King George's Medical University, U.P., Lucknow

Office of the Dean, Research & Development

Institutional Ethics Committee

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Notice No.: 06/R-Cell-24 *Dated:* 27/5/24

Notice

In partial modification to the Institutional Ethics Committee constituted vide notice no. 03/R.Cell-24 dated 21.03.2024, I have been directed to communicate to all the concerned that Hon. Justice K. L. Sharma is being included as member (Legal Expert) of Institutional Ethics Committee with immediate effect in place of Hon. Justice Ritu Raj Awasthi.

The following is the revised list of members of Institutional Ethics Committee:

Structure	*Name*
Chairperson	**Dr. J. S. Srivastava,** Ex-Chief Scientist, Central Drug Research Institute, Lucknow
Senior Clinicians of the University	1. **Dr. D. N. Upadhayay,** Professor, Deptt. of Plastic Surgery, KGMU
	2. **Dr. Sujita Kar,** Additional Professor, Deptt. of Psychiatry, KGMU
	3. **Prof. Rajeev Kumar Singh,** Head, Deptt.of Paediatric & Preventive Dentistry, KGMU
Senior Clinicians Non-Affiliated	1. **Dr. Amit Goel** Prof. & Head, Deptt. of Hepatology, SGPGIMS
	2. **Dr. Pradeep Maurya** Professor (Junior Grade), Deptt. of Neurology, RMLIMS
	3. **Dr. Ritu Karoli,** Professor (Junior Grade), Deptt. of Medicine, RMLIMS
Basic Medical Scientist of the University	1. **Dr. Riddhi Jaiswal** Professor, Deptt. of Pathology, KGMU
	2. **Dr. Kalcem Ahmad** Additional Professor, Deptt. of Biochemistry, KGMU
	3. **Dr. Rahul Kumar** Additional Professor, Deptt. of Pharmacology, KGMU
Basic Medical Scientist Non-affiliated	**Prof. Girdhar Gopal Agarwal,** Former Head, Deptt. of Statistics, Lucknow University, Lucknow
Legal Expert	**Hon. Justice K. L. Sharma**
Social Scientist/ Philosopher/ Ethicist/Theologian	**Mr. Jayant Krishna** CEO, Foundation for Advancing Science and Technology (FAST India)
Lay person	**Prof. Meenakshi Pawha,** Professor (Retired), Department of English and Modern European Languages, University of Lucknow
Member Secretary	**Prof. Hardeep Singh Malhotra** Dean, Research & Development

for DKmal 27/5/24

Dean
Research & Development

Distribution:

- Notice Book
- The Drug Controller General of India, Central Drug Standard Control Organization(CDSCO), FDA Bhawan, ITO, Kotla Road, New Delhi -110002
- One copy to each member concerned
- The Dean, Faculty of Medicine/Dental Sciences/Nursing/Paramedical, KGMU, Lucknow
- All the Heads of Departments, KGMU, Lucknow
- Faculty In-charge, IT Cell, KGMU, Lucknow with the request to upload it on the KGMU website
- P.S. to Hon'ble Vice Chancellor for information

Fax: 2257539
E-mail: res@kgmcindia.edu

Institutional Ethics Committee

Structure	Name	Roles & responsibilities (ICMR Regulations, 2017)
Chairperson	**Dr. J. S. Srivastava** Ex-Chief Scientist, Central Drug Research Institute, Lucknow +91 93352 84299 ss_cdri@yahoo.com cdri.jss@gmail.com	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice-Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
Senior Clinicians of the University	1. **Dr. D. N. Upadhaya,** Professor, Deptt. of Plastic Surgery, KGMU +91 93352 52998 dnu1@hotmail.com	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
	2. **Dr. Sujit Kumar Kar** Additional Professor, Deptt. of Psychiatry, KGMU +91 99562 73747 sujitakumarkar@kgmcindia.edu	
	3. **Prof. Rajeev Kumar Singh** Head, Deptt.of Paediatric & Preventive Dentistry, KGMU +91 94508 49528 rajkids2000@yahoo.co.in	
Senior Clinicians Non-Affiliated	1. **Dr. Amit Goel** Prof. & Head, Deptt. of Hepatology, SGPGIMS +91 99362 75741 agoel.ag@gmail.com	
	2. **Dr. Pradeep Maurya** Professor, Deptt. of Neurology, RMLIMS +91 98391 29968 pkm730@gmail.com	
	3. **Dr. Ritu Karoli**	

