Title: Continuing Review of Study Protocols

SOP Code: SOP 10/V3.2 dated 15th February 2013

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1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Institutional Review Board (IRB).
The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving research participants at intervals appropriate to the degree of risk. All the projects approved by the Institutional Review Board will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IRB Secretariat to remind the IRB and the principal investigators regarding study protocols that should be continuously reviewed. All the approved protocols will be reviewed annually (at least once a year). The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IRB meeting wherein the project is finally approved or can be taken subsequently based on the SAE reports, monitoring reports, adequacy documentation procedures followed by the investigators or new safety data received.

The IRB is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

The IRB has the same options for decision making on a continuing review package as for an initial review package. The decision is made as approval to continue the study; approval with recommendations; or disapproval.

4. Flow chart

No.	Activity	Responsibility
1	Determine the date of continuing review	IRB Secretariat and Chairperson
2	Notify the Principal Investigator or study team	IRB Secretariat
3	Manage continuing review package upon receipt	IRB Secretariat
4	Notify the members of the IRB	IRB Secretariat
5	Prepare meeting agenda	IRB Secretariat

6	Review of Continuing review report	IRB Secretariat, Members, and Chairperson
7	Store original documents	IRB Secretariat
8	Communicate the IRB decision to the Principal Investigator	IRB Secretariat

5. Detailed instructions

5.1 Determining the date of continuing review

- The Administrative Officer will look through the document archives/master chart of projects approved by the IRB for the due date of continuing reviews.
- The Secretariat will plan for continuing review of annual progress reports to be reviewed as close as possible to the due date or the anniversary of the effective date (date of original approval) of the protocol.

5.2 Notifying the Principal Investigator or the study team

- If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 13th months from the date of approval, unless specified otherwise), the IRB secretariat will send a reminder as per the format mentioned in *AX 01/SOP 10/V3.2* within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IRB secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to
  a) A letter of reprimanding the Investigator.
  b) Not reviewing future projects from the PI for a specified period of time.
  c) A letter asking the Investigator to put recruitment of new participants on hold.

5.3 Managing the continuing review package upon receipt.

- The Secretariat will receive a package submitted by the Study Team of continuing review for each approved protocol. Only one set of continuing review report shall be submitted by the Principal Investigator to the IRB as per the format Continuing Review Application Form (*AX 02/SOP 10/V3.2)*.

5.3.1 Verifying the contents of the package

- The Secretariat will make sure that the contents of the package include the following documents:
  - Continuing Review Application Form (*AX 02/SOP 10/V3.2)*
  - The Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 10/V3.2)* answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team,

any unexpected complications etc. have to be discussed in the attached narrative.

- The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (*AX 02/SOP 10/V3.2*).

5.3.2 Storing the continuing review package.

The Administrative Officer shall store the original package in the protocol specific file.

5.4 Notifying the Members of the IRB

- The Chairperson /Member Secretary will review the Continuing Review Application Form (*AX 02/SOP 10/V3.2)* and inform about the decision to the IRB members at a forthcoming full board meeting or place it before the IRB members at the Full Board meeting. The Chairperson can designate two IRB members (letter of nomination – *AX 01/SOP 07/V3.2*) to review the Study report and related documents and inform the decision to the other IRB members at the next full board meeting.
- The Secretariat will send the Continuing Review Application Form (*AX 02/SOP 10/V3.2)* to the designated IRB members (letter of nomination – *AX 01/SOP 07/V3.2*)

5.5 ***Protocol Review Process***

The IRB Chairperson/ Member Secretary / Members will use the Continuing Review Application Form (*AX 02/SOP 10/V3.2)* to guide the review and deliberation process. The IRB members could arrive at any one of the following decisions at the IRB meeting:

1. Noted : The IRB approves the continuation of the above mentioned project without