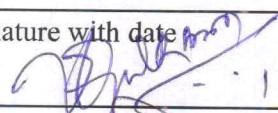


Title: Dealing with Requests and/or Complaints of all stakeholders to Yenepoya Ethics Committee-1


SOP Code: SOP17/v4

Effective Date: 01/07/2023

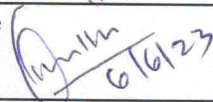
Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date  - 1/6/2023
--	--

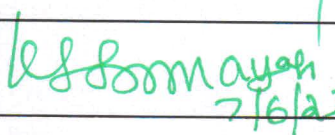
Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with Date  1/6/23
--	--

Approved by:

Dr. Vikram Shetty Chairperson, YEC-1	Signature with Date  6/6/23
---	---

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date  7/6/23
---	--

Details of superseded SOP17

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP17/v41

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	<ol style="list-style-type: none"> 1. Glossary section added in the SOP 2. Corrected discrepancy in responsibilities of who will receive the complaints 3. Title revised to include "all stakeholders" 4. Timelines for resolving queries/complaints specified

Table of Contents:

No.	Content	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Detailed Instructions	4
5	Annexures	6
6	Flowchart	7
7	Glossary	7

1. **Purpose:** The purpose of this SOP is to describe procedures for dealing with requests for information about the rights of research participants, resolving complaint(s) and receiving research participant feedback that is/are related to participation in research approved by Yeneploya Ethics Committee -1 (YEC-1).
2. **Scope:** This SOP applies to the handling of requests for information/complaints made by participants/participant representatives/any other research-related stakeholders concerning the rights of human participants of research protocols approved by the YEC-1.
3. **Responsibility:**
 - 3.1. **YEC-1 Chairperson will**
 - 3.1.1. Ensure that all requests/queries/complaints are resolved in a satisfactory and timely manner
 - 3.1.2. Approve the formation of a subcommittee to inquire into any research-related complaints by a participant/representative, or assign the task to either the Member-Secretary or any other member of YEC-1.
 - 3.1.3. Oversee the functioning of said subcommittee to inquire into any research-related complaints by the participant/representative.
 - 3.2. **YEC-1 Member- Secretary will**
 - 3.2.1. Take forward the request/query/complaint from the research participant, or representative, a member of the research team or other research-related stakeholders after the Secretariat informs about the receipt of the complaint in written format or through email.
 - 3.2.2. Assist the complainant in filling out the relevant form (Ann01/SOP17/v4)
 - 3.2.3. Communicate with the Chairperson whether to create a subcommittee or attempt to resolve the issue at the level of the Member-Secretary.
 - 3.2.4. Constitute a subcommittee, if needed, with the approval of the Chairperson.
 - 3.2.5. Inquire details of and respond to the request or query by the research participant/representative
 - 3.2.6. Table the recommendation of the subcommittee in the subsequent meeting
 - 3.2.7. Communicate the recommendation of the enquiring member/ YEC-1 to the participant/representative, researcher or the research-related stakeholder
 - 3.2.8. Follow-up the complaint to ensure that the complaint is resolved
 - 3.2.9. Ensure that the participant charter of rights and responsibilities is displayed in prominent places in the hospital building (in English and local languages).
 - 3.2.10. Will develop a feedback form for research participants to share their experiences.
 - 3.3. **YEC-1 Secretariat will**
 - 3.3.1. Inform the Member-Secretary/Chairperson about the request/query/complaint
 - 3.3.2. Provide assistance to the complainant (if needed) to fill the complaint form (Ann01/SOP17/v4)

- 3.3.3. Communicate the formation of the subcommittee
- 3.3.4. Ensure that the Clinical Trial site has a stock of the research participant feedback form always available.

4. Detailed instructions:

4.1. Dissemination of information regarding participant rights and responsibilities:

The hospital will prominently display the participant charter of rights and responsibilities which clearly contains the following information in local languages.

- 4.1.1. Rights and voluntariness of the participants of research
- 4.1.2. Responsibilities of the research participant
- 4.1.3. Rights of participants to complain to YEC-1 and how to access the forms
- 4.1.4. Contact details of YEC-1 in the case of requests or queries or complaints

4.2. Receipt of requests or complaints from research participants:

- 4.2.1. When a written (or email) request/ query/ complaint is made by a research participant, a representative of the participants of research, a member of the research team, or any other stakeholder in the research process, the same will be received by the YEC-1 Secretarial staff and they will inform the Member-Secretary within one calendar day.
- 4.2.2. The request/ query/ complaint is entered in the form (Ann01/SOP17/v4) either directly by the participant/representative of the participant or with the assistance of the Secretarial staff/Member-Secretary.

