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Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road,New Delhi – 110001
Date : 03-May-2023

To

The Chairperson
Institutional Ethics Committee ,Malla Reddy Institute Of Medical Sciences
Malla Reddy Institute Of Medical Sciences survey No 138,Suraram Main Road,GHMC Quthbullapur Jeedimetla, City-Hyderabad , District-Medchal-Malkajgiri - Telangana - 500055

Subject: Ethics Committee Registration No. EC/NEW/INST/2023/TE/0235 issued under New Drugs and Clinical Trials Rules, 2019

Sir/Madam,

Please refer to your file No. EC/NEW/INST/2019/437, dated 24-Dec-2019 submitted to this National Ethics Committee Registry for Biomedical and Health Research (NECRBHR, Department of Health Research) for the Registration of Ethics committee.

Please find the enclosed registration of the Ethics committee in form CT-03 vide Registration No. EC/NEW/INST/2023/TE/0235, dated 22-Feb-2023. The said registration is subjected to the conditions as mentioned below.

Yours faithfully,

BISWABANDAN SENAPATI
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Date: 2023.05.03 13:52:46 +05'30'

(B. Senapati)
Deputy Secretary to Govt. of India

Conditions of Registration

The following include few of the conditions to be followed by the Ethics Committees (ECs) registered with the Designated Authority (NECRBHR, DHR).

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Designated Authority, NECRBHR, DHR. The EC has been registered for the purpose of reviewing Biomedical and Health Research. For Clinical Trials review, registration with CDSCO is required.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. An institution or organization or any person shall conduct any Biomedical and Health Research with the approval of the Ethics Committee registered under rule 17, Chapter IV of New Drugs and Clinical Trials Rules 2019.

4. The Ethics Committee should be constituted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 as may be specified by the Indian Council of Medical Research from time to time and shall function in accordance with said guidelines.
   a) EC composition should be as follows:
      i) ECs should be multi-disciplinary and multi-sectoral.
      ii) There should be adequate representation of age and gender.
      iii) Preferably 50% of the members should be non-affiliated or from outside the institution.

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iv) The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.
v) The EC should have a balance between medical[*1] and non-medical members/technical[*2] and non-technical members, depending upon the needs of the institution.

b) Composition of the said Ethics Committee is as per the Annexure-I.
c) Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Designated Authority NECRBHR, DHR.

5. The Chairperson of an Ethics Committee (EC) should be a non-affiliated person from any background with prior experience of having served/serving in an EC whereas the Member Secretary should be a staff member of the Institution and should have knowledge and experience in clinical research and ethics.

6. EC Members should be conversant with the provision of New Drugs and Clinical Trials Rules 2019, ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other regulatory requirements to safeguard the rights, safety and well-being of the human participants.

7. Conflict Of Interest (COI) should be declared and managed in accordance with Standard Operating Procedures (SOPs) of the EC. EC members are responsible for declaration of COI to the Chairperson, if any, at each meeting. The member who has declared COI should withdraw from the EC meeting while the research proposal is being discussed and the quorum must be rechecked and it should be recorded in the minutes of meeting.

8. In case of studies involving vulnerable population and stigmatized populations, the Ethics Committee, may associate with representatives of patient groups and subject experts who are not its members, in its deliberations but such experts shall not have voting rights, if any.

9. Ethics Committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing to the Principle Investigator.

10. The EC should continuously evaluate progress of ongoing proposals, review Serious Adverse Event (SAE) reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activity.

11. 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 2017. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of Biomedical and Health Research study, as the case may be, for a period of three years after completion of such study.

12. Where any SAE occurs to a study participant during its conduct of Biomedical and Health Research, the Ethics Committee shall analyse the relevant documents pertaining to such event and maintain reports and comply with the provisions of chapter – IV, New Drugs and Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017.

13. The Ethics Committee shall undertake proper causality assessment of Serious Adverse Events (SAE's) with the help of subject expert's wherever required, for deciding relatedness and quantum of compensation as per condition no. (12) mentioned above.

14. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

15. SOP's for funding of the Ethics Committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

16. The EC should be competent and independent in its functioning. The institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support, etc.. Ethics Committee records will be maintained.

17. The Ethics Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of Biomedical and Health Research.

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18. When Ethics Committee fails to comply with any provisions of the New Drugs & Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017, the Designated Authority may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee the Designated Authority, NECRBHR, DHR may take one or more actions specified under provision of Rule 18, Chapter IV of New Drugs and Clinical Trials Rules 2019.

19. To maintain independence, the Head of the Institution should not be part of the EC but should act as an appellate authority to appoint the committee, including Chairperson or to handle disputes. The appointment letter issued to all members should specify the Terms of References (TORs) and should include, at the minimum, the role and responsibility of the member in the committee, duration of appointment and conditions of appointment.

20. The Chairperson and Member Secretary could have dual roles in the EC as they could fulfil a role based on their qualifications (i.e. clinician, legal expert, etc.) in addition to taking on the role of Chairperson or Member Secretary.

21. The Institutions could have subcommittees such as SAE subcommittee or expedited review committee which should be a part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main EC as defined in the SOPs.

22. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements and can have the same TORs as regular members and can attend meetings in the absence of regular members.

23. 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.

*1 Medical members are clinicians with appropriate medical qualifications.

*2 Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example: - Social Science.

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File No. EC/19/000601

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 16-Nov-2020

To

The Chairman
Institutional Ethics Committee MRIMS
Malla Reddy Institute of Medical Sciences
Survey number 138, Suraram Main Road GHMC
Quthbullapur, Jeedimetla Hyderabad Medchal–
Malkajgiri Telangana - 500055 India

Subject: Ethics Committee Re-Registration No. ECR/828/Inst/AP/2016/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/6938 dated 14-Dec-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/828/Inst/AP/2016/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VENUGOPAL GIRDHARILAL SOMANI

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(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 16-Nov-2020 to 15-Nov-2025, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

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5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,

(i) one lay person;

(ii) one woman member;

(iii) one legal expert;

(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. 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 New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the

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from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. 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.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. 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.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. 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.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

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Malla Reddy Institute of Medical Sciences

File No. EC/19/000601

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

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FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 16-Nov-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Somnath Motgi	MBBS (MD - Pharmacology and Therapeutics)	Medical Scientist
2	Dr. Thakur Rohit Singh	B.pharm, M.S., Ph.D (Pharmacology)	Member
3	Dr. Udutha Shobha JagdishChandra	MBBS (MD-Pharmacology, DNB	Chair Person
4	Dr. Visnubhotla Visweswara Sastry	MBBS (MD-Community Medicine)	Member Secretary
5	Dr. Anand Bhogaraju	MBBS (DPM, DNB-Psychiatry)	Clinician
6	Dr. BVS Lakshmi	(M. Pharm, Ph.D-Pharmacology)	Scientific Member
7	Dr. Indira V	MBBS (MD- Pathology)	Medical Scientist
8	Dr. Amrut Dambal	MBBS (MD-Biochemistry)	Medical Scientist
9	Mr. Teppavari Sathyanarayana	MA (LLB)	Legal Expert
10	Mr. B Chiranjeevi Reddy	HSC, SSC (B.Com)	Social Scientist
11	Mr. P Sreenivas	BA (MA-Political Science,MSW)	Lay Person
12	Mr. Mohd Mahmood	HSC, SSC (B.Com-Computer Science)	Lay Person

VENUGOPAL GIRDHARILAL SOMANI

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(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

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