


Ethical Clearance

This is to certify that the project entitled “A Group Sequential, Response Adaptive Randomized Double-Blinded Clinical Trial to Evaluate the Safety and Efficacy of an Add-on Combination of Olanzapine and Pregabalin for the Prevention of Chemotherapy-Induced Nausea and Vomiting in Patients Receiving Highly Emetogenic Chemotherapeutic Regimen in a Day Care Setting.” submitted for Sun Pharma Science Foundation Science Scholar Awards-2023 has received “Ethical Clearance” from the concerned authorities. A copy of the Ethical Clearance from Institute Ethics Committee, All India Institute of Medical Sciences , Bhubaneswar(IEC/AIIMS BBSR /2021-22/06) has been attached.



Dr. Mathan Kumar Ramasubbu
Junior resident,
Department of Pharmacology,
All India Institute of Medical Sciences,
Bhubaneswar



INSTITUTIONAL ETHICS COMMITTEE

(Registration No. ECR/534/Inst/OD/2014/RR-20)

All India Institute of Medical Sciences Bhubaneswar

Level 3 Academic Block, AIIMS Bhubaneswar (At Sijua)
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Date: June 26, 2021

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Dr Suresh Chandra Dash

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(Lay Person)

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(Social Scientist)

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Dr Priya Das
(Pharmacologist)

Dr Sonali Kar
(Scientific Member)

Member- Secretary

Dr Arvind Kumar Singh

Dr Mathan Kumar

Post Graduate Student
Department of Pharmacology,
AIIMS, Bhubaneswar

Ref Number: IEC/AIIMS BBSR/PG Thesis/2021-22/06

Through Guide: Dr Anand Srinivasan

Subject: A Group Sequential, Response Adaptive Randomized Double-Blinded Clinical Trial to Evaluate the Safety and Efficacy of Add-on Combination of Olanzapine and Pregabalin for the Prevention of Chemotherapy-Induced Nausea and Vomiting in Patients Receiving Moderately to Highly Emetogenic Chemotherapeutic Regimen in a Day Care Setting.

Dear Dr Mathan Kumar

This is regarding above-mentioned **post graduate thesis protocol** which was discussed and reviewed in the Institutional Ethics Committee, AIIMS Bhubaneswar meeting held on June 19, 2021 and your subsequent letter dated June 25, 2021 responding to queries raised during IEC meeting.

The protocol has been approved from ethical angle prospectively with effect from **June 26, 2021** till the entire period of the conduct of study according to the study duration mentioned in the protocol under guidance of Dr Anand Srinivasan, thesis guide.

Student and guide are responsible for following requirements

1. All co-guides must be kept informed of the status of the project
2. No significant change to the protocol should be made and implemented without prior intimation and approval of the IEC
3. IEC should be reported about all Serious Adverse Events (SAEs) occurring during the study.
4. Only approved informed consent form and participant information sheet to be used for enrolment of the participants. All consent forms and other documents must be archived safely with PI for IEC audit
5. A six-monthly study progress report of the project must be submitted to IEC
6. It is hereby confirmed that neither you nor any of the study team members have participated in the voting/ decision making process of Institute Ethics Committee of AIIMS Bhubaneswar related to this study.

Member Secretary
(IEC AIIMS Bhubaneswar)

सदस्य सचिव / Member Secretary
संस्थागत आचार समिति
Institutional Ethics Committee
एम्स, भुवनेश्वर / AIIMS, Bhubaneswar