File No. EC/19/000392

सत्यमेव जयते

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: 10-Oct-2019

To

The Chairman
Institutional Ethics Committee, PGIMS UHS Rohtak
PGIMS UHS Rohtak
Pt. BD Sharma, Post Graduate Institute Of Sciences
PGIMS UHS Rohtak-124001 Rohtak Rohtak Haryana -
124001 India

Subject: Ethics Committee Re-Registration No. ECR/293/Inst/HR/2013/RR-19 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/5407 dated 26-Jul-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/293/Inst/HR/2013/RR-19. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

V G SOMANI

Digitally signed by 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 10-Oct-2019 to 09-Oct-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.

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Government of India
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Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 10-Oct-2019

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Alpana Raizada	MBBS (MD - Medicine)	Clinician
2	Dr. Yatish Agarwal	MBBS (MD-Radio-diagnosis,D.Sc.)	Chair Person
3	Dr. Savita Verma	MBBS (MD-Pharmacology)	Member Secretary
4	Dr. Sunita Siwach	B.Ed. (MA,PhD-Psychology, PDF)	Social Scientist
5	Mr. Yogender Rathee	BA, LLB (MA-Sociology,LLM)	Legal Expert
6	Ms. Vandana Verma	MJMC (M.Phil)	Lay Person
7	Dr. Harpreet Singh	MBBS (MD-General Medicine)	Clinician
8	Dr. Sumit Sachdeva	MBBS (MS-Opthalmology)	Clinician
9	Dr. Reetu Hooda	MBBS (MD-Obstetrics and Gynecology)	Clinician
10	Dr. Raj Singh	MBBS (MS-Orthopaedics)	Clinician
11	Dr. Kapil Bhalla	MBBS (MD-Pediatrics)	Clinician
12	Dr. Aarti Rohila	MBBS (MD-Anatomy)	Basic Medical Scientist
13	Ms. N Sankareshwari	MA-Political Science (BSc.-Chemistry, B.Ed.)	Lay Person
14	Dr. Pradeep Garg	MBBS (MS-General Surgery)	Clinician
15	Dr. K S Sangwan	BA-Sociology (M.Phil, Ph.D)	Social Scientist

V G SOMANI

Digitally signed by V G SOMANI
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Date: 2019.10.10 14:58:46 +05'30'

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

PT. B. D. SHARMA UNIVERSITY OF HEALTH SCIENCES, ROHTAK.

OFFICE ORDER

The **Biomedical Research Ethics Committee, PGIMS/UHS, Rohtak** is reconstituted as under with immediate effect-

Sr No	Name of Member	Qualification with specification	Designation/ Current organization	Role in Ethics committee	Affiliation with The Institute
1	Dr Sham Singla	MS, Surgery	Pro-Chancellor, SGT University, Gurugram	Chairperson	No
2	Dr Savita Verma	MD, Pharmacology	Professor, Pt. B D Sharma PGIMS, Rohtak	Member Secretary	Yes
3	Dr. Ashish Goel	MD, Medicine	Prof and Head, Medicine, AIMS, Mohali	Clinician	No
4	Dr. Pradeep Kamboj	MS, Orthopaedics	Sr. Professor, Pt. B D Sharma PGIMS, Rohtak	Clinician	Yes
5	Dr Sumit Sachdeva	MS, Ophthalmology	Professor, Pt. B D Sharma PGIMS, Rohtak	Clinician	Yes
6	Dr Reetu Hooda	MD, Obstetrics & Gynaecology	Professor, Pt. B D Sharma PGIMS, Rohtak	Clinician	Yes
7	Dr Aarti	MD, Anatomy	Professor, Pt. B D Sharma PGIMS, Rohtak	Basic Scientist	Yes
8	Dr Kapil Bhalla	MD, Pediatrics	Professor, Pt. B D Sharma PGIMS, Rohtak	Clinician	Yes
9	Dr Pawan Kumar Singh	MD, DM, PCCM	Associate Professor, Pt. B D Sharma PGIMS, Rohtak	Clinician	Yes
10	Dr Sunita Siwach	M.Sc, Ph.D	UGC, New Delhi	Scientific Member	No
11	Mrs N. Sankareswari	MA, Political Science	Indus Public School	Lay Person	No
12	Mr Varun Sharma	LLB	Assistant District Attorney, Prosecution Department, Haryana	Legal Expert	No
13	Prof. K.S. Sangwan	M.Phil., Ph.D	Superannuation, MDU, Rohtak	Social Scientist	No
14	Mrs. Prem Wati	JBT	Associated with Krish Hope Foundation, NGO	NGO/ Lay person	No

VICE CHANCELLOR

Endst. No.RC/22/102-117 Dated: 14.06.2022

A copy of above is forwarded to the following for information and necessary action pl.

