


Title: Waiver of Informed Consent

SOP Code: SOP15/v3

Effective Date: 03/10/2019

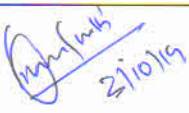
Prepared by:

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| Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee | Signature with date  3/10/2019 |
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Reviewed by:

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| Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee | Signature with Date  30/9/19 |
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Approved by:

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| Dr. Vikram Shetty, Chairperson, YEC-1 | Signature with Date  2/10/19 |
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Notified by:

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| Registrar Yenepoya deemed to be University | Signature with Date  3/10 |
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- 1. Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the type of research protocols for which Yenepeya Ethics Committee - 1 (YEC-1) may grant a waiver of consent.
- 2. Scope:** This SOP applies to all protocols submitted for initial ethical review by the YEC-1 that submit a request for consent waiver.
- 3. Responsibility:**
 - 3.1. YEC-1 Chairperson will:**
 - 3.1.1. Sign and date the decision form.
 - 3.2. YEC-1 Member-Secretary will:**
 - 3.2.1. Decide on the waiver of consent request and categorize the protocol according to the risk involved
 - 3.2.2. Communicate the decision on the waiver of consent to the PI
 - 3.3. YEC-1 Secretarial staff will:**
 - 3.3.1. Check the protocol for completeness and the waiver of consent duly filled
 - 3.4. YEC-1 member(s) will:**
 - 3.4.1. Review and approve/disapprove the request for waiver of consent
 - 3.4.2. Vote in the decision-making of the waiver request when kept for full review.
- 4. Detailed instructions:**
 - 4.1. Eligibility for waiver of consent:** The following protocols may be considered for waiver of consent. In addition to the waiver being scientifically justified, the request for waiver must also fulfill any one of the following criteria:
 - 4.1.1. Retrospective studies, where the participants are de-identified or cannot be contacted;
 - 4.1.2. Research on anonymized biological samples/data;
 - 4.1.3. Public health studies/surveillance programmes/programme evaluation studies where the data are anonymized and all participant and community identifiers delinked;
 - 4.1.4. Research on data available in the public domain; or

- 4.1.5. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. In such a case, an attempt should be made to obtain the participant's consent at the earliest.

4.2. Receipt of the application for waiver of consent:

- 4.2.1. Principal Investigator (PI) will request for waiver of consent in the given format to the YEC-1 (Ann01/SOP15/v3)
- 4.2.2. The YEC-1 Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed
- 4.2.3. The YEC-1 Member-Secretary will check the protocol for eligibility for waiver of consent before categorizing the protocol
- 4.2.4. When a waiver of consent is requested for research on sensitive data, or when the research proposes to recruit vulnerable populations like HIV/leprosy, or when the study is in the nature of genetic research, the Member-Secretary may recommend to keep the waiver request for a full review, and in the meeting all members will take a decision on whether to approve the waiver or not .

4.3. Review of the waiver of consent application:

- 4.3.1. The YEC-1 member(s) assigned to review the protocol will review the waiver of consent application form and approve/disapprove the waiver of consent based on the merits of the protocol (as described in Annexure Ann03/SOP15/v3).
- 4.3.2. The YEC-1 member reviewing the protocol should look for description and adequacy of mechanisms for the protection of the identity of the research participants and maintaining confidentiality of the study data.

4.4. Decision making:

- 4.4.1. The decision of approval of waiver of consent for protocols which are categorized as expedited review are ratified in the subsequent YEC-1 meeting. (as described in Ann04/SOP15/v3)
- 4.4.2. The decision to grant waiver of consent for protocols which are

categorized as full review will be done in the YEC-1 meeting. (as described in Annexure Ann04/SOP15/v3)

4.5. Communication with the Principal Investigator:

- 4.5.1. The decision of approval of waiver of consent application will be informed to the Principal Investigator in writing on the YEC-1 approval letterhead for the protocol.
- 4.5.2. The decision of disapproval of waiver of consent application will be communicated to the Principal investigator in writing, stating reasons for the same and the Principal investigator is recommended to submit the informed consent documents.

5. Annexures:

- 5.1. Ann01/SOP15/v3: Application form for requesting waiver of consent and declaration of maintenance of data anonymity for samples/data collected after waiver of consent
- 5.2. Ann02/SOP15/v3: Reviewer's decision on request for waiver of consent
- 5.3. Ann03/SOP15/v3: YEC-1 decision on request for waiver of consent

Ann01/SOP15/v3

**Application form requesting waiver of consent and declaration of maintenance of data
anonymity for samples/data collected after waiver of consent**

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| 1. | Protocol No.: | |
| 2. | Title of the project: | |
| 3. | Name of the Principal investigator: | |
| 4. | Department | |
| 5. | Names of the Co-investigators and departments: | |
| 6. | Reason for request for waiver of informed consent | Please tick the reason (vide infra - more details) |
| a. | Research involves 'less than minimal risk' | |
| b. | There is no direct contact between the researcher and participant | |
| c. | Emergency situations as described in ICMR Guidelines | |
| d. | Any other (please specify) | |
| 7. | Nature/source of data collection (anonymized) | Tick whichever applicable and mention the department or source from where this will be collected |
| a. | Medical records/ investigation reports | |
| b. | Clinic/ Hospital Registers | |
| c. | Radiological/ ultrasound/ other imaging films AV recordings | |

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| d. | Blood samples collected for diagnostic tests | |
| e. | Tissues/ body fluids collected for diagnostic purposes | |
| f. | Tissues/ body parts removed surgically for therapy | |
| g. | Tissues/blood removed surgically for donation | |
| h. | Samples collected for previous research | |
| i. | Microorganisms cultured in the laboratory from samples obtained for diagnosis/treatment | |
| j. | Data (including protographs, soft copies stored on computers) collected for previous research, healthcare, academic or therapeutic purposes | |
| k. | Medical education technology studies and feedback analysis | |
| l. | Medical or academic audit reports or hospital administrative policies/procedures | |
| m. | Commercially available cell lines/ tissue | |
| n. | Data in public domain | |
| o. | Any other (Specify with details) | |
| <p>Declaration of confidentiality of participants for anonymized data from the MRD files/images/samples/ other sources of data</p> | | |

| | | |
|----|---|--|
| 1. | I declare that I shall maintain the privacy of the participants by not collecting any personal information like name, phone number, address or other identifying data from the MRD files/images/samples/ other sources of data mentioned above collected for the purpose of this research and related publications. | |
| 2. | I declare that I will not use any of the personal information like name, phone number, address or other identifying data in order to contact the patient for any details which are not available in the MRD files/images/samples/ other sources of data for the purpose of this research. | |
| 3. | I declare that I will not take photocopies/ photographs/ scans of MRD files/images/samples/ other sources of data for the purpose of this study | |
| 4. | I declare that I will maintain the confidentiality of data collected from the MRD files/images/samples/ other sources of data during and after the study. | |
| 5. | I declare that I will access the files/images/samples/other sources of data only after the approval from YEC-1. | |
| 6. | I declare that only one of the research team members will access the MRD files/images/samples/other sources of data and will not be accessed by any other person. | |

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| 7. | I declare that I will collect only that data which is relevant to meet the objectives of the study as per the data collection form approved by YEC-1. | |
| 8. | I declare that I will access only those numbers of MRD files/images/samples/ other sources of data as is approved by the YEC-1. | |
| 9. | I declare that I will access only those MRD files/images/samples/ other sources of data that fit in the inclusion and exclusion criteria as per the protocol approved by YEC-1. | |
| 10. | I declare that the MRD files/images/samples/ other sources of data accessed for the purpose of this research will be anonymized using the following method: | |
| 11. | I declare that the above method of anonymization will be carried out by Dr./Mr./Ms. _____ who is not part of the research team. | |
| Signature of the Principal investigator with date: | | |
| Signature of the Guide (if applicable) with date: | | |
| Signature of the HOD with date: | | |

Copy to MRD/ concerned department with the custody of the samples. (after the EC approval is given for information):

COO/ Dean

Ann02/SOP15/v3

Reviewer's decision form for waiver of consent

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| Decision of the reviewer: | | |
| 1. | Waiver of consent may be approved | |
| 2. | More information required. Details of information required | |
| 3. | Waiver of consent may not be approved: | |
| 4. | Reasons for not approving | |
| 5. | Recommend discussion in the YEC-1 meeting | |
| 6. | Signature of the reviewer with date | |

Ann03/SOP15/v3

Final decision of the YEC-1 on the request for waiver of consent

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| Final decision at the YEC-1 meeting held on (date): | |
| Approved | Yes / No |
| Reasons if not approved | |
| Extract of the minutes of the meeting attached | Yes / No |
| Signature of the Chairperson with date | |

6. Flowchart:

