

Title: Review of Resubmitted Protocols

SOP Code: SOP 08/V1 dated 18th February 2017

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Institutional Ethics Committee (IEC) manages resubmitted study protocols.

2. Scope

This SOP applies to study protocols that have been resubmitted to the IEC with the Principal Investigator responding to clarifications and modifications sought and comments made by the IEC during initial review.

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC for reconsideration of a protocol; which is previously reviewed earlier with recommendations from IEC for some changes.

A re-submitted protocol may be reviewed by either the Chairperson or two or more IEC members designated by the Chairperson/ Member secretary, or all the IEC members as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting. This information can be found on the IEC Decision Form (AX 03/SOP 06/V1).

4. Flow chart

No.	Activity	Responsibility
1	Receive resubmitted protocol package, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents	IEC Secretariat
2	Review the revised protocol	IEC Members/Member Secretary/ Chairperson
3	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed instructions

5.1 Receipt of resubmitted protocol package and its distribution

- The Secretariat will verify if the principal investigator has forwarded the reply within 180 days of receipt of the letter of comments by the IEC.
- The Secretariat will check the resubmitted protocol packages (hard and soft copy) for the following items
 - ✓ Reply to the IEC letter of comments
 - ✓ Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc are included as part of the package with the changes made to the documents either underlined or highlighted.
 - ✓ Additional documents sought during initial review
- If above items are not submitted the Principal Investigator will be told to submit the complete package along with all the required documents.
- The Secretariat will refer to the IEC Decision Form *AX 03/SOP 06/V1* on the given protocol and distribute this package containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to
 - The Member Secretary for summarizing and including it on the agenda for full board discussion in the forthcoming meeting if the decision on the protocol was 'to be discussed at full board'
 - The designated IEC members if the decision on the protocol was 'to be reviewed by two or more IEC members'. The selection of the two or more IEC members is done by the Chairperson at the time of initial full board review or later.
 - The Chairperson/Member Secretary if the decision on the protocol was 'Approved with recommendations subjected to review by Chairperson/Member Secretary only' as per IEC Decision Form *AX 03/SOP 06/V1*.

5.2 Review the revised protocol to be carried out by IEC member/ Member Secretary/ Chairperson:

- The IEC member/ Member Secretary/ Chairperson will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the IEC have been followed or adequately responded to.
- The IEC member/ Member Secretary/ Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol *AX 01/SOP08/V1*

- The Secretariat will retrieve the Assessment Form for resubmitted protocol *AX 01/SOP 08/V1* from the members/Member Secretary/Chairperson.
- In case the decision is to discuss the revised protocol at the full board meeting, the Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.
- The Chairperson shall entertain discussion on the protocol revision from all the IEC members.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
 - a) Approved
 - b) Modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC members after receipt of the requested modifications:
 - c) Disapproved giving reasons for disapproval
- In case the revised protocol is already approved by the chairperson, the decision is informed to the members at the full board meeting.

5.3 Review of the revised protocol to be carried out at IEC meeting

- The Secretariat shall receive the Assessment Form for resubmitted protocol *AX 01/SOP 08/V1* from the members/Member Secretary/Chairperson.
- The Secretary shall present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
 - a) *Approved*
 - b) Require modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC members after receipt of the requested modifications: *Approved with modification*
 - c) *Resubmission*
 - d) *Disapproved* giving reasons for disapproval

5.4 Recording of the decision

- This IEC decision will be recorded by the Secretariat in the IEC Decision Form *AX 03/SOP 06/V1*.

5.5 Written communication of the IEC decision.

- The Administrative Officer will place the original completed documents along with the completed Form AX 01/SOP 08/V1, the Assessment Form and the Initial Review Application Form AX 01/SOP 06/V1 as well as the others in the protocol package.

The Secretariat shall then prepare a letter addressed to the investigator notifying the IEC decision (approval/ disapproval with reasons/ letter of comments) and shall take the Member Secretary or Chairperson's signature on it. The letter of comments sent to the investigator shall state that the reply to the letter is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records.

6. Glossary

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.
Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.

7. References

- [1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2013)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st August 2013)

8. Annexure

ANNEXURE 1 AX 01/SOP 08/V1 Assessment of Resubmitted Protocol

Annexure 1

AX 01/SOP 08/V1

Assessment of Resubmitted Protocol

Protocol Number	
Protocol Title:	
Number of review : <input type="checkbox"/> 2 nd Review <input type="checkbox"/> 3 rd Review <input type="checkbox"/> 4 th Review _____	
Principal Investigator:	Department:
Date of Initial Review by IEC:	Date of Last Review:
The IEC Decision recorded in the meeting minutes : (meeting held on _____)	
Opinion of the reviewer:	
Revision or Modification according to the recommendation	<input type="checkbox"/> Yes <input type="checkbox"/> No: Explain: _____
Approved	<input type="checkbox"/> Yes <input type="checkbox"/> No
If disapproved, reasons for disapproval	_____
Further revision or modification required	_____
To be discussed at the forthcoming full board meeting	_____
Any Other	_____
Name of the Reviewer: 1) _____ Signature: _____ Date: _____	
Name of the Reviewer: 2) _____ Signature: _____ Date: _____	
Final Decision: Approved YES <input type="checkbox"/> NO <input type="checkbox"/>	
If disapproved, reasons for disapproval _____	
Further revision or modification required/Resubmission <input type="checkbox"/>	
Any Other <input type="checkbox"/>	
Signature of the Member Secretary/ Chairperson: _____ Date: _____	