Title: Waiver of Consent

SOP Code: SOP15/v1

Effective Date: 20/02/2025

Prepared by:

Dr. Geetha B Shetty Member, YEC-3 SOP Subcommittee	Signature with date

Reviewed by:

Dr. Asir John Samuel Convenor, YEC-3 SOP Subcommittee	Signature with Date

Approved by:

Dr Haripriya S Chairperson, YEC-3	Signature with Date

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date

Table of Contents:

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the type of research protocols for which YEC-3may approve a waiver of consent.

2. **Scope:** This SOP applies to all protocols submitted for initial ethical review by YEC-3 that submit a request for consent waiver.

3. **Responsibility:**

3.1. YEC-3 Chairperson will:

3.1.1. Will ensure that waivers are granted as per the existing guidelines

3.2. YEC-3Member-Secretary will:

3.2.1. Carry out an initial review of waiver of consent application, for level of risk at the time of categorization (SOP7/v1)

3.2.2. Communicate the decision on the waiver of consent to the PI

3.3. YEC-3 Secretarial staff will:

3.3.1. Check the completeness of the waiver of consent form duly filled

3.3.2. Send the waiver request to the member assigned as reviewer by the Member-Secretary

3.4. YEC-3 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 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 anonymous/anonymized biological samples/data;

4.1.3. Public health studies/surveillance/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-3 (Ann01/SOP15/v1)

4.2.2. The YEC-3Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed

4.2.3. The YEC-3Member-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 the waiver request for 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-3member(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 Ann02/SOP15/v1).

4.3.2. The YEC-3member reviewing the protocol should look for description and adequacy of mechanisms for the protection of the identity of the research participants and maintain confidentiality of the samples/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-3meeting. (as described in Ann02/SOP15/v1)

4.4.2. The decision to approve waiver of consent for protocols which are categorized as full review will be done in the YEC-3meeting (Ann02/SOP15/v1).

4.5. Communication with the Principal Investigator:

4.5.1. The decision of approval of waiver of consent application will be included in the YEC-3approval letter for the protocol.

4.5.2. The decision of disapproval of waiver of consent application will be communicated to the PI in writing, stating reasons for the same and PI is recommended to submit the informed consent documents.

5. References:

5.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

6. Annexures:

6.1. Ann01/SOP15/v1: Application form for requesting waiver of consent and declaration of maintenance of data anonymity for samples/data collected after waiver of consent

6.2. Ann02/SOP15/v1: Decision form for waiver of consent

Ann01/SOP15/v1

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

1.	Protocol No			
2.	Title of the project:			
3.	Name of the Principal investigator:			
4.	Department:			
5.	Names of the Co-investigators and departments *(add rows if necessary)*:			
6.	Reason for request for waiver of informed consent	Please tick the reason		
	A. Research involves 'less than minimal risk'			
	B. Research involves anonymized human tissue samples/data and does not collect personal identifiers like name, contact details, address, MRD number			
	C. There is/will be no direct contact between the researcher and participant			
	D. Emergency situations as described in ICMR Guidelines			
	E. Any other (please specify)			
7.	Nature/source of data collection (anonymized)	Applicable/ not applicable	Source of data	Permission obtained Yes/No
a.	Medical records/ investigation reports			
b.	Clinic/ Hospital Registers			
c.	Radiological/ ultrasound/ other imaging films AV recordings			
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 (provide details of the research, EC approval and consent form as attachment)			
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.	Any other (Specify with details)			
n.	Commercially available cell lines/ tissue			
o.	Data in public domain			
Anonymization of the data/samples				
a.	Describe the method of anonymization			
b.	Name, designation and department of the individual who will carry out the anonymization/coding			
c	Signature of the person carrying out the anonymization/coding			
Declaration of confidentiality of participants for anonymized data from the MRD files/images/samples/ other sources of data				
I declare that				

