UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and current work place/organization of the Chairman

2. Name and complete address of office of the Ethics Committee

3. Name, address, qualifications (specialization), current work place/organization, designation of the members of the Ethics Committee and affiliation status of each member of Ethics Committee with the Institute/organization that has constituted Ethics Committee.

Sr. No	Name	Educational Qualification with specialization	Current organization (Name & Address)	Current Residential Address,Telephone/Mobile No. & e-mail ID	Designation/ Role of member in Ethics Committee	Affiliation of member with Institute that has constituted the Ethics Committee (Yes/No)
					Chairperson	
					Member Secretary	
					Medical Scientist	
					Clinician	
					Legal Expert	
					Social Scientist	
					Lay person	

4. Commitments:

   I. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and well-being of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

   II. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

   III. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable

regulations for safeguarding the rights, safety and well-being of trial subjects.

IV. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

(Signature of the Chairperson)

Date:

(Signature of the Member Secretary)

Date: