study shall also be Rs.20,000 (INR) and should be in the form of a cheque addressed to “AMC Medical Education Trust”

Ethics Committee Members Conveyance Allowance has to be given by sponsor/Investigator as per the existing rules as on the date of submission of the protocol/amendment. The member secretary will be aware of the amount decided by the Institutional Head.

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 as per the “Financial distribution pattern” in the CTA by the institution with the consent of the Dean/Institutional Head and the Principal Investigator.

Notification of randomization of first patient

Any Serious Adverse Events occurring in the course of the study within 24 hrs. of their occurring [Report directly to Chairperson]

Any changes in the protocol and patient information/informed consent documents, prior to their implementation.

Amendments/revisions to any study-related document as well as patient safety related information

Study completion and discontinuation with reasons

Justification for approval to restart studies discontinued earlier

The final report of the study shall be submitted to the NHLIEC in all cases, even when the study abandoned for any reason (s).

SUSAR reports(if any)

CIOMS-supporting SUSAR reports

Member Secretary
Institutional Ethics Committee

Date: