



INSTITUTE ETHICS COMMITTEE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
Room No 102, 1st Floor Old O.T. Block,
ANSARI NAGAR, NEW DELHI 110029
Tel.No.4579 (Internal), 26594579 (Direct)

Date: 07-08-2024

Chairman

Dr. T.P. Singh
Basic Scientist

Members:

Dr. Rama V. Baru
Social Scientist

Dr. Promila Kumar
Lay Person

Sh. Rajan Khosla
Legal Person

Dr. S.K. Maulik
Basic Scientist

Dr. V. Sreenivas
Biostatistician

Dr. Mamta Sood
Clinician

Dr. Rakesh Lodha
Clinician

Dr. Vijay Zutshi
Clinician

Dr. Sameer Bakhshi
Clinician

Dr. Atul Sharma
Clinician

Dr. Sanjay Pandey
Clinician

Dr. B.K. Mohanti
Clinician

Dr. Subodh Kumar Garg
Clinician

Member Secretary:

Dr. Rohit Saxena
Clinician

Dr. Krithika Rangarajan
Associate Professor
Deptt. of Radiology, IRCH
AIIMS, New Delhi.

Ref. No.: AIIMSA1985 / 06.08.2024

Sub: Multi-Centre evaluation of artificial intelligence for triage of mammograms in Indian Population

Dear Dr. Rangarajan

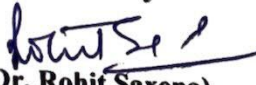
This has reference to your above-mentioned project. The project was discussed in the Ethics Committee meeting held on 06.08.2024 at 03:00 P.M. in the Ethics Committee Room, AIIMS & the following members of the Ethics Committee attended the meeting:

- | | |
|---|------------------|
| 1. Dr. T.P. Singh, SERB, Distinguished Professor, Deptt. of Biophysics | Chairman |
| 2. Mr. Rajan Khosla, LLB, - Member Ethics Committee, | Member |
| 3. Dr. Promila Kumar, Former Principal, Gargi College Lay Person | Member |
| 4. Dr. V. Sreenivas, Former Professor, Deptt. of Biostatistics, AIIMS | Member |
| 5. Dr. Sanjay Pandey, Prof. and Head, Deptt. of Neurology, Amrita Hospital, Faridabad | Member |
| 6. Dr. M.K. Daga, Professor & Director, Deptt. of Medicine, MAMC | Special Invitee |
| 7. Dr. B.K. Mohanti, Director, KIMS Cancer Centre (KIMS), Bhubaneswar | Member |
| 8. Dr. S.K. Maulik, Former Professor, Deptt. of Pharmacology, AIIMS | Member |
| 9. Dr. Sameer Bakhshi, Professor & Head, Deptt. of Medical Oncology, IRCH, AIIMS | Member |
| 10. Dr. Atul Sharma, Principal Director, Medical Oncology, Max Institute of Cancer Care | Member |
| 11. Dr. Vijay Zutshi, Professor, Deptt. of Obs. & Gynae., Safdarjung Hospital | Member |
| 12. Dr. Rohit Saxena, Professor, Deptt. of Ophthalmology R.P. Centre, AIIMS | Member Secretary |

The Project has been approved from ethical angle w.e.f. 06.08.2024 Subject to the following conditions:

- The approval is valid for the period of the conduct of study according to this protocol under the responsibility **Dr. Krithika Rangarajan**, Principal Investigator.
- The Social Scientist Dr. Rama V. Baru evaluated the project online.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- It is confirmed that the Ethics Committee of AIIMS is composed of and functions as per ICH GCP and other applications regulatory guidelines.
- It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
- The study progress report should be submitted to the IEC for review annually in notification section of online portal: <https://eirbindia.com>.
- IEC should be informed about all SAE's occurring in the study as per DCGI guidelines, and should be submitted through online portal: <https://eirbindia.com>, tutorial for submission of SAE: <https://youtu.be/obLNKfJcdzU>

With Warm regards
Yours sincerely


(Dr. Rohit Saxena)

