Title: Request for Waiver of Written Informed Consent

SOP Code: SOP 23/V1 dated 18th February 2017

Table of Contents:

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Review Board (IEC) may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent. The Application Form *AX 01/SOP 23/V1* is designed to standardize the process of applying for consent waiver.

2. Scope

This SOP applies to the all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members at the Full Board meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Application Form. The Chairperson must sign and date letter conveying the decision *AX 01/SOP 23/V1.*

4. 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 at Full Board meeting
4	Communicate the decision to the Investigator	IEC Secretariat
5	Recording and filing the decision	IEC Secretariat

5. Detailed instructions

- When a request for waiver of consent is submitted by the Principal Investigator to the IEC secretariat, in the given format *AX 01/SOP 23/V1* stating the reasons for the consent waiver; 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. (Criteria stated on the back of the annexure *AX 01/SOP 23/V1)*.
  - ✓ 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. 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 decision 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 IEC will provide reasons for the same.

6. References:

[1] Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethical_guidelines.pdf* (last accessed 31st August 2013).

[2] 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website *http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm*, paragraph 46.116- 'General Requirements for Informed Consent' (last accessed on 31st August 2013).

7. Annexure

Annexure 1 *AX 01/SOP 23/V1* Application form for requesting waiver of consent

Annexure

AX 01/SOP 23/V1

Application form for requesting waiver of consent

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

_____

_____

_____

4. **Names of other participants, staffs and students:**

_____

_____

_____

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

☐ Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC 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 Guidelines (ICMR 2006 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)

[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 Chairperson with Date: _____

Type of research projects which may qualify for consent waiver:

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 2006 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. (*ICMR guidelines,* 45CFR 46*)* 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. *(ICMR 2006 guidelines)*

   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 IEC.

   [In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].

   The following points need to be considered.

   a. The following documents need to be submitted for the IEC review

      - 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 can indicate the paticipants as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.

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. (ICMR 2006 guidelines)

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. (ICMR 2006 guidelines)

5. In emergency situations when no surrogate consent can be taken. *(ICMR 2006 guidelines)* when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC 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.

References:

[1] Ethical Guidelines for Biomedical research on Human Participants, ICMR 2006 http://www.icmr.nic.in/ethical_guidelines.pdf.

[2] 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm, paragraph 46.116- 'General Requirements for Informed Consent'.