Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (Headquarters)
FDA Bhawan, Kotla Road, New Delhi – 110002
(Ethics Committee Division)

Dated: _____

NOTICE

13 JUL 2026

Subject: Regulatory Alert regarding Cancellation of Registration Certificates of Ethics Committees under the New Drugs and Clinical Trials Rules, 2019 – Reg.

The Central Drugs Standard Control Organisation (CDSCO), as part of its regulatory oversight of clinical trials in the country, has undertaken **Risk-Based Inspections (RBI)** of Ethics Committees registered under the provisions of the **New Drugs and Clinical Trials Rules, 2019 (NDCT Rules, 2019)**. These inspections are conducted to assess compliance with the applicable regulatory requirements, Good Clinical Practice (GCP) guidelines, and the effectiveness of the Quality Management Systems (QMS) implemented by the Ethics Committees, with the objective of ensuring the protection of the rights, safety, well-being, and dignity of clinical trial participants.

Based on Risk-Based Inspections of registered Ethics Committees across the country. significant deficiencies and major non-compliances with the provisions of the NDCT Rules, 2019, Good Clinical Practice (GCP) guidelines, and other applicable regulatory requirements were observed in certain Ethics Committees.

Following the due regulatory process, including issuance of inspection reports, evaluation of the Corrective and Preventive Action (CAPA) responses submitted by the concerned Ethics Committees, issuance of Show Cause Notices, and grant of personal hearings, wherever applicable, CDSCO has taken appropriate regulatory action. Accordingly, the Registration Certificates of the following Ethics Committees have been cancelled under the provisions of the NDCT Rules, 2019:

S. No.	Name of the Ethics committee	Address	RC no.	Date of cancellation
1.	M/s Hurip Independent Bioethics Committee	situated at Ground Floor, 77/2M/1, Ibrahimpur Road, Jadavpur, Kolkata-700032	ECR/103/Indt/ WB/ 2013/RR-19	07.07.2025

2.	RationalIndependent Ethics Committee	SocietyforPromotionof Health and EnvironmentalSciences, J-36, Saket, New Delhi, SouthDelhi,Delhi-11001	ECR/1/Indt/DL/2013/RR-19	07.07.2025
3	EthiwellEthics Committee	Flat No. 202, Jai Omkar Apartment,PlotNo.36, Sector 20, Airoli, Navi Mumbai, Thane, Maharashtra	ECR/91/Indt/MH/2013/RR-19	10.11.2025
4	Institutional Ethics CommitteeAatmanHospital	5,AnveshanRowHouse, OppUmiya Mata Mandir, Bopal-Ghuma Main Road, BopalGhuma, Ahmedabad, Gujarat-380058	ECR/1565/Inst/GJ/ 2021	08.11.2025
5	EthosEthicsCommittee	AshivApartment,Sector 5, OppKoparkhairneStnKoparkhairne, Navi Mumbai Navi Mumbai India Pincode:400709	ECR/139/Indt/MH/ 2013/RR-19	21.08.2025
6	DR. T. K. PAL MEMORIALBIOETHICS COMMIITEE	Dr. T. K. Pal Memorial Bioethics Commiitee, Taab Biostudy Services, 69,IbrahimpurRoad,1st Floor Flat No. 1A, JadavpurKolkataKolkata West Bengal - 700032 India	ECR/395/Indt/WB/ 2025	27.10.2025
7.	Royal Pune Independent Ethics Committee	Office No. 13, Survey No. 18/A, Anupam Arcade, Opposite Snake Park, Pune-Satara Road, Katraj, Pune - 411046, Maharashtra, India.	ECR/45/Indt/MH/2013/RR-24	04.05.2026

The cancellation of the above Registration Certificates has been necessitated due to serious deficiencies and major non-compliances adversely affecting the functioning of the respective Ethics Committees and their ability to discharge their responsibilities in accordance with the provisions of the NDCT Rules, 2019, Good Clinical Practice (GCP) guidelines, and other applicable regulatory requirements.

All registered Ethics Committees are hereby advised to ensure strict compliance with the provisions of the **New Drugs and Clinical Trials Rules, 2019**, applicable CDSCO guidance documents, Good Clinical Practice (GCP) guidelines, and other relevant regulatory requirements. Particular emphasis should be placed on Establishing and maintaining a robust Quality Management System (QMS), Ensuring independence, transparency, and impartiality in ethical review, Maintaining complete, accurate, and contemporaneous documentation and records, Effective identification and management of conflicts of interest, Timely continuing review and oversight of approved clinical trials, Protection of vulnerable participants and safeguarding the rights, safety, and well-being of all clinical trial participants, Timely review and reporting of Serious Adverse Events (SAEs), protocol deviations, and other reportable events; and Compliance with all applicable regulatory obligations under the NDCT Rules, 2019.

This notice is issued in the interest of safeguarding the rights, safety, well-being, and dignity of clinical trial participants and strengthening the ethical and regulatory oversight of clinical research in India.

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

To
All stakeholders through CDSCO-website

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