



**INSTITUTIONAL ETHICS COMMITTEE (IEC)**  
Seth G. S. Medical College and KEM Hospital, Mumbai.

**Annexure 1**

**AX 01/SOP 19/V7**

**Application form for Requesting Waiver of Consent**

1. **IEC No. of the Project:** .....
2. **Principal Investigator's Name:** ..... **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).
    - a. Research involves 'not more than minimal risk'.
    - b. There is no direct contact between the researcher and participant.
    - c. Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines), National Guidelines for Ethics Committees Reviewing Biomedical & Health Research.
    - d. 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 participants .....

**Signature with date of Principal Investigator:** .....

**Final decision at full board meeting held on:** .....

**Waiver granted:** Yes  No

If not granted, reasons: .....

**Signature of the Chairperson/Member Secretary with Date:** .....



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**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 2017 & National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) 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 2017, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) 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 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research). 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 participants 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 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research).

4. Research on anonymized 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 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research).

5. In emergency situations when no surrogate consent can be taken. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) 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.