

Title: Waiver of Written / Verbal Informed Consent

SOP Code: SOP15/v2

Effective Date: 01/08/2016

Prepared by:

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Notified by:

Registrar Yenepoya University vide Notification No. YU/REG/ACA/YUEC/FERCAP/01/2016 dated 01/08/2016	Signature with Date
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which Yenepoya University Ethics Committee (YUEC) 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 IEC that ask for consent waiver.

3. Responsibility

It is the responsibility of the YUEC 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 (Ann01/SOP15/v2). The Chairperson will sign and date the letter conveying the decision.

4. Detailed instructions:

- 4.1 The application form (Ann01/SOP15/v2) is designed to standardize the process of applying for consent waiver.
- 4.2 When a request for waiver of consent is received from the Principal Investigator (PI) to the YUEC in the given format (Ann01/SOP15/v2), the following steps are taken:
 - 4.2.1 The YUEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed
 - 4.2.2 The YUEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. (as described in Annexure Ann01/SOP15/v2).
 - 4.2.3 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*).

- 4.2.4 The final decision whether to grant the waiver is taken at the next YUEC meeting, unless the project is considered under expedited review, in which case the waiver is ratified *post facto* in the next meeting.
- 4.2.5 The decision regarding approval/disapproval of waiver is informed to the Principal Investigator in writing. If the waiver is not granted, YUEC will provide reasons for the same.

5 Annexures:

Ann01/SOP15/v2

Application form for requesting waiver of consent

**Ann01/SOP15/v2
Application form for requesting waiver of consent**

Sl No	Details	Response from PI
1	Study title	
2	Name and affiliation of the Principal Investigator	
3	Name(s) and affiliation(s) of co-investigators (if any)	
4	Request for waiver of informed consent	Please tick the reason (vide infra more details) <ol style="list-style-type: none"> 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)

5	Separate signed statement assuring that rights of participants are not violated	Yes/No
6	Clarify the measures described in the protocol for protecting confidentiality of data and privacy of participants	

Principal Investigator's Name and signature with date:

Final decision at the YUEC meeting held on (date):	Extract of resolution of minutes:
If waiver not granted please state the reasons, if not already mentioned in the resolution:	
Signature of 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. 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 YUEC. [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 YUEC 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 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.

6 Flowchart:

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