	Professor (Junior Grade), Deptt. of Medicine, RMLIMS +91 94155 47894 ritukaroli@gmail.com	
Basic Medical Scientist of the University	1. **Dr. Riddhi Jaiswal** Professor, Deptt. of Pathology, KGMU +91 94156 24729 riddhiadvay@gmail.com	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
	2. **Dr. Mohammad Kaleem Ahmad** Additional Professor, Deptt. of Biochemistry, KGMU +91 94521 81357 mohdkaleemahmad@kgmcindia.edu	
	3. **Dr. Rahul Kumar** Additional Professor, Deptt. of Pharmacology, KGMU +91 78393 18371 rahulkgmu@gmail.com	
Basic Medical Scientist Non-affiliated	**Prof. Girdhar Gopal Agarwal** Former Head, Deptt. of Statistics, Lucknow University, Lucknow +91 94150 02047 girdhar1751@gmail.com	• All statistical aspects related to submitted proposals
Legal Expert	**Hon. Justice K.L. Sharma** Retired, High Court, Lucknow +91 87078 37134 justiceklsharma@gmail.com	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
Social Scientist/ Philosopher/ Ethicist/ Theologian	**Mr. Jayant Krishna** CEO, Foundation for Advancing Science and Technology (FAST India) +91 98390 22488 Jayant.krishna@hotmail.com	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal/ community representative and bring in ethical and societal concerns.
Secular perspective/ Non-professional opinionator/ Lay person	**Prof. Meenakshi Pawha** Professor (Retired), Department of English and Modern European Languages, University of Lucknow, Lucknow +91 98390 13530 meenakshipawha@gmail.com	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.
Member Secretary	**Prof. Hardeep Singh Malhotra** Dean, Research & Development Professor, Deptt. of Neurology, KGMU	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

	+91 95596 77084 deanresearch@kgmcindia.edu	• Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.

CDSCO REGISTRATION

File No. EC/24/000511

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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: 11-Apr-2025

To

The Chairman
Institutional Ethics Committee
King Georges Medical University
King Georges Medical University Shahmina Road,
Chowk, Lucknow Lucknow Uttar Pradesh - 226003
India

Subject: Ethics Committee Re-Registration No. **ECR/262/Inst/UP/2013/RR-24** issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2024/18197 dated 30-Oct-2024 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/262/Inst/UP/2013/RR-24**. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.04.11 17:03:42 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 29-Nov-2024 to 28-Nov-2029, 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.

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 protocol 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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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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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: 11-Apr-2025

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Amit Goel	MBBS (DM - Gastroenterology)	Clinician
2	Dr. Pradeep Kumar Maurya	MBBS (DM - Neurology)	Clinician
3	Dr. Divya N Upadhyaya	MBBS (M.Ch - Plastic Surgery	Clinician
4	Mr. K L Sharma	LLB (Master of Laws (LL.M.))	Legal Expert
5	Dr. Ritu Karoli	MBBS (MD - Medicine)	Clinician
6	Dr. Sujita Kumar Kar	MBBS (MD - Psychiatry)	Clinician
7	Dr. Rahul Kumar	MBBS (MD-Pharmacology)	Medical Scientist
8	Dr. Rajeev Kumar Singh	BDS (MDS Paediatric and Preventive Dentistry)	Clinician
9	Dr. Mohammad Kaleem Ahmad	BSc (Ph.D.)	Scientific Member
10	Dr. Meenakshi Pawha	BA (Ph.D. English)	Lay Person
11	Mr. Jayant Krishna	BSc (MBA)	Social Scientist
12	Dr. Jagdishwar Sahai Srivastava	MBBS (DM Clinical Pharmacology)	Chair Person
13	Dr. Hardeep Singh Malhotra	MBBS (DM Neurology)	Member Secretary
14	Dr. Girdhar Gopal Agarwal	BSc (Ph.D.)	Scientific Member
15	Dr. Riddhi Jaiswal	MBBS (MD Pathology)	Scientific Member

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.04.11 17:03:52 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. **ECR/262/Inst/UP/2013/RR-24**

The Central Licencing Authority hereby registers and permits **Institutional Ethics Committee , King Georges Medical University King Georges Medical University Shahmina Road, Chowk, Lucknow Lucknow Uttar Pradesh - 226003 Contact No.: 522-2257540 Fax No.: 522-2257539** to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

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

RAJEEV SINGH RAGHUVANSHI

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Date: 2025.04.11 17:01:36 +05'30'

Place : New Delhi

Date : 11-APR-2025

Central Licencing Authority

Stamp

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 : 22-Apr-2024

To

The Chairperson
Institutional Ethics Committee
King Georges Medical University Shahmina Road, City-Lucknow, District-Lucknow - Uttar Pradesh - 226003

Subject: Ethics Committee Registration No. EC/NEW/INST/2024/UP/0449 issued under New Drugs and Clinical Trials Rules, 2019

Sir/Madam,

Please refer to your file No. EC/NEW/INST/2020/1070, dated 07-Sep-2020 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/2024/UP/0449, dated 18-Apr-2024. The said registration is subjected to the conditions as mentioned below.

