File No. EC/21/000171

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-May-2021

To

The Chairman
Hospital Institutional Ethics Committee
Swami Dayanand Hospital
Dilshad Garden, Delhi 110095 Adjacent To IHBAS
Shahdara North East Delhi Delhi - 110095 India

Subject: Ethics Committee Registration No. ECR/1549/Inst/DL/2021 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2019/6937 dated 26-Sep-2020 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1549/Inst/DL/2021. The said registration is subject to the conditions as mentioned below:

Yours faithfully

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

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority 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 such application.

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 50kms 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
Directorate General of Health Services
Central Drugs Standard Control Organization
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FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 28-May-2021

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. MMA Faridi	MBBS (MD-Pediatrics, DCH)	Chair Person
2	Dr. Surender Singh Bisht	MBBS (MD-Pediatrics)	Member Secretary
3	Mr. Ajay Kumar Sharma	BA (NGO Representative)	Social Scientist
4	Mr. Krishan Kumar Tomar	LLB (MA-Political Science)	Legal Expert
5	Mr. Rakesh Kumar Saxena	HSC,SSC (BA)	Lay Person
6	Mr. Sanjay Verma	BA (MA-Sociology)	Social Scientist
7	Dr. Janet L Stephens	MBBS (MD- General Medicine)	Clinician
8	Dr. Kalpana Kumar	MBBS (MD-Obstetrics and Genecology)	Clinician
9	Dr. Tishu Saxena	MBBS (MS-Ophthalmology)	Clinician
10	Dr. Ramakant Gupta	MBBS (MS-Orthopedics)	Clinician
11	Dr. Awaindra Kumar	MBBS (MD-Pathology)	Medical Scientist
12	Dr. Lallan Kumar Bharti	MBBS (MD-Pediatrics)	Clinician

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

File No. - EC/NEW/INST/2021/1838

सत्यमेव जयते

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

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 13-Nov-2025

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 :	**Hospital Institutional Ethics Committee**
Address :	**Swami Dayanand Hospital, Dilshad Garden, Shahadara, Delhi, East Delhi, Delhi - 110095**
Contact No:	**01161367150**
Fax :	**01161367150**

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.

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

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

दिल्ली नगर निगम,
स्वामी दयानन्द हस्पताल,
दिलशाद गार्डन, शाहदरा,
दिल्ली - ११००९५

Municipal Corporation of Delhi,
Swami Dayanand Hospital,
Dilshad Garden, Shahadara
Delhi - 110095

No. SDNH/MS/2025/ D-1968

Date: 30/07/2025

OFFICE ORDER

Sub: - Reconstitution of Hospital Institutional Ethics Committee (HIEC), SDN Hospital

The Hospital Institutional Ethics Committee (HIEC) is hereby reconstituted as per direction of the Medical Superintendent.

The newly reconstituted HIEC of SDN Hospital should be as follows:

S.No.	Name	Qualification with Specialization	Current organization	Contact no. & Address	Designation/ Role in Committee	Affiliation of member with that has constitute Ethics Committee
1	Dr. Ashok Kumar Saxena	MD, DA, FAMS,FICA & WHO Fellow	UCMS & GTB Hospital	Flat No. 705, Parivar Apartments, I. P. Extension, Patparganj, Delhi-110092, Mobile-9810431367	Chair Person	No
2	Dr. Rumpa Saha	MD Microbiology PGI Chandigarh	UCMS & GTB Hospital	A1-1505, Saya Zenith, Indirapuram, Ghaziabad, U.P. 201014, Mobile No. 9212116906	Vice-Chairperson	No
3	Dr. Surender Singh Bisht	MBBS, MD Paediatrics, DNB Paediatrics	SDN Hospital	B-83, Sec-36, Noida, Gautam Buddha Nagar, U.P.201303 Mob. No.9650012819	Member Secretary	Yes
4	Dr. Aashish Dang	MBBS, DA, DNB Anaesthesiology	SDN Hospital	Flat No.4, New Doctor's Flats, Hindu Rao Hospital, Delhi-110007, **Mobile No.** 9810710458	Link Officer to DNB Coordinator & Clinician	Yes
5	Dr. Proteesh Rana	MD Pharmacology	UCMS & GTB Hospital	Flat No 1908 Migsun Vilasa Greater Noida, Up 201308, Mobile No 9350306513	Basic Medical Scientist & Pharmacologist	No
6	Dr. Lallan Bharti	MBBS, MD Paediatrics	Jag Parvesh Chandra Hospital	C-4, Dharma Apartment, Patparganj 2, IP Extension, Mobile No. 9811463510	Basic Medical Scientist & Clinician	No

7	Dr. L. T. Yangla	MBBS, DGO	SDN Hospital	397 C, Pocekt 2, Mayur Vihar Phase-I Delhi-110091, Mobile No. 9891744233	Clinician	Yes
8	Dr. Bithi Chowdhury	MBBS MS Ophthalmology. FRCS Ophthalmology	SDN Hospital	D 668, Chittaranjan Park. New Delhi-110019 Mobile No. 9811362844	Clinician	Yes
9	Dr. Devmalya Chakravartty	MBBS (Hons), MD Gen. Medicine	SDN Hospital	D-152, First Floor, Vivek Vihar, Ph-1, Delhi-110095, Mobile No. 9811237178	Clinician	Yes
10	Mr. Mridul Awasthi	M.Com, L.L.B	Educational Institute	100 Kala Vihar, Ph-I Extn. Dilshad garden, Delhi- 110095, Mobile No. 9810226422	Philosopher	NO
11	Mr. Umesh Chand	M. SC.	ICHFW	4th Floor 82, Vigyan Vihar, Delhi- 110095, Mobile no. 9013365060	Social Scientist	NO
12	Mr. Vijay Tyagi	LLB, LLM ILI	Advocate	H. No.10, Naveen Shahdara, Delhi-110032, Mobile No. 9650010743	Legal Expert	NO
13	Mr. Raj Kumar	M.A. (Economic), LLB, Diploma in MRS	Social Activist	B-7-B, Sector-12, Swadeshi Chowk, Pratap Vihar, Ghaziabad, Mobile No. 9891079509	Lay Person	NO

Member Secretary, H

Memebr Secretary
Hospital Institutional Ethics Committee
Swami Dayanand Hospital (MCD)
Dilshad Garden, Delhi-110095

Copy to:

- All Concerned
- DNB Coordinator

Copy for kind information to:

- Addl. MS, SDNH
- MS, SDNH