- I shall maintain the privacy of participants by not collecting any personal information like name, phone number, address or other identifying data from MRD files/images/samples/ other data sources mentioned above collected for the purpose of research and related publications.
- I will not 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.
- I will not take photocopies/ photographs/ scans of MRD files/images/other sources of data for the purpose of this study
- I will maintain the confidentiality of data collected from the MRD files/images /samples/ other sources of data during and after the study. \
- I will access files/images/samples/other sources of data only after the approval from YEC-3.
- Only research team members will access the MRD files/images/samples/other sources of data and will not be accessed by any other person.
- 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-3.
- I will restrict to the approved sample size as approved by the YEC-3.
- 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-3.
- The MRD files/images/samples/ other sources of data accessed for the purpose of this research will be anonymized as described above

Signature of the Principal investigator with date:

Signature of the Guide (if applicable) with date:	
Signature of the HOD with date:	

Please submit a copy of this declaration to the MRD/ concerned department which holds custody of the samples after the EC approval is given.

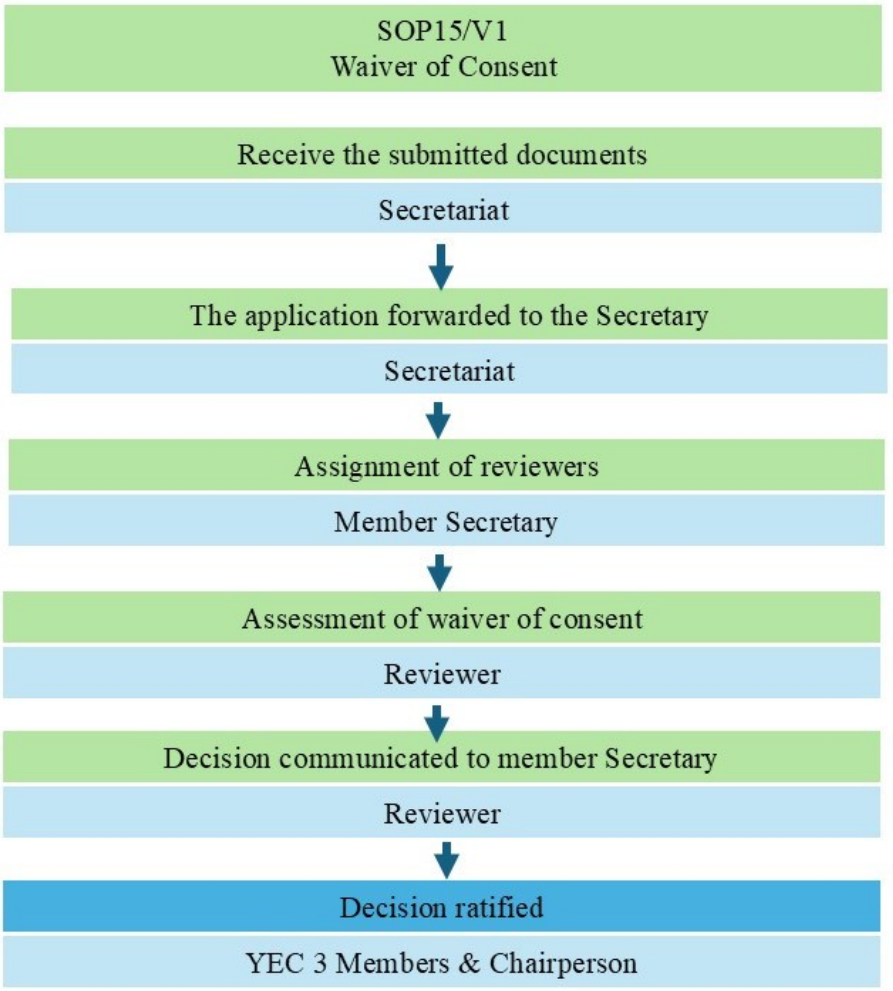
Ann02/SOP15/v1

Decision form for waiver of consent

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 YEC-3meeting	
6.	Signature of the reviewer with date	

Final decision at the YEC-3meeting 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	

7. Flowchart:



8. Glossary:

ICMR: Indian Council of Medical Research

MRD: Medical Records Department