

**Institutional Ethics Committee
Regional Institute of Ophthalmology
88, College Street
Kolkata – 700073
West Bengal, India**

Ethics Committee Reg. no. – EC/NEW/INST/2023/4130
Issued under New Drugs and Clinical Trials Rules, 2019 by DCGI & ICMR Guidelines

Memo No: RIO/EC/18/2024

Date: 15-July-2024

To,

Dr. Dichen Wangdi Bhutia
Post-graduate Trainee,
Regional Institute of Ophthalmology
88 College Street
Kolkata-700073
West Bengal, India

PROTOCOL TITLE: “Assessment Of Clinico-Surgical Outcome Of Orbitotomy.”

Subject: Ethics Committee Approval Letter for the above mentioned Study

Dear Dr. Dichen Wangdi Bhutia,

The Institutional Ethics Committee, Regional Institute of Ophthalmology has reviewed and discussed the submitted documents by you on 15-June-2024 for the above mentioned Study Protocol.

The Meeting was held on 28-June-2024 at 2:30 p.m.

Following Study documents were reviewed by the Institutional Ethics Committee:

S. No.	Study Documents
1.	Study Protocol

The list of Ethics Committee members who attended the meeting on 28-June-2024 at 02:30 p.m. at Director Sir Room, Ground Floor, Regional Institute of Ophthalmology , Kolkata-700073, West Bengal, India.

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Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail I.D, and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Santanu Sen	MBBS, D.O. M.S. (Ophthalmology), PhD (Ophthalmology)	Visiting Consultant, Indian Statistical Institute, Kolkata)	9433103348 drsantanusen@g mail.com	Chairman	EC Chairperson (Outside the Institute)
2	Dr. Purban Ganguly	MBBS, M.S (Ophthalmology)	RMO cum Clinical Tutor, Regional Institute of Ophthalmology, 88, College Street, Kolkata - 700073	9830558823 Drpurban85@g mail.com	Member- Secretary	EC Member Secretary, RMO cum Clinical Tutor, Regional Institute of Ophthalmology
3	Dr. Lakshmi Kanta Mondal	MBBS, M.S, (Ophthalmology), PhD (Ophthalmology)	Professor, Regional Institute of Ophthalmology, 88, College Street, Kolkata - 700073	9830830216 Lakshmi.monda l62@gmail.com	Clinician	EC Member, Clinician, Professor, Regional Institute of Ophthalmology
4	Dr. Manab Nandi	MBBS, MD (Pharmacology) M.Phil (Regenerative Medicine)	Associate Professor, Medical College, Kolkata, 88, College Street, Kolkata - 700073	9830835743 manabn@gmail. com	Basic Medical Scientist	EC Member, Basic Medical Scientist, (Outside the Institute)
5	Mr. Rajesh Arora	B.Sc	Member of Swasthya Sankalp, 12, Kyd Street, Kolkata	9331016096 rajesharora@gm ail.com	Scientific member	EC Member, Scientific member, (Outside the Institute)
6	Mandabi Bhattacharrya	M.Sc (Psychology)	Psychologist, baul Mon, 34, Jadavpur, Central Rd, Golf Green, Kolkata, West Bengal - 700032	9475218866 Mandabi.ju@g mail.com	Social Worker	EC Member, Social Worker (Outside the Institute)
7	Mr. Rakesh Arora	B.Com	Businessman, Blue Cross Surgical Co., Kolkata - 700073	2234- 8067/2221-5273	Lay Person	EC Member, Lay Person, (Outside the Institute)
8	Suparna Ray	B.Sc, B.A.L.L.B	Advocate, Calcutta High Court	9831105688 Chatterjeesupar na878@gmail.c om	Legal person	EC Member, Legal Person, (Outside the Institute)

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Ethics Committee has conducted a scientific and ethical review of the aforesaid clinical trial and hereby grants you permission to conduct the clinical study in its presented form at Regional Institute of Ophthalmology. This approval is valid for the entire period of the study.

The IEC follows ICH-GCP, New Drugs and Clinical Trial Rules 2019, National Ethical Guidelines for Biomedical and Health Research involving human participants 2017, ICMR Guidelines and all applicable regulatory guidelines.

You are requested to inform the following to the ethics committee:

- Any changes or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial Subject.
- Any changes in the patient information / Informed consent.
- All Serious adverse event
- New information that may affect adversely/safety of the subjects or the conduct of the trials

You are requested to inform the Institutional Ethics Committee of any amendments in the protocol for which a fresh approval needs to be taken.

You are required to submit a progress report half yearly and a final study report at the end of the study.

Thanking you,
Yours Sincerely,


Signature & Date

Dr. Purban Ganguly
Member Secretary,
Institutional Ethics Committee
Regional Institute of Ophthalmology
88, College Street, Kolkata – 700073,
West Bengal, India

**MEMBER SECRETARY
ETHICS COMMITTEE
R.I.O., KOLKATA-73**