

**Title:**            Review of Amended protocol/ Protocol related documents

**SOP Code:**    **SOP 09/V1 dated 18<sup>th</sup> February 2017**

**Table of Contents**

<b>No.</b>	<b>Contents</b>	<b>Page No.</b>
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	5
7	References	5
8	Annexure	5

## **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe how amended protocol/ protocol related documents are managed and reviewed by the Institutional Review Board (IEC).

## **2. Scope**

This SOP applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols will not be implemented until reviewed and approved by the IEC.

## **3. Responsibility**

It is the responsibility of the IEC Secretariat to manage protocol amendments. The Member Secretary/ Chairperson will decide whether the proposed protocol amendment(s) need to undergo a full board review, review by designated IEC members or a review by the Member Secretary/Chairperson. The Member Secretary / Chairperson can take the decision if the amendment(s) is / are of administrative nature.

## **4. Flow chart**

<b>No.</b>	<b>Activity</b>	<b>Responsibility</b>
1.	Receive the Amendment Package and Verify the contents	IEC Secretariat
2.	Notify the Member Secretary/Chairperson of the IEC	IEC Secretariat
3.	Determine whether full board review/ review by designated members is needed	IEC Member Secretary / Chairperson
4.	Nomination of Members for review	IEC Chairperson
5.	Distribution to IEC members	IEC Secretariat
6.	Protocol Amendment Review Process	IEC Members / Member Secretary /Chairperson
7.	IEC Decision	IEC Member Secretary / Chairperson
8.	Communication of the Decision to the Principal Investigator	IEC Secretariat
9.	Store documents	IEC Secretariat

## **5. Detailed instructions**

### ***5.1 Receiving the Amendment Package and Verification of the contents***

- The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the Secretariat.

The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form *AX 01/SOP 09/V1*.

- The request form should:
  - ✓ state/describe the amendment
  - ✓ provide the reason for the amendment
  - ✓ state any untoward effects with original protocol
  - ✓ state expected untoward effects, if any because of the amendment
- The Administrative Officer will confirm that the:
  - ✓ amended version of the protocol and related documents is present
  - ✓ Changes or modifications in the amended version are underlined or highlighted.
- The Secretariat will check for completeness of the contents of protocol amendment submission package and inform the Principal Investigator telephonically to submit the required documents at the earliest, if any of the documents are missing / incomplete.

### **5.2 Notify the Chairperson of the IEC**

- After receipt of the amendment package, the Secretariat will inform the Member Secretary/ Chairperson of the IEC verbally.
- The Secretariat will send the request for amendment memorandum and the protocol and related documents to the Member Secretary / Chairperson within 7 working days of receipt of the package with the Protocol Amendment Assessment Form *AX 01/SOP 09/V1*.

### **5.3 Determine whether full review or review by designated members.**

- After review of the materials, the Chairperson / Member Secretary will determine whether the protocol requires a full board review.
- The amended protocol / protocol related document will require Full Board review if any of the following criteria are met:
- The Protocol amendment which increases risk to study participants, as judged by the Chairperson and/ or the Member Secretary, such as a change in study design, which may include but is not limited to:
  - a. additional treatments or the deletion of treatments
  - b. Changes in inclusion/exclusion criteria.
  - c. change in method of dosage formulation, such as, oral changed to intravenous
  - d. a significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
  - e. a significant decrease or increase in dosage amount

- If the Chairperson and / or the Member Secretary decides the protocol requires full board IEC review or review by two/more IEC members or review by Member Secretary/ Chairperson,
- The Chairperson/Member Secretary will indicate this decision on the Protocol Amendment Assessment Form *AX 01/SOP 09/V1*. The Form *AX 01/SOP 07/V1* will be used to nominate members by the Chairperson.

#### **5.4 Distribution to IEC members**

- The following documents will be distributed to the designated IEC members as per the decision regarding review
  - The amendment's revision documents to clearly identify each change.
  - Protocol Amendment Assessment Form *AX 01/SOP 09/V1*.
- Whenever the decision is Full Board review, the Secretariat shall summarise the points for discussion regarding the amended protocol/protocol related documents and shall place the protocol amendment request on the agenda for discussion at the next convened meeting.

