

Undertaking by Principal Investigator - Academic Clinical Trial
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR – Academic Clinical Trial

1	Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)	
2	Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)	
3	Name and address of all clinical laboratory facilities to be used in the study	
4	Name and address of the Ethics Committee that is responsible for approval and continuing review of the study	
5	Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations	
6	Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator	
7	Name and address of the Sponsor [for internal projects, Institute shall be the Sponsor]	

8. Commitments:

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals, if needed, have been obtained.
- (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor [if any including Head of Institute] and prior review and documented approval or favourable opinion from the Ethics Committee of the amendment, except where necessary to

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- eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
- (iii) I agree to personally conduct or supervise the academic clinical trial at my site.
 - (iv) I agree to inform all trial participants, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019, Good Clinical Practices guidelines and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 are met.
 - (v) I agree to report to the Sponsor [if any, including Head of Institute] all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
 - (vi) I am aware of the potential risks and side effects of the drug to be used for Academic Trial purposes.
 - (vii) I agree to ensure that all associates, colleagues, students and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the academic trial.
 - (viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor [if any, including Head of Institute], Ethics Committee, Central Licencing Authority or their authorised representatives [if needed], in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor [if any, including Head of Institute].
 - (ix) I agree to promptly report to the Ethics Committee all changes in the academic clinical trial activities and all unanticipated problems involving risks to human participants or others.
 - (x) I agree to inform all serious adverse events to the Sponsor [if any, including Head of Institute] as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Ethics Committee along with the report of the serious adverse event.
 - (xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Chairperson of the Ethics Committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
 - (xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.
 - (xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to Investigators participating in academic clinical trials.

Signature of Investigator with date