4.3. Initiate response to the request/query/complaint:

- 4.3.1. The Member Secretary will inform the Chairperson about the request, query or complaint received from the research participant/representative within 24 hours
- 4.3.2. In case of a request for information or a query, the Member-Secretary/ Chairperson will provide the information or will designate one or more YEC-1 member(s) to provide such information until the request has been satisfactorily responded.
- 4.3.3. In case of a complaint received from a research participant/representative, the Member-Secretary/Chairperson will initiate the process to address the complaint, to redress the grievance within 48 hours, by either constituting a subcommittee or handling the issue at the level of the Member-Secretary.
- 4.3.4. The Member Secretary or YEC-1 member assigned the task of enquiring may gather additional details of the request/query/complaint by interviewing the participant/representative or by examining any relevant documents as necessary.
- 4.3.5. If required, the Member-Secretary or YEC-1 member assigned the task of inquiring may call for additional relevant information and documents from the Principal Investigator (PI).

4.4. Formation of a subcommittee:

- 4.4.1. Chairperson will direct the Member-Secretary to form a subcommittee consisting of two or more YEC-1 members to conduct an enquiry
- 4.4.2. A meeting of the subcommittee will be held for discussion regarding the complaint and the redressal mechanisms in case of urgent and serious matters or the matter is considered for discussion at the subsequent YEC-1 meeting
- 4.4.3. The subcommittee will gather essential facts to determine the seriousness and impact of the situation
- 4.4.4. Wherever required, the subcommittee will assess the situation and mediate a dialogue between participant and PI in an attempt to resolve the matter.
- 4.4.5. The subcommittee will submit a detailed report of its enquiry to the YEC-1 Chairperson/Member-Secretary within 4 weeks.
- 4.4.6. Member-Secretary will table this item in the agenda of the subsequent meeting

4.5. Discussion in the YEC-1 meeting:

- 4.5.1. The subcommittee report will be discussed in the YEC-1 meeting
- 4.5.2. The final decision will be taken by the YEC-1 members based on the recommendation of the subcommittee and the decision of the YEC-1
- 4.5.3. The recommendation is informed to the research participant and the PI by the Secretariat.
- 4.5.4. A brief summary report without compromising confidentiality will be sent to the office of the Registrar.
- 4.5.5. The final decision will include one of the following
 - 4.5.5.1. No further action required:
 - 4.5.5.2. Request information:
 - 4.5.5.3. Recommend further action
- 4.5.6. The final decision, action taken and the follow-up will be recorded in the form (Ann01/SOP17/v4) signed and dated by the Chairperson/Member-Secretary.

4.6. Documentation and follow-up:

- 4.6.1. Secretariat staff will place all documents in the relevant protocol file.
- 4.6.2. The Member-Secretary will follow-up to ensure that the complaint is resolved.

4.7. Feedback from research participants:

- 4.7.1. The Member-Secretary will prepare a feedback form designed to allow research participants to share their experiences in the clinical trial/research study (Ann02/SOP17/v4)
- 4.7.2. The Secretariat will print these forms and hand them over to the Coordinator of the Clinical Trial Site and request the forms to be handed over to research

participants soon after enrollment in the clinical trial.

5. **Annexure:**

5.1. Ann01/SOP17/v4: Request/Query/Complaint form

5.2. Ann02/SOP17/v4: Feedback from participants

Ann01/SOP17/v4

Request/Query/Complaint form

To be filled in by the participant/LAR/complainant:	
If the request/query/complaint is being raised by a person external to the research process, he/she may fill in whatever information is available and known.	
Protocol Number:	
Title of the Project:	
Name of the Principal Investigator:	
Starting date of participant enrollment:	
Name of the participant/LAR/person with the request/ query/complaint	
Date of enrollment of the participant into the study	
Date of request/query/complaint	
Please provide details of the request/query/complaint	Add extra sheets if necessary
To be filled in by the Member-Secretary YEC-1/Member-designate:	
Details of the facts gathered	
Date of meeting of the subcommittee, if any	
Recommendation(s) of the Member-Secretary / enquiring YEC-1 Member/subcommittee, if any	
Name(s) of the Member-Secretary/enquiring YEC-1 member/subcommittee members	
To be filled in by the Member-Secretary	
Final decision at the YEC-1 meeting	1. No further action required: 2. Request information: 3. Recommend further action
Date of YEC-1 meeting	
Signature of Chairperson/Member-Secretary	
Date and entry of communication with complainant/PI/YU/Regulatory authorities <i>Attach copy of communication with this form before filing in the concerned protocol</i>	
Follow-up by Member-Secretary to confirm that the	

complaint is resolved	
Signature of the Member-Secretary and date	

Ann02/SOP17/v4:

