



TATA MEDICAL CENTER

Tata Medical Center
Institutional Review Board

New
document
Version
No.:
13.1
Effective
Date:
03-10-2025
To be reviewed (on
or before):
31.03.2026

TMC/IRB/SOP-22 : Request for Waiver of Written Informed Consent

TMC/ IRB/ SOP-22

Request for Waiver of Written Informed Consent



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REQUEST FOR WAIVER OF WRITTEN INFORMED CONSENT:

ANNEXURE 1 (PAGE 1/2): APPLICATION FORM FOR REQUESTING WAIVER OF CONSENT

Protocol No. : Version 1.1

Protocol Title: "Predicting Pathological Complete Response to Neoadjuvant Chemotherapy (NACT) in Breast Cancer Patients using High-Throughput Images and Machine Learning – A Retrospective Study."

Principal Investigator's name: Dr. Sanjit Kumar Agarwal

Department: Breast Oncology-surgery

Names of other participating staff and students:

1. Dr. Rosina Ahmed
2. Dr. Vidita Modi
3. Dr. Indu Arun
4. Saipradeep V. G.
5. Thomas Joseph

Prepared by : Dr Indranil Mallick

IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder

TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun

Head of the Institution

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Request for waiver of written informed consent:

Please check the reason(s) for requesting waiver

Please refer to the back of this annexure for criteria that will be used by IRB to consider waiver of consent.

- Research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- Retrospective studies, where the participants are de-identified or cannot be contacted;
- Research on anonymized biological samples/data;
- Research on data available in the public domain; or
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempts should be made to obtain the participant's consent at the earliest.
- Any other – please specify

Statement assuring that the rights of the participants are not violated.

State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:

Principal Investigator's signature with date: • *Sand & Arul. 30/07/26*

Final decision at full board meeting held on:

Waiver granted

☐ Yes/

☐ No.

If not granted, reasons

Signature of Chairperson/Member Secretary: