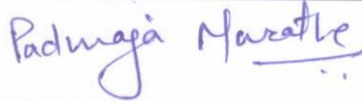
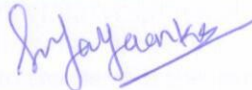

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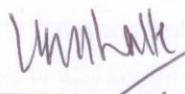
Title: Management of complaints by investigators

SOP Code: SOP 18/V5 dated 26th July 2017

Authors:

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Reviewed by:

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Approved by:

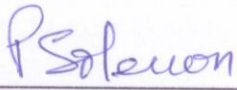
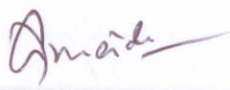

 Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with the appeal/complaint made by investigator (principal investigator, co-investigator) against the IEC office/members.

2. Scope:

This SOP applies to handling of appeal/complaint made by investigator (principal investigator, co-investigator) against the IEC office/ members. The investigator/s may submit the appeal/complaint to IEC office/ IEC Chairperson/ Member Secretary/ Members/ to the Head of the Institution

3. Responsibility:

It is the responsibility of the IEC to adhere to the principals of fairness, confidentiality, integrity and prevention of detriment while addressing appeal/ investigating the complaints by investigators.

It is the responsibility of the Member Secretary in consultation with the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred if complaints are received from investigators.

4. Flow chart

No.	Activity	Responsibility
1.	Receiving the appeal/complaint from investigators	IEC Members Secretary/ Secretariat/ Members
2.	Initiating process to identify the problem	IEC Member secretary/ Chairperson
3.	Deliberations to arrive at solution	IEC Chairperson/ Member Secretary/ Members
4.	Communication with the investigator	IEC Member Secretary/ Secretariat
5.	File the request document	IEC Secretariat


5. Detailed instructions:

5.1 Receiving the appeal/complaint from investigators

- IEC secretariat will receive a request, complaint or appeal by the investigator through Via Letter to Head of the Institution, Telephone call, fax, email or Walk-in etc.
- The annexure 1, AX 01/SOP 18/V5 will filled and forwarded by the secretariat to the member secretary / chairperson.

5.2 Initiating process to identify the problem

- The Member Secretary /Secretariat will call for relevant information and documents from the Investigator, as required

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- In case of a request for additional information or clarification, the Chairperson/ Member Secretary may decide to provide the information himself / herself or will designate one or more IEC member to provide such information. The Secretariat will make all documents relevant to the request, available to the Chairperson/ designated member.

5.3 Deliberations to arrive at solution

- The Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the investigator and member/ IEC office representative against whom complaint is lodged in an attempt to reach the amicable solution.
- The Chairperson / Member Secretary may consider the matter for discussion at the next full board meeting or call an emergency meeting of two or more IEC members for discussion in order to resolve the matter.
- The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The Head of the institution if involved in the matter by investigator will be informed about the deliberations between investigator/s and IEC and the final decision on the matter. The suggestions/ recommendations of the Head of the institution will be followed by IEC and the investigator/s.
- If the mutual agreement regarding workable solution is reached the matter will be considered as resolved.
- If there is no mutual agreement and matter is not resolved, a meeting will be called as soon as possible of Head of the institution/ Chairperson/Member secretary and / or IEC member and the concerned investigator/s to resolve the matter.
- The information of all these meetings including any action taken or follow-up will be recorded in the form AX 01/SOP 18/V5 and the form is signed and dated.

5.4 Communication with the investigator


- The final decision will be informed to the investigators by the Secretariat.
- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting.

5.5 File the request document

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

6. Reference

Kathleen J. Motil, Janet Allen and Addison Taylor, "When a Research Subject Calls with a Complaint, What Will the Institutional Ethics Committee do?" *IEC: Ethics and Human Research* 26, no.1 (January –February 2004):9-13

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7. Annexure


Annexure 1 *AX 01/SOP 18/V5* Complaint/ Appeal Record Form

Annexure 1

AX 01/SOP 18/V5

Complaint / Appeal Record Form for Investigators

Date	
Received by :	
Complaint/ Appeal received through:	<input type="checkbox"/> Letter to Head of the Institution <input type="checkbox"/> Telephone call No _____ <input type="checkbox"/> Fax No _____ <input type="checkbox"/> Letter / Date _____ <input type="checkbox"/> E-mail / Date _____ <input type="checkbox"/> Walk-in / Date / Time _____ <input type="checkbox"/> Other, specify _____
Investigator's Name:	
Contact Address:	
Phone:	
Details of complaint/appeal	_____ _____
Deliberations with investigators	

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Actions taken:	<hr/> <hr/> <hr/> <hr/>
Outcome:	<hr/> <hr/> <hr/>

Signature of the IEC Member Secretary/ Chairperson

Date _____