1. All concerned officers
2. PA to Vice Chancellor for kind information of Honorable Vice Chancellor
3. P.A to Director for kind information of Worthy Director.

(Dr. Dhruva Chaudhry),
Prof In charge, Research Cell

PT. B.D. SHARMA POSTGRADUATE INSTITUTE OF MEDICAL SCINCES, ROHTAK

OFFICE ORDER

On the request of Chairperson of IAEC committee, the name of Dr. Deepak Kumar, Assistant Professor from Department of Biotechnology & Molecular Medicine, PGIMS, Rohtak is hereby included in place of Dr. Monica, Associate Professor, Biochemistry Department as committee member already constituted vide office order bearing Endst. No. MG-II/2021/9848-57 dated 22.11.2021.

The following faculty will be the members of the Institutional Animal Ethics Committee (IAEC) for registration with Committee for Purpose of Control & Supervision of Experiments on Animals (CPCSEA):

Sr. No.	Name of Member	Qualification	Designation	Role/Designation IAEC
1	Dr. Savita Verma,	MD	Professor, Department of Pharmacology, PGIMS, Rohtak	Chairperson
2	Dr. Mridul	MD	Associate Professor, Physiology, PGIMS, Rohtak	Scientist from differen discipline
3	Dr. Himanshu P. Raikwar	Ph.D	Assistant Professor, Biotechnology & Molecular Medicine, PGIMS, Rohtak	Biological Scientis (Member Secretary)
4.	Dr Deepak Kumar	Ph.D	Assistant Professor, Department of Biotechnology & Molecular Medicine, PGIMS, Rohtak	Scientist from differe discipline
5.	Dr. Pardeep Kharab	B.V.Sc.	Veterinary Surgeon, Government Vety. Hospital, Kahneli, Rohtak	Veterinarian

Dr. Savita Verma, Professor of Pharmacology department, PGIMS, Rohtak has already been assigne the duties as Chairperson of Institutional Animal Ethics Committee (IAEC) vide Office Order End No. ME-I/A-II/2021/8545-52 dated 02.06.2021.

DIRECTOR

Endst. No. MG-II/2022/3136-47 Dated: 25/03/2022

A copy of the above is forwarded to the following for kind information and necessary acti please:

1. Dean Academic Affairs, UHS, Rohtak.
2. Dean, PGIMS, Rohtak
3. Dr. Savita Verma, Professor, Department of Pharmacology, PGIMS, Rohtak w.r.t. her off letter No. IAEC/2022/05-06 dated 08.03.2022.
4. Dr. Monica, Associate Professo , Biochemistry Department through Sr. Prof. & Head Biochemistry Department, PGIMS , Rohtak.
5. Dr. Mridul, Assoc. Prof. of Physiology department through Sr. Prof. & Head of Physiol Department, PGIMS, Rohtak.
6. Dr. Himanshu P. Raikwar, Assistant Professor of Biotechnology & Molecular Medic department through HOD, Biotechnology & Molecular Medicine, PGIMS, Rohtak.
7. Dr Deepak Kumar, Assistant Professor of Biotechnology & Molecular Medicine departm through HOD Biotechnology & Molecular Medicine, PGIMS, Rohtak
8. Dr. Pardeep Kharab, B.V.Sc, Veterinary Surgeon, Government Vety. Hospital, Kahn Rohtak through Dr. Savita Verma, Professor, Department of Pharmacology, PGIMS, Rohtak Chairperson of the committee.
9. Superintendent, ME-I, PGIMS, Rohtak with the request to take-up the matter with authorities regarding appointment of permanent/ full time Veterinarian for ensuring proper and well being of the Laboratoty Animals (copy of request dated 08.03.22 received fr Chairperson of the said committee).
10. PA to Vice-Chancellor for kind information of Ld. Vice-Chancellor, UHS, Rohtak.
11. Secretary to Registrar for kind information of Worthy Registrar, UHS, Rohtak.
12. PA to Director for kind information of Worhty Director, PGIMS, Rohtak.

25.3.22

Dy. Superintendent (MG)
For Director