

NOIDA INTERNATIONAL INSTITUTE OF MEDICAL SCIENCES



Office of IEC-NIIMS

REF. NO.: NIIMS/EC/MoM/2022/01 Date: 16.12.2022

MINUTES OF MEETING

An Institutional Ethics Committee (IEC) meeting of Noida International Institute of Medical Sciences, Noida International University was held in the Medical Education Unit Room on dated 16.12.2022 at 11:00AM.

A notice was circulated for the same on 12.12.2022.

Institutional Ethics Committee (IEC) meeting started with the introduction of all members and the welcome speech was delivered by the Chairperson. He gave a presentation on the motto and objectives of the Institutional Ethics Committee. He also described the role of each of the members of the Institutional Ethics Committee (IEC).

Following Research Proposals as per the agenda were reviewed in this meeting:

1. **Title:** Study of Electrocardiographic & Echocardiographic profile in patients with Chronic Obstructive Pulmonary Disease.

Principal Investigator: Dr Sumol Ratna, Assistant Professor, Department of Medicine Following changes in Research protocol were cited: -

- a) Exact duration of Patient Allocation needs to be mentioned
- b) Proper sample size needs to be calculated.
- c) Materials & methods need to be added properly.
- d) Statistical analysis to be mentioned.
- e) Funding/ budget of all tests should be declared and permission from MS should be taken.
- f) Inclusion criteria should be corrected.
- g) Consent forms & PIS should be in both English and Hindi languages, and should have header with details of the institution.
- 2. **Title:** Spirometric evaluation of diabetic patients and its correlation with elevated glycated haemoglobin levels.

Principal Investigator; - Dr Sumol Ratna, Assistant Professor, Department of Medicine.

Following changes in Research protocol were cited: -

- a) Cost of screening tests to be mentioned, Declaration & Permission for the waiver of amount of tests should be enclosed. It has to be assured that patient should not bear any extra financial burden.
- b) Statistical analysis should be mentioned properly.



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3. **Title:** Effect of perceived stress among medical undergraduates across different Terms on cardiovascular system and academic performance: A cross sectional study.

Principal Investigator: Dr Garima Singh, Associate Professor, Department of Physiology.

Following changes in Research protocol were cited: -

- a) As mentioned by the Investigator, this is a cross sectional study, but the Investigator has mentioned cases and controls only in the materials and methods & not in the Title. So, either the study design or the title should be changed in accordance with methodology.
- b) If no budget is required from the college and hospital, a proper declaration should be mentioned by the investigator.

After ethical review of research proposals following suggestions were given by the members:

- 1. Chairperson suggested that all HODs and a statistician should be included in the Research Committee, so that proper protocol is formed before it is presented in the Ethics Committee.
- 2. All research proposals should be signed and forwarded by Head of the Department.
- 3. Mr. Kulwinder suggested that Informed Consent Document and Participant Information Sheet should be in simplified form so that it would be easy to understand by research participants.
- 4. Chairperson suggested to arrange training of IEC Members & IEC Secretariat Staff or Good Clinical Practice as per New Drug & Clinical Trial Rule 2019.

After incorporating all suggestions given by the IEC members, meeting ended with Vote of Thanks given by the Member Secretary to the Chairperson & all IEC members.

With Regards

Dr. Yogendra Bhati Member Secretary IEC

NIIMS

MEMBER SECRETARY

INSTITUTIONAL ETHICS COMMITTEE NOIDA INTERNATIONAL INSTITUTE OF MEDICAL SCIENCES, G. B. NAGAR, U.P.

<u>Institutional Ethics Committee</u> <u>Noida international Institute of Medical Sciences</u> <u>Attendance Sheet</u>

Institutional ethics committee meeting Dated: 16.12.2022 at 11:00 AM at MEU Room

SI No	Name	Designation/Role in IEC	Signature
1	Dr Sachin Manocha	Professor and Head, Pharmacology SMS&R- Chairperson	Kawelo
2	Dr Yogendra Bhati	Associate Professor, Pharmacology NIIMS- Member Secretary	J. A.
3	Dr Ambri Agrawal	Associate Professor, Obs. & Gynae. (Clinician)	
4	Dr Amit Modi	Associate Professor, Pediatrics (Clinician)	Sund
5	Dr. Manjari Kishore	Assistant Professor, Pathology Basic Medical Scientist	Marjori Kistore
R	Dr. Rajiv Kumar,	Social Worker	-200
事	Adv. Mikhil Vij	Lawyer	Arkhil
8	Mr.Kulwinder	Lay Person	Trains.

MEMBER SECRETARY OF Bhati
INSTITUTIONAL ETHICS COMMINERATE, Department of

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OF MEDICAL SCIENCES, G. B. Wember Secretary-IEC NIIMS