File No. ED/ECI/2025/01-June
Government of India,
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Division)

FDA Bhawan Kotla Road,
New Delhi - 110002.
Dated:

Suspension order 12 JUN 2026

Subject: Suspension of Registration Certificate of HCG Central Ethics Committee, HCG Bangalore institute of Oncology. HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India –Reg.

References-. 1. Letter no. File No. ED/ECI/2025/01-June dated 02 July 2025 from DCGI, CDSCO, HQ, New Delhi
2. Show-cause notice issued by this office dated17.07.2025.

WHEREAS, The HCG Central Ethics Committee, HCG- Bangalore institute of Oncology, HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India was granted ethics committee registration certificate vide No. ECR/386/Inst/KA/2013/RR-24 on 04.11.2024 under the NDCT Rules, 2019.

AND WHERAS, Risk Based Inspection (RBI) of the Central Ethics Committee was conducted by a team comprises of officials of CDSCO,(HQ), New Delhi and Zonal office Bangalore, SLA, Bangalore along with subject expert on 03.07.2025 & 04.07.205 at HCG- Bangalore institute of Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka – 560027 to assess the status of compliance of Ethics Committee formed under New Drugs and Clinical Trial Rules 2019 as per Risk Based approach.

AND WHEREAS, on the basis of recommendation of inspection team, the show-cause notice under Rule 14(1) of NDCTR 2019 was issued by Central Licensing Authority on 17.07.2025 to Ethics Committed for submission of reply/clarification/compliance within 10 days.

AND WHEREAS, the response/clarification with respect to the show-cause notice received by this office on 26.07.2025 and noted that response submitted by you was not found in compliance with the provisions of NDCTR 2019.

AND WHEREAS, you were given opportunity of personal hearing under Rule 14(2) of NDCT Rule 2019 vide letter dated 01-09-2025 & accordingly you had presented your case on 12-09-2025 at 2:00 PM before Central Licensing Authority at First Floor, Conference hall, FDA Bhawan, Kotla Marg, ITO, Mandi house, New Delhi ,110002.

AND WHEREAS, upon perusal of the submitted reply and consideration of the submissions/clarification made during personal hearing, the following have emerged:
1. You failed to submit the SAE reports to CLA in due timeline as per Rule 42(2)(iii) of the NDCTR 2019 at the following instances -

S. no	Subject Id	Protocol No.	SAE Date	SAE reported to CDSCO beyond time line.
1.	08003/SKR	C25030	18.06.2025 (Injury)	24-07-2025
2.	10-004	13Y-IN-JPEC	19.08.2021(Injury)	06-12-2021

3.	SB270607005	SB27-3004	17.09.2024-(Death)	10-03-2025
4.	10601	J2J-OX-JZLC	22.01.203 (Injury)	11-12-2023
5.	10486	J2J-OX-JZLC	11.02.2023 (Death)	14-12-2023
6.	E3501002	D0967SC00001	17.12.2022 (Death)	16-03-2023
7.	E3503003	D910VC0001	01.03.2023	11-12-2023
8.	IN0420001	NIVO.22.001	21.10.2023	12-12-2023

2. You failed to report SAE to CLA at the following instances which is violation of Rule 42(2)(iii) of the NDCTR 2019 as follow:

Sr. No.	**Subject Id**	**Protocol No.**	**SAE Details**	**SAEs not reported by EC to CLA till date.**
1.	32001/S	AUR107-101	20.05.2025 (Injury)	Not Submitted
2.	10-004	13Y-IN-JPEC	30.08.2021 (Death)	Not Submitted
3.	0002-00028	CA209-7C9	25.01.2022 Sepsis with multi-organ failure on 25.01.2022 and Death on 30.01.2022	Not submitted
4.	10-023	13Y-IN-JPEC	22.06.2022 (Injury) & 14.07.2022 (Death)	Not Submitted
5.	10-022	13Y-IN-JPEC	05.09.2022 (Injury)	Not Submitted
6.	600060003	BAY1841788/21140	14.12.2022 (Death)	Not Submitted.
7.	E3503001	D910VC0001	06.06.2023 and Death on 07.06.2023	Not Submitted.
8.	IN0420006	NIVO.22.001	03.08.2023 (Injury)	Not Submitted.
9.	10486	J2J-OX-JZLC	01.02.2023 (Injury)	Not Submitted.

3. You has informed that you have constituted sub-committee for review of SAEs, however failed to submit the constitutional details along with rule and responsibilities of sub-committee.

4. You failed to provide the details of delivery mode, tracking details which confirmed that you have intimated change of chairperson on 03.01.2023 i.e. within thirty working days, since letter was signed

on 03.01.2023 and same was acknowledged by CDSCO vide dairy No. 2028 on 09.03.2023, after 6 months later.

5. You failed to submit MOM for the year 2022 signed by Chairperson in compliance with NDCT Rule 13 (2) (vii) & Para 2.4.2.8(viii) of Indian GCP.

6. You agreed with the observation that quorum of MOM dated 29.07.2022 and 04.03.2022 was not fulfill the requirement of Rule 12 (1) of NDCT Rules, 2019 and this was happened due to waves of COVID-19 from 2020 to 2022, and often members could not remain present and therefore the remaining members regulated the proceedings. However, in aforementioned circumstances, you failed to conduct virtual meeting with the requisite quorum as specified in the NDCT Rule 2019. Further you clarified that protocols were re-deliberated in presence of full quorum, however not submitted the MOM for the same in compliance of Rule 12(1) of NDCTR 2019.

7. You has not provided the documents w.r.t. intimation to CLA & it's opinion/ follow up for medical management of 2 active subjects enrolled under Protocol No. J2J-OX-JZLC, hence, you failed to perform EC function w.r.t. safety and well-being of the trial participants as per Rule 11 of NDCTR 2019.

8. Your SOP No. SOP-00-v11 effective from 10.08.2023 mentioned that "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". In the MOM dated 25.09.2024, Dr. Govind Babu has signed a declaration to the effect that there is no conflict of interest, however he acted as Principal Investigator in the study which was conflict of Interest since he was also member of EC and you failed to record it. Further you agreed that Conflict of interest was inadvertently not obtained for Protocol No. 61186372NSC3002 in which he acted as Principal Investigator. Hence, you have violated NDCT Rule 7 (10) & 7 (11) read with Indian GCP Para No. 2.4.2.6(2).

9. For Subject ID-IN0420006, you have done casualty assessment on 02.09.2023, and understood that the SAE was medically managed and the event Progressive liver disease was not related to Study drug. The patient completed the ongoing treatment, since recovered and discharged in a stable condition and opined that there is no compensation for Clinical trial related to this SAE. However, on review of casualty assessment report, the trial subject was not recovered from the SAE since he was suffering from progressive liver disease with lungs Carcinoma, however you opined "as he has recovered and discharge from the hospital and inform the patient to retest the LFT after a week". Furthermore, the record of follow up and free medical management w.r.t. indoor treatment and retest report of LFT carried out after a week was not submitted.

10. You have replied that for Protocol No. NIVO.22.001, the protocol deviations have been communicated from time to time. On review of deviation was reported by PI to you on 13.04.2024, several protocol deviation was occurred in 2023 and not reported to CLA immediately in line with para 1(vii) of Third Schedule of NDCTR.

11. It was stated that the subject id no. 10486 enrolled under protocol no. J2J-OX-JZLC experienced a Serious Adverse Event (SAE) from 01.02.2023 to 10.02.2023, and same SAE was intimated to you and CLA on 17.02.2023. Even proper management found not provided to him as the hospital did not advise any further treatment and asked subject to continue her existing medications (details of existing therapy not mentioned which subject was taking from treatment of Fatigue, breathless and cough. Subject was shifted from emergency to OPD and the site has not taken follow up of the subject after discharge on 10.02.2023 and meanwhile subject was died on 11.02.2023 and same issue not considered by you during causality assessment which was submitted to CLA after 10 months later by you.

AND THEREFORE, after consideration of the above facts and circumstances, it is concluded that you failed to perform your responsibilities as per para no. 3.2 of Third Schedule of NDCTR 2019 and violated Chapter III of NDCTR 2019.

Hence as per power conferred under Rule 14.3 (iv) of the New Drugs and Clinical Trials Rules, 2019, and in the interest of public health & the protection of human participants in clinical trials/BA-BE studies, you are hereby suspended for the period of **24 months** from receipt of this order to oversight and approve any new clinical trial or BA-BE study.

Further, you are also

directed to submit CAPA/Casualty assessment report along with the compensation, if any for aforementioned non reported SAEs to CLA. Furthermore, you are directed to continue the monitoring of ongoing clinical trials of BA-BE studies and submit monthly status report for safety and well-being of trial participants to CLA and CDSCO, zonal office, Bangalore.

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

To
Member secretary/Chairperson,
HCG- Bangalore institute of Oncology
HCG Towers, Tower-I P. Kalinga Rao Road,
Sampangiram Nagar Bangalore Bengaluru (Bangalore)
Urban Karnataka – 560027.

CC to:
1.Deputy Drugs Controller (India), CDSCO Zonal Office, Bangalore with direction for compliance of this order.