Title: Waiver of written / verbal informed consent

1. Purpose

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

2. Scope

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

3. Responsibility

It is the responsibility of the EC 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 Chairman will sign and date letter conveying the decision.

4. Detailed instructions

- The Application Form *AX 01/SOP15/V3* is designed to standardize the process of applying for consent waiver.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the EC in the given format *AX 01/SOP 15/V3*, the following steps are taken:
  - The EC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
  - The EC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. (as described in Annexure *AX 01/SOP 15/V3).*
  - The EC 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. (*This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted*).
  - The final decision (ratification) whether to grant the waiver is taken at a full board meeting

- The decision regarding approval / disapproval of waiver is informed to the Principal Investigator in writing. If the waiver is not granted, the EC will provide reasons for the same.

5. Annexure

Annexure 1 *AX 01/SOP 15/V3* Application form for requesting waiver of consent

Annexure 1 : AX 01/SOP 15/V3

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

  [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 2017 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 board meeting held on:

_____

Waiver granted
Yes No
If not granted, ☐ ☐
reasons

_____

_____

_____

_____

_____

_____

Signature of the Chairman with Date: _____

<u>Type of research projects which may qualify for consent waiver:</u>

A request to waive written informed consent must be accompanied by a detailed explanation. 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. The

following criteria (ICMR 2017 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. e.g. a retrospective review of patient case records to determine the incidence of disease / recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].

2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. e.g. *conducting interviews with citizens about their religious beliefs / people with HIV and AIDS / conducting phone interviews with homosexuals.*

   The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the EC.

   [In case of ***telephonic interviews***, waiver of written informed consent may be requested but verbal consent is mandatory].

   a. The following documents need to be submitted for the EC review for verbal consent

      - ✓ A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
      - ✓ The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.

   b. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart indicating the participants as participant 1, participant 2, etc and a column indicating that verbal consent was given along with the date.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc.
5. In emergency situations when no surrogate consent can be taken. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the EC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he / she gains consciousness or to relative / legal guardian when available later.

7. Flow chart

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

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
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