MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

New Delhi, the 19th March, 2019

CHAPTER I

PRELIMINARY

Rule 2: Definitions

a) “academic clinical trial” means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licencing Authority or regulatory authority of any country for marketing or commercial purpose;

h) “biomedical and health research” means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined in clause (j)

u) “medical management” means treatment and other necessary activities for providing the medical care to complement the treatment;

ff) “serious adverse event” means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalisation of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;

CHAPTER IV
ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH

Rule 15: Ethics Committee for biomedical and health research

Any institution or organisation which intends to conduct biomedical and health research shall be required to have an Ethics Committee to review and oversee the conduct of such research as detailed in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

Rule 16: Constitution of Ethics Committee for biomedical and health research

(1) The Ethics Committee referred to in rule 15, relating to biomedical and health research shall be constituted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants as may be specified by the Indian Council of Medical Research from time to time and shall function in accordance with said guidelines.

(2) The Ethics Committee referred to in sub-rule (1), shall review the work of the biomedical and health research centre before initiation and oversee throughout the duration of the biomedical and health research as per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

(3) An institution or organisation or any person shall conduct any biomedical and health research with the approval of the Ethics Committee for biomedical and health research registered under rule 17.

(4) Any biomedical and health research shall be conducted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants as may be specified by the Indian Council of Medical Research from time to time.

(5) Institutions desirous of conducting biomedical and health research as well as clinical trials or bioavailability or bioequivalence study shall require obtaining registration from specified authorities as provided in rule 8 and rule 17.

Rule 17: Registration of Ethics Committee related to biomedical and health research

(1) An Ethics Committee constituted under rule 16, shall be required to register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research under these rules for which an application shall be made in Form **CT-01** to the said authority.

(2) The application referred to in sub-rule (1) shall be accompanied with the information and documents as specified in **Table 1 of the Third Schedule**.

(3) On receipt of application in Form **CT-01** under sub-rule (1), the authority designated under sub-rule (1) shall grant **provisional registration** which shall remain valid for a period of **two years.**

(4) After the grant of provisional registration under sub-rule (3), the authority designated under sub-rule (1) shall scrutinise the documents and information furnished with the application, and if satisfied that the requirements of these rules have been complied with, grant **final registration** to Ethics Committee in Form **CT-03**; or if not satisfied, reject the application, for reasons to be recorded in writing and the final registration in Form CT-03 shall supersede the provisional registration granted under sub-rule (3)

(5) An **applicant who is aggrieved** by the decision of the authority designated under sub-rule (1), may file an **appeal** within **sixty working days** from the date of receipt of such rejection before the Central Government in the Ministry of Health and Family Welfare, and the Central Government, may, after such enquiry as is considered necessary in the facts and circumstances

of the case, and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty working days.

(6) The Ethics Committee shall make an application for **renewal of registration** in Form **CT-01** along with documents as specified in sub-rule (2) at least **ninety days prior to the date of the expiry** of its final registration: Provided that if the application for renewal of registration is received by the authority designated under sub-rule (1), ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on the application: Provided further that fresh set of documents shall not be required to be furnished, if there are no changes in such documents furnished at the time of grant of final registration, and if the applicant renders a certificate to that effect indicating that there is no change.

(7) The authority designated under sub-rule (1) shall after scrutiny of information furnished with the application and after such further enquiry, as considered necessary and on being satisfied that the requirements of these rules have been complied with, renew the registration of Ethics Committee in Form CT-03, or if not reject the application, for reasons to be recorded in writing.

(8) The **authority shall take a decision** under sub-rule (7) within a period of **forty-five working days**, from the date of application made under sub-rule (1).

(9) The **registration** granted in Form CT-03 shall remain valid for a period of **five years** from the date of its issue, unless suspended or cancelled by the authority designated under sub-rule (1).

(10) The function, proceedings of ethics committee and maintenance of records shall be as per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
(11) In case there is a change in composition of a registered Ethics Committee in an institution it shall be reported to the authority designated under sub-rule (1).

Rule 18: Suspension or cancellation of registration of Ethics Committee for biomedical and health research

(1) Subject to provisions of rule 17, where the Ethics Committee fails to comply with any provision of these rules, the authority designated under sub-rule (1), may, after giving an opportunity to show cause and after affording an opportunity of being heard, by an order in writing, take one or more of the following actions, namely:—

(i) issue warning to the Ethics Committee describing the deficiency or defect observed, which may adversely affect the rights or well-being of the study subjects;

(ii) suspend for such period as considered appropriate or cancel the registration issued under rule 17;

(iii) debar its members to oversee any biomedical health research in future for such period as may be considered appropriate.