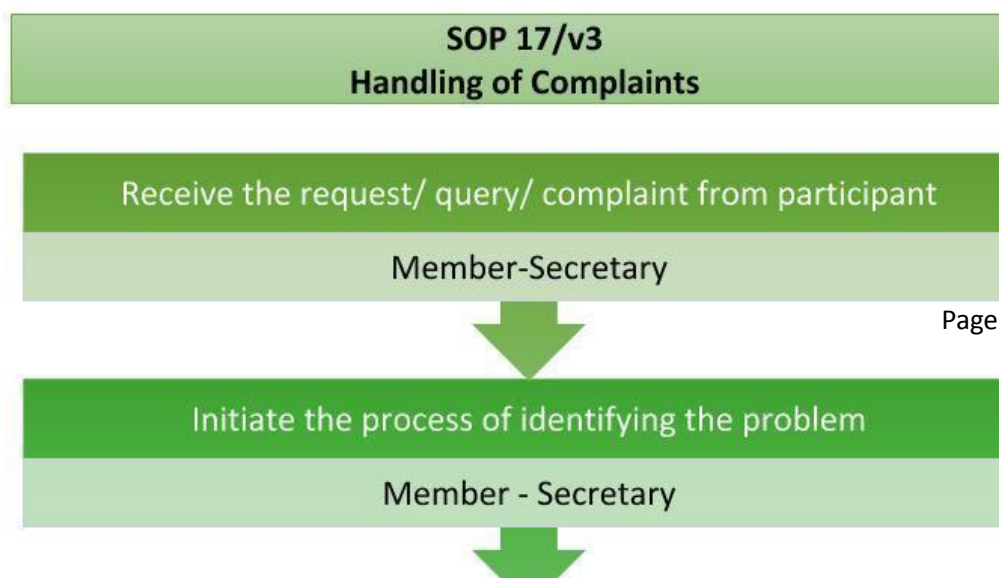
Feedback from participants

(May be filled by the participant/LAR/other stakeholder on behalf of the participant is unable to fill the form)

To be filled in by the participant/LAR:	
Please provide us a feedback on the safety and wellbeing of the participants of research	
Protocol Number: (Optional)	
Title of the Project: (Optional)	
Name of the Principal Investigator: (Optional)	
Starting date of participant enrollment:	
Name of the participant/LAR/person: (Optional)	
Date of enrollment of the participant into the study	
1. Was the recruitment done without any force or coercion?	Yes/No Comments:
2. Was the informed consent process done in a detailed manner providing all the information required to make a decision?	Yes/No Comments:
3. Was adequate opportunity provided to discuss and clarify doubts?	Yes/No Comments:
4. Was adequate time given to decide to participate or not?	Yes/No Comments:
5. Have you been informed about your rights as a research participant?	Yes/No Comments:
6. Have you been informed about your responsibilities as a research participant?	Yes/No Comments:
7. Have you been assured privacy and anonymity?	Yes/No Comments:
8. Have you been informed about the harms and benefits of the study?	Yes/No Comments:
9. Have you been informed that this is research and not part of your treatment?	Yes/No Comments:
10. Have you been provided a copy of the participant information sheet and signed informed consent form?	Yes/No Comments:
11. Have you been provided with contact details of the researcher?	Yes/No Comments:
12. Do you feel that your rights, safety and well	Yes/No

being is being protected?	Comments:
13. Have you been provided contact details of the Ethics Committee whom you may contact in case you have any concerns about the research?	Yes/No Comments:
Date of feedback:	
Name and signature of the participant/LAR/other representative with date	
To be filled in by the Member-Secretary	
Details of the facts gathered	
Date of meeting of the subcommittee, if any	
Recommendation(s) of the Member-Secretary / enquiring YEC-1 Member/subcommittee, if any	1. No further action required: 2. Request information: 3. Recommend further action
Name(s) of the Member-Secretary/enquiring YEC-1 member/subcommittee members	
Final decision at the YEC-1 meeting	1. No further action required: 2. Request information: 3. Recommend further action
Date of YEC-1 meeting	
Signature of Chairperson/Member-Secretary	
Date and entry of communication with complainant/PI/YU/Regulatory authorities <i>Attach copy of communication with this form before filing in the concerned protocol</i>	
Follow-up by Member-Secretary to confirm that the complaint is resolved	

6. **Flowchart:**



7. **Glossary:**

LAR: Legally Acceptable Representative

PI: Principal Investigator