**ANNEXURE.10: FORM V**

**UNDERTAKING BY THE INVESTIGATOR**

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator):

Email ID:

Contact No:

1. 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, and /or other statement(s) of qualification(s)
2. Name and address of all clinical laboratory facilities to be used in the study.
3. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
4. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
5. Protocol Title and study number (if any) of the clinical trial to be conducted by the Investigator.
6. Commitments:
   1. 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 have been obtained.
   2. 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 and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, expect where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.
   3. I agree to personally conduct and/or supervise the clinical trial at my site.
   4. I agree to inform all trial subject, 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 and Good Clinical Practices guidelines are met.
   5. I agree to report to the sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.
   6. I have read and understood the information in the Investigator’ brochure, including the potential risks and side effects of the drug.
   7. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about obligations in meeting their commitments in the trial.
   8. I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, Ethics Committee, Licensing Authority or their authorized representative, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.
   9. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risk to human subjects or others.
   10. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor 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 Central Licensing Authority along with the report of the serious adverse event.
   11. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, 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.
   12. I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.
   13. I agree to comply with all other requirement, guidelines and statutory obligations as applicable to clinical Investigator participating in clinical trials.

Signature of Investigator with date.