Yours faithfully,

BISWABANDAN SENAPATI
Digitally signed by BISWABANDAN SENAPATI
Date: 2024.04.22 15:14:50 +05'30'

(B. Senapati)
Director

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. EC registration number provided by DHR should be displayed on every certificate of approval issued by the Ethics committee.

5. 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.

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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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/NEW/INST/2020/1070

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 : 18-Apr-2024

FORM CT-03

(See rules 17 and 18)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No. **EC/NEW/INST/2024/UP/0449**

The designated authority hereby registers and permits Institutional Ethics Committee , King Georges Medical University Shahmina Road , City-Lucknow, District-Lucknow - Uttar Pradesh - 226003 Contact No.: 5222257540 Fax No.: 5222257539 to perform duties of ethics committee as specified in the 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.

ANU NAGAR
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Date: 2024.04.18 15:31:18 +05'30'

Place : New Delhi

Date : 18-Apr-2024

Designated Registration Authority
Stamp

File No. - EC/NEW/INST/2020/1070

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 26-Feb-2021

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**Institutional Ethics Committee, KGMU**
Address :	**King Georges Medical University, Shahmina Road, Chowk, Lucknow, Lucknow, Uttar Pradesh - 226003**
Contact No:	**5222257540**
Fax :	**5222257539**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU NAGAR
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Date: 2021.02.26 14:14:10 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/262/Inst/UP/2013/RR-19

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee , King Georges Medical University King Georges Medical University Shahmina Road, Chowk, Lucknow Lucknow Uttar Pradesh - 226003 Contact No.: 522-2257540 Fax No.: 522-2257539 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

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

V G SOMANI

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Date: 2019.11.29 11:42:22 +05'30'

Place : New Delhi

Date : 28-NOV-2019

Central Licencing Authority
Stamp

File No. EC/19/000303

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

सत्यमेव जयते

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 28-Nov-2019

To

The Chairman
Institutional Ethics Committee
King Georges Medical University
King Georges Medical University Shahmina Road,
Chowk, Lucknow Lucknow Uttar Pradesh - 226003
India

Subject: Ethics Committee Re-Registration No. ECR/262/Inst/UP/2013/RR-19 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/4358 dated 19-Jun-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/262/Inst/UP/2013/RR-19. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

V G 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 29-Nov-2019 to 28-Nov-2024, 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.

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

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.

File No. EC/19/000303

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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: 28-Nov-2019

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Vimal Kumar Paliwal	MBBS (DM - Neurology)	Clinician
2	Dr. Surajit Bhattacharya	MBBS (M.Ch - Plastic Surgery)	Clinician
3	Dr. Manju Agrawal	BA (MA - Psychology)	Social Scientist
4	Dr. Anoop Kumar Verma	MBBS (MD - Forensic Medicine/Forensic Medicine & Toxicology)	Basic Medical Scientist
5	Dr. Preeti Agarwal	MBBS (MD - Pathology & Microbiology)	Basic Medical Scientist
6	Dr. Amita Jain	MBBS (MD - Pathology & Microbiology)	Basic Medical Scientist
7	Dr. Rajendra Nath	MBBS (MD - Pharmacology and Therapeutics)	Basic Medical Scientist
8	Dr. Rajeev Garg	MBBS (MD - Tuberculosis & Respiratory Diseases / Pulmonary Medicine)	Clinician
9	Dr. Abhinav Arun Sonkar	MBBS (MS - General Surgery	Clinician
10	Mr. Vishnu Sahai	LLB (MA)	Legal Expert
11	Mr. Suresh Pratap Singh Gaur	MBBS (MD Medicine)	Chair Person
12	Mr. Ram Niwas Jain	BE Mechanical (BE Mechanical)	Lay Person
13	Dr. Ravindra Kumar Garg	MBBS (DM Neurology)	Member Secretary
14	Dr. Smrati Bhadauria	Ph.D-Biochemistry (Not Applicable)	Scientific Member

V G SOMANI

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Date: 2019.11.29 11:43:48 +05'30'

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