#### **5.5 Protocol Amendment Review Process**

- The IEC member will review the amended documents and write his/her comments in the form- *AX 01/SOP 09/V1*.
- The reviewer may request the secretariat to keep the documents for full board discussion after review.
- The IEC members performing the review must sign and date the form i.e. *AX 01/SOP 09/V1* and return this to the Secretariat after the review.

#### **5.6 IEC Decision**

- In case the project is kept for full board review, the Member Secretary / designated member will read the comments on the amended protocol/ protocol related documents in the meeting. The Chairperson shall call for voting on the proposed amendment to:
  - Approve the protocol amendment
  - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review/ IEC review.
  - Suspend the entire study, until further information is obtained
  - Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
- The Secretariat will record the decision reached on the proposed amendment in the minutes of the meeting.
- The decision by the designated reviewers may be
  - Approved
  - Disapproved

- Suggested Recommendation
- Next full board discussion

### **5.7 Communication of the Decision to the Principal Investigator**

- If the IEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter i.e. AX 02/SOP 09/V1 to the Principal Investigator (PI) within 14 days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 days of the meeting.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

### **5.8 Store documents**

- The Administrative Officer will place the original completed documents, the amended version of the protocol and related documents, the amendment assessment form in the same project file sequentially

## **6. Glossary**

<b>Amendment protocol package</b>	A package of the amended parts and related documents of the protocol, previously approved by the IEC. In the course of the study, the PI may decide to make changes in the protocol.
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## **7. References**

- [1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000) - [www.who.int/tdr/publications/publications/](http://www.who.int/tdr/publications/publications/) (last accessed 31<sup>st</sup> 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 31<sup>st</sup> August 2013)
- [3] Code of Federal Regulation (CFR), 21 §56.110, the United States of America, 1998.

## **8. Annexure**

ANNEXURE 1	AX 01/SOP 09/V1	Protocol Amendment Request and Assessment Form
ANNEXURE 2	AX 02/SOP 09/V1	Project Amendment/Document Amendment Approval letter

### Annexure 1

AX 01/SOP 09/V1

#### Protocol / Protocol related documents Amendment Request and Assessment Form

IEC Protocol Number:	
Protocol Title: _____ _____ _____ _____	
Principal Investigator and Department: _____ _____	
Approved date:	No. of amendment:
○ State/describe the amendment :type of document/ part of document amended _____ _____	
○ Reasons for the amendment _____ _____	
○ Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other ) _____ _____	
Have the changes modifications in the amended versions been highlighted/ underlined? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Name of Principal Investigator: _____ Signature with Date: _____	

**Type of review :-** (Decision by the Chairperson/ Member Secretary)

Review by Member Secretary/ Chairperson   

Review by designated IEC members   

Full Board discussion and review   

Comments of the reviewer :-

\_\_\_\_\_

\_\_\_\_\_

Decision:

Approved

Suggested Recommendation(s)

Disapproved

Next full board discussion

Name of IEC Member / Member Secretary

/ Chairperson reviewing the project: \_\_\_\_\_

Signature with Date: \_\_\_\_\_

**Final Decision:**

Approved    YES   

No   

If disapproved, reasons for  
disapproval \_\_\_\_\_

\_\_\_\_\_

Further revision or modification required

Any Other

**Signature    of    the    Chairperson/Member    Secretary:** \_\_\_\_\_

Date: \_\_\_\_\_

**Annexure 2**

*AX 02/SOP 09/V1*

**Protocol Amendment/Document Amendment Approval letter**

To

XXXXX (PI)

Department

Ref: - IEC No. Project title

Dear Dr. \_\_\_\_\_

We have received from you the following document (s).

1.

2.

At the Institutional Review Board meeting held on \_\_\_\_\_ the above mentioned documents were reviewed.

After consideration, the IEC has decided to approve:

(a) The aforementioned study-related documents OR

(b) The following documents:

- 1.
- 2.

The members who attended this meeting held on \_\_\_\_\_ at which the above mentioned document was discussed are listed below.

- 1.
- 2.
- 3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board.

**OR**

After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

Yours truly,

**Signature of Chairperson/ Member Secretary  
with Date  
IEC**