

	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

<i>Prepared by : Dr Indranil Mallick</i>	<i>Reviewed by: Prof Partha Pratim Majumder</i>	<i>Reviewed by: Dr Pattatheyil Arun</i>
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution

	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

REQUEST FOR WAIVER OF WRITTEN INFORMED CONSENT:

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

Protocol No. :

Protocol Title: Outcomes in advanced endometrial cancer: A retrospective cohort study of 14 years of data at a tertiary cancer care centre : AdEnCa-Retro

Principal Investigator's name: Dr. Jaydip Bhaumik

Department: Gynaecological Oncology

Names of other participating staff and students:

- **Dr. Subhashree Rout , Consultant**
- **Dr. Guneet Kaur, Senior Fellow**

<i>Prepared by : Dr Indranil Mallick</i>	<i>Reviewed by: Prof Partha Pratim Majumder</i>	<i>Reviewed by: Dr Pattatheyil Arun</i>
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution

	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

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:

31/7/26

Final decision at full board meeting held on:

Waiver granted Yes/ No.

If not granted, reasons

Signature of Chairperson/Member Secretary:

Date:

Prepared by : Dr Indranil Mallick	Reviewed by: Prof Partha Pratim Majumder	Reviewed by: Dr Pattatheyil Arun
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution

	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

REFERENCES

- ICMR guidelines 2017. [ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017](#).
- New Drugs and Clinical Trials (Third Amendment) Rules, 2022.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTEzOQ
- Declaration of Helsinki 2013. [GUIDELINE FOR GOOD CLINICAL PRACTICE E6\(R3\)](#)
- NABH Accreditation Standards for Clinical Trial (Ethics Committees) 1st Edition: [Explore NABH Standards - National Accreditation Board for Hospitals and Healthcare Providers \(NABH\)](#).
- Council for International Organisations of Medical Sciences (CIOMS). [Bioethics - CIOMS](#).
- ICH-GCP (E6) R3 06 January 2025. [Efficacy Guidelines](#).

Signatures

Dr Indranil Mallick IRB Member Secretary	Prof Partha Pratim Majumder IRB Chairperson

Effective Date: 03-10-2025

To be reviewed (on or before): 31-03-2026

Prepared by : Dr Indranil Mallick	Reviewed by: Prof Partha Pratim Majumder	Reviewed by: Dr Pattatheyl Arun
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution