15.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Ethics Committee (IEC) may grant waiver of written or verbal informed consent.

15.2 Scope

This SOP applies to all protocols submitted for review by the IEC that ask for consent waiver.

15.3 Responsibility

It is the responsibility of the IEC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the Application Form. The Chairperson will sign and date letter conveying the decision.

15.4 Detailed instructions

- The Application Form (*AX 01/SOP 15/V1)* is designed to standardize the process of applying for waiver of written/verbal consent.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the IEC in the given format, the following steps are taken:
  - The IEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
  - The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- The final decision whether to grant the waiver is taken at a full committee meeting unless the project is considered under expedited review.
- The decision regarding approval/ disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the IEC will provide reasons for the same.

15.5. Annexure

Annexure 1**: AX O1/SOP 15/V1** Application form for requesting waiver of consent

Annexure 1: AX 01/SOP 15/V1

Application form for requesting waiver of consent

1. **Principal Investigator's name:**_____
2. **Department:**_____
3. **Title of project:**

   _____

   _____

   _____
4. **Names of co-investigators and Department/s:**

   _____

   _____
5. **Request for waiver of informed consent:**

- Please tick the reason(s) for requesting waiver
  1. Research involves 'not more than minimal risk'
  2. There is no direct contact between the researcher and participant
  3. Emergency situations as described in ICMR Guidelines
  4. 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:_____

Final decision at full committee meeting held on:_____

Waiver granted Yes No

If not granted, reasons

_____

_____

_____

Signature of the Chairperson with Date:_____

A request to waive written informed consent must be accompanied by a detailed explanation justifying waiver. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants.

15.5 Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents	IEC Secretariat
2	Review of protocol and application for waiver of consent	IEC Members
3	Decision regarding waiver of consent	IEC Members during Full committee meeting
4	Communicate the decision to the Investigator	IEC Secretariat
5	Recording and filing the decision	IEC Secretariat