Member Secretary Ethics Committee



INSTITUTE ETHICS COMMITTEE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
Room No 102, 1st Floor Old O.T. Block,
ANSARI NAGAR, NEW DELHI 110029
Tel.No.4579 (Internal), 26594579 (Direct)

Date: 08.10.2025

Chairman

Dr. T.P. Singh,
Basic Scientist

Members:

Dr. Rama V. Baru
Social Scientist

Dr. Promila Kumar,
Lay Person

Mr. Rajan Khosla,
Legal Person

Dr. S.K. Maulik,
Basic Scientist

Dr. V. Sreenivas
Biostatistician

Dr. Atul Sharma
Clinician

Dr. B.K. Mohanti
Clinician

Dr. Mamta Sood
Clinician

Dr. Rakesh Lodha
Clinician

Dr. Manish Soneja
Clinician

Dr. Sameer Bakhshi
Clinician

Dr. Anu Sachdeva
Clinician

Dr. Subodh Kumar Garg
Clinician

Member Secretary:

Dr. Rohit Saxena
Clinician

Dr. Krithika Rangarajan

Associate Professor

Deptt. of Radiology, IRCH

AIIMS, New Delhi.

Ref. No.: AIIMS1985/06.08.2024, OP-1/03.10.2025

Sub: Multi-Centre evaluation of artificial intelligence for triage of mammograms in Indian Population

Dear Dr. Rangarajan,

This has reference to your above-mentioned project. The project was discussed in the Ethics Committee meeting held on 03.10.2025 at 3:00 P.M. in the Ethics Committee Room, AIIMS & the following members of the Ethics Committee attended the meeting:

1. Dr. T.P. Singh, Sr. Scientist INSA, New Delhi
2. Dr. S.K. Maulik, Former Professor, Deptt. of Pharmacology, AIIMS
3. Mr. Rajan Khosla, LLB, Legal Person
4. Dr. Rama V. Baru, Professor, Jindal Global University Sonipat, Haryana
5. Dr. Promila Kumar, Former Principal, Gargi College, Lay Person
6. Dr. V. Sreenivas, Former Professor, Deptt. of Biostatistics, AIIMS
7. Dr. Subodh Garg, Professor, Deptt. Of Surgery, JPNATC, AIIMS
8. Dr. Sameer Bakhshi, Professor & Head, Deptt. of Medical Oncology, AIIMS
9. Dr. Manish Soneja, Additional Professor, Deptt. of Medicine, AIIMS
10. Dr. Anu Sachdeva, Additional Professor, Deptt. of Pediatrics, AIIMS
11. Dr. Atul Sharma, Principal Director, Medical Oncology, Max Institute
12. Dr. Mamta Sood, Professor, Deptt. of Psychiatry, AIIMS -
13. Dr. Rohit Saxena, Professor, Deptt of Ophthalmology R.P. Centre

Chairman

Member

Member

Member

Member

Member

Member

Member

Member

Member

Member

Member

Member Secretary

The following documents have been submitted for ethical approval:

1. Permission for use of AI model for the multicentre study.
2. Addition of following centres in Uttar Pradesh to this multicentre study:
 - Kalyan Singh super speciality cancer institute & Hospital, Lucknow.
 - Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Varanasi.
 - Hanuman Prasad Poddar Cancer Hospital, Gorakhpur.
 - Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow.

The Changes have been approved from ethical angle w.e.f 03.10.2025 subject to the following conditions:

- The approval is valid for the period of the conduct of study according to this protocol under the responsibility **Dr. Krithika Rangarajan**, Principal Investigator.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- It is confirmed that the Ethics Committee of AIIMS is composed of and functions as per ICH GCP and ICMR and New Drugs and clinical guidelines-2019.
- It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
- The study progress report should be submitted to the IEC for review annually in notification section of online portal: <https://www.eirbindia.com/home>.
- IEC should be informed about all SAE's occurring in the study as per DCGI guidelines and should be submitted through online portal: <https://www.eirbindia.com/home>

With Warm regards

Yours sincerely

(Dr. Rohit Saxena)

Member Secretary Ethics Committee



INSTITUTE ETHICS COMMITTEE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
Room No 710-711, 7th Floor NCA Building,
ANSARI NAGAR, NEW DELHI 110029
Tel.No.1176, 1178 (Internal), 26551176 (Direct)

Date: 17.04.2026

Chairman

Dr. T.P. Singh,
Basic Scientist

Members:

Dr. Rama V. Baru
Social Scientist

Dr. Promila Kumar,
Lay Person

Mr. Rajan Khosla,
Legal Person

Dr. S.K. Maulik,
Basic Scientist

Dr. V. Sreenivas
Biostatistician

Dr. Atul Sharma
Clinician

Dr. B.K. Mohanti
Clinician

Dr. Mamta Sood
Clinician

Dr. Rakesh Lodha
Clinician

Dr. Manish Soneja
Clinician

Dr. Sameer Bakhshi
Clinician

Dr. Anu Sachdeva
Clinician

Dr. Subodh Kumar Garg
Clinician

Member Secretary:

Dr. Rohit Saxena
Clinician

Dr. Krithika Rangarajan

Associate Professor

Deptt. of Radiology, IRCH

AIIMS, New Delhi.

Ref. No.: AIIMSA1985/06.08.2024, OP-01/03.10.2025, OP-12/10.04.2026

Sub: Multi-Centre evaluation of artificial intelligence for triage of mammograms in Indian Population

Dear Dr. Rangarajan,

This has reference to your above-mentioned project. The project was discussed in the Ethics Committee meeting held on 10.04.2026 at 3:00 P.M. in the Ethics Committee Room, AIIMS & the following members of the Ethics Committee attended the meeting:

1. Dr. T.P. Singh, Sr. Scientist INSA, New Delhi
2. Mr. Rajan Khosla, LLB, Legal Person
3. Dr. Rama V. Baru, Professor, Jindal School
4. Dr. Promila Kumar, Former Principal, Gargi College, Lay Person
5. Dr. V. Sreenivas, Former Professor, Deptt. of Biostatistics, AIIMS
6. Dr. B.K. Mohanti, Dir. & Head of Radiation Oncology (BSSCCRI), Bhubaneswar
7. Dr. Atul Sharma, Chairman, Medical Oncology, Max Hospital Saket
8. Dr. Subodh Garg, Professor, Deptt. Of Surgery, JPNATC, AIIMS
9. Dr. Manish Soneja, Professor, Deptt. of Medicine, AIIMS
10. Dr. Anu Sachdeva, Additional Professor, Deptt. of Pediatrics, AIIMS
11. Dr. Mamta Sood, Professor, Deptt. of Psychiatry, AIIMS -
12. Dr. M.K. Daga, Senior Professor, Medicine, Vice Chancellor ILBS
13. Dr. Rohit Saxena, Professor, Deptt of Ophthalmology R.P. Centre

Chairman

Member

Member

Member

Member

Member

Member

Member

Member

Member

Member

Special Invitee

Member Secretary

The following documents have been submitted for ethical approval:

- Permission to incorporate the following study centres into the multicentre trial:-
 1. All India Institute of Medical Sciences Nagpur.
 2. Agartala Government Medical College Government of Tripura.

The Changes have been approved from ethical angle w.e.f. 10.04.2026 subject to the following conditions:

- The approval is valid for the period of the conduct of study according to this protocol under the responsibility **Dr. Krithika Rangarajan**, Principal Investigator.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- It is confirmed that the Ethics Committee of AIIMS is composed of and functions as per ICH GCP and ICMR and New Drugs and clinical guidelines-2019.
- It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
- The study progress report should be submitted to the IEC for review annually in notification section of online portal: <https://www.eirbindia.com/home>.
- IEC should be informed about all SAE's must be reported strictly within the timelines prescribed under the New Drugs and Clinical Trials (NDCT) Rules, 2019 occurring in the study and should be submitted through online portal: <https://www.eirbindia.com/home>.
- In cases where compensation has been granted, documentary evidence for the same must be submitted.

With Warm regards

Yours sincerely

(Dr. Rohit Saxena)

Member Secretary Ethics Committee