(2) Where the Ethics Committee or its member, as the case may be, is aggrieved by an order of the authority designated under sub-rule (1), it may, within a period of forty-five working days of the receipt of the order, make an appeal to the Central Government in the Ministry of Health and Family Welfare, and that Government may, after such enquiry, as deemed necessary, and after giving an opportunity of being heard, pass such order in relation thereto as may be considered appropriate in the facts and circumstances of the case.

CHAPTER V
CLINICAL TRIAL, BIOAVAILABILITY AND BIOEQUIVALENCE STUDY OF NEW DRUGS AND INVESTIGATIONAL NEW DRUGS
PART A
CLINICAL TRIAL

Rule 28: Academic clinical trial

(1) No permission for conducting an academic clinical trial shall be required for any drug from the Central Licencing Authority where,

(i) the clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes for a new indication or new route of administration or new dose or new dosage form; and

(ii) the clinical trial referred to in clause (i) has been initiated after prior approval by the Ethics Committee for clinical trial; and

(iii) the observations generated from such clinical trial are not required to be submitted to the Central Licencing Authority; and

(iv) the observations of such clinical trial are not used for promotional purposes.

(2) In the event of a possible overlap between the academic clinical trial and clinical trial or a doubt on the nature of study, the Ethics Committee concerned shall inform the Central Licencing Authority in writing indicating its views within thirty working days from the receipt of application to that effect.

(3) The Central Licencing Authority shall, after receiving the communication from the Ethics Committee referred to in sub-rule (2), examine it and issue necessary clarification, in writing, within thirty working days from the date of receipt of such communication:

Provided that where the Central Licencing Authority does not send the required communication to such Ethics Committee within thirty working days from the date of receipt of communication

from the said Ethics Committee, it shall be presumed that no permission from the Central Licencing Authority is required.

(4) The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, notified by the Indian Council of Medical Research with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of clinical trial of licenced and approved drug or drug

CHAPTER VI
COMPENSATION

Rule 43: Medical management and compensation for injury or death relating to biomedical and health research overseen by an Ethics Committee for biomedical and health research as referred to in Chapter IV.

Notwithstanding anything contained in these rules, medical management and compensation for injury or death relating to biomedical and health research, overseen by an Ethics Committee for clinical trials as referred to in Chapter IV, shall be in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants specified by the Indian Council of Medical Research from time to time.

Appendix
FORM CT-01
APPLICATION FOR REGISTRATION/RENEWAL OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALENCE STUDY OR BIOMEDICAL HEALTH RESEARCH

I/We, ... (name, designation and full postal address of the applicant) of..... (name and full address with contact details of the ethics committee) hereby apply for grant of registration of ethics committee.

The details of the application are as under:

1. Name of applicant:
2. Nature and constitution of applicant: (proprietorship, company, society, trust, independent, institutional, other to be specified)
3. (i) Applicant address including telephone number, mobile number, fax number and e-mail id: (ii) Address for correspondence: corporate or registered office or clinical trial site or bioavailability and bioequivalence study centre or biomedical health research
4. Details of accreditation, if any (self-attested copy of certificate to be attached):
5. I have enclosed the documents as specified in the Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019.
6. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Place: **Digital Signature**

Date: (Name and designation)

FORM CT-03
(See rules 17 and 18)
GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No.

The designated authority is hereby register and permit----------
(Name and full address with contact details of the ethics committee) to perform duties of the ethics committee as specified in the Regulation of New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place: …… Central Licencing Authority

Date: ..... Stamp

TABLE 1 OF THIRD SCHEDULE
INFORMATION TO BE SUBMITTED BY AN APPLICANT FOR GRANT OF REGISTRATION OF ETHICS COMMITTEE AND FORMAT FOR ACCORDING APPROVAL

(A) Information required to be submitted by the applicant for registration of ethics committee:

(a) Name of the ethics committee.

(b) Authority under which the ethics committee has been constituted, membership requirements, the term of reference, conditions of appointment and the quorum required.

(c) The procedure for resignation, replacement or removal of members.

(d) Address of the office of the ethics committee.

(e) Name, address, qualification, organisational title, telephone number, fax number, email, mailing address and brief profile of the Chairperson.

(f) Names, qualifications, organisational title, telephone number, fax number, e-mail and mailing address of the members of the ethics committee. The information shall also include the member's specialty (primary, scientific or nonscientific), member's affiliation with institutions and patient group representation, if any.

(g) Details of the supporting staff.

(h) The standard operating procedures to be followed by the committee in general.

(i) Standard operating procedures to be followed by the committee for vulnerable population

(j) Policy regarding training for new and existing committee members along with standard operating procedures.

(k) Policy to monitor or prevent the conflict of interest along with standard operating procedures.

(l) If the committee has been audited or inspected before, give details.