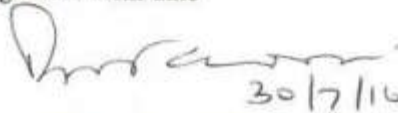


Title: Dealing with Participants' Requests and/or Complaints to Institutional Ethics Committee


SOP Code: SOP17/v2

Effective Date: 15/07/2016


Prepared by:

Dr. Ravi Vaswani Member, YUEC	Signature with date  30/7/16
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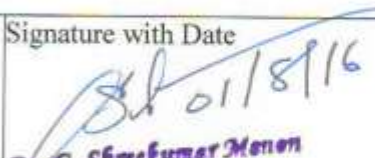
Reviewed by:

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with Date  30/07/2016
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Approved by:

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date  3/8/16
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Notified by:

Registrar Yenepoya University vide Notification No. YUREG/ACA/YUEC/FERCAP/01/2016	Signature with Date  01/8/16 Dr. G. Shree Kumar Menon Registrar Yenepoya University Mangaluru - 575 018
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Title: Dealing with Participants' Requests and/or Complaints to Institutional Ethics Committee

SOP Code: SOP17/v2

Effective Date: 01/08/2016

Prepared by:

Dr. Ravi Vaswani Member, YEC-1	Signature with date
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Reviewed by:

Dr. Uma Kulkarni Jt Secretary, YEC-1	Signature with Date
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Approved by:

Dr. Sayeegeetha Hegde Chairperson, YEC-1	Signature with Date
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Notified by:

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

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Yenepoya Ethics Committee -1 (YEC-1).

2. Scope

This SOP applies to handling of requests for information/complaints made by participants concerning the rights and well-being of research subjects participating in research studies by the YEC-1.

3. Responsibility

It is the responsibility of the YEC-1 Secretariat and Chairperson/Member-Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

4. Detailed instructions:

- 4.1 A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the YEC-1 Member-Secretary after entering into the request record form as provided in the Annexure 1 (*Ann01/SOP17/v2*)
- 4.2 Alternately, the Member-Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form (*Ann01/SOP17/v2*) and notify the Secretariat.
- 4.3 The Member Secretary will additionally ascertain details of the request/complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member-Secretary will call for additional relevant information and documents from the Principal Investigator (PI).

4.4 The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.

4.5 In case of a request for additional information or clarification, the Member-Secretary in consultation with the Chairperson will provide the information himself/herself or will designate one or more YEC-1 member(s) to provide such information.

4.6 In case of a complaint received from a research participant:

- Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to
 - Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter
 - Call an emergency meeting of two or more IEC members for discussion or
 - Consider the matter for discussion at the next YEC-1 meeting
- The Chairperson/Member Secretary/designated YEC-1 members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The YEC-1 will insist on factual details to determine gap, if any, between truth and individual perception.

4.7 The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.

4.8 The information including any action taken or follow-up and final decision will be recorded in the form (*Ann01/SOP17/v2*) and the form will be signed and dated.

4.9 YEC-1 members will be informed about the action taken and the outcomes in the forthcoming meeting (in case of requests/ complaints not discussed in previous meeting) and minuted.

4.10 The Secretariat will place all documents in the relevant study file.

5. Annexure

Ann01/SOP17/v2

Request / Complaint Form

Title of the Project	
Starting date of participant enrollment	
Date of enrollment of requestor/complainant	
Information requested/ complaint/query	
Action taken	
Reviewed by	
Final Decision	
Date of IEC meeting (if applicable)	

Signature of Member-Secretary:

Date:

6. Flow Chart

No	Activity	Responsibility
1	Receiving the request/ query/complaint from research participant	YEC-1 Member Secretary/ Member
2	Initiating process to identify the problem	YEC-1 Chairperson/ Member Secretary
3	Deliberations to arrive at solution	YEC-1 Chairperson/ Member Secretary/ Members
4	Communication with the research participant	YEC-1 Secretariat
5	File the request document	YEC-1 Secretariat