

गुरु गोरक्षनाथ इंस्ट्टियूट ऑफ मेडिकल साइंसेस,आयुर्वेद संकाय

Guru Gorakshnath Institute of Medical Sciences - Faculty of Ayurveda

Constituent unit of Mahayogi Gorakhnath University Gorakhpur Established under UGC ACT 1956 SECTION 2(f) Aarogya Dham, Balapar Road, Sonbarsa-273007 (UP)

Date:-21-01-2025

Ref.No.-GGIMS/Committee/2025/002

Constitution of "Institutional Ethics Committee (Human Studies)" of GGIMS &MDAC of MGUG **CIRCULAR**

Institute (Guru Gorakshnath Institute of Medical Sciences, Faculty of Avurveda, &MahantDigvijaynathAyurvedChikitsalay of MahayogiGorakhnath University Gorakhpur GGIMS & MDAC of MGUG)) has constituted an "Institutional Ethics Committee (IEC)for Human Studies" as a part of Research promotion activity. IEC is constituted as per ICMR Biomedical Ethical guidelines and New Drugs and Clinical Trials Act 2019 to screen the study proposals involving human beings based on ethical guidelines.

Institutional Ethics Committee Members#:

S No	Name	Designation & Institute	Responsibility*	Institute / Outside
1.	Dr. Shashikant Singh	Principal, MGUG College of Pharmacy	Chairman	Outside
2.	DR. Reshmi Pushpan	Professor, GGIMS	Member Secretary (Ayurveda Pharmacologist)	Institute
3.	DR. Gopikrishna S Acharya	Professor, GGIMS	Member (Ayurvedic Pathologist)	Institute
4.	Dr. Shridhar S Lakkundi	Professor, GGIMS	Member (Ayurveda Clinician)	Institute
5.	DR. N R Navoday Raju	Associate Professor, GGIMS	Member (Ayurveda Scientist)	Institute
6.	DR. Rinjin G Krishna	Associate Professor, GGIMS	Member (Clinician)	Institute
7.	Dr.Vimal Kumar Dubey	Dean, Agriculture Department, MGUG	Member (Scientist)	Outside
8.	Dr. Gaurav Raj Dwivedi	Scientist D ICMR-RMRC, Gorakhpur	Member (Scientist)	Outside
9.	Mr. Pramath Nath Mishra	Advocate, Gorakhpur	Member (Legal)	Outside
10.	Smt. Sheelam Bajpai	Director, SamadhanAbhiyan (NGO)	Member (Social Scientist: NGO or socially service)	Outside
11.	Mr. Asheesh Singh	Civil Engineer, Gorakhpur	Member (Layman)	Outside

[#] IEC is constituted for a period of three years, if needed, it will remain active for one more year, or until new committee is constituted.

^{**}Chairman will be nominated from outside the institute. At least one female member from outside the institute has to be nominated as a member. Adequate representation of gender and age is advised.

^{***}External Members may be invited to IEC meeting based on the need.



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Guidelines for Chairman, Members of IEC and Investigators:

- IEC will be helping the institute in screening the research proposals of the faculty and students for ethical review, who would like to submit them to either our University or other funding agencies, for studies which involve human beings in their study.
- IEC would suggest the researchers to submit the research proposals as per Good Clinical Practices and Ethical Guidelines as applicable in the country.
- IEC will suggest the investigators for any modifications if needed in their proposals.
- IEC can approve or reject or recommend for major or minor modification to the study protocols submitted by the investigators, the proposals from the submitted before applying to the funding agency.
- Decision of the IEC will be final and obligatory.
- IEC permission is mandatory for conducting any study related to human beings e.g. clinical studies, observational studies, surveys etc.
- For all Clinical studies, after IEC permission, CTRI registration is mandatory.
- No recruitment of subjects should be done in study involving human being prior to IEC permission and CTRI registration. No post permission or post registration is allowed.
- IEC will screen the research proposals periodically or based on the need if proposals have to be submitted to funding agencies at their timeline.
- IEC Member Secretary will call for a meeting based on the requirement. One-week prior notice will be served to all members for conducting a IEC meeting.
- Minimum of 5 members should be present in an IRC meeting to meet the quorum. Legal and Social service persons must be present in the meeting.
- Chairman may conduct the IEC meeting either online or offline or hybrid mode for the screening of proposals. Based on Ethics guidelines, waiver may be granted to certain research proposals.
- Recommendations of the IEC will be shared to the applicant researchers.
- Rejected or recommended with modifications have to resubmit the proposals after due modifications as suggested to get permission.
- Approved projects have to submit for approval if any protocol modifications have to be done. And Approved projects have to be register with CTRI, before initiating recruitment.
- Approved project investigators have to submit the status report, AE report and final study completion reports to IEC.

Note: All the IEC activities and approval or rejection of proposals are as per current regulatory requirements for ethical review of the country.

Note: Wherever applicable IEC and activities will derive their guidelines from below regulations (as may be amended in future):

- New Drug and Clinical Trials Rules 2019
- ICMR -Hand book on National Ethical Guidelines for Biomedical And Health Research involving Human Participants, 2019

AYUSH GCP by Ministry of AYUSH, Government of India

AROGYADHAM, SOMBARSA, BALAPAR GORAKHPUR (U.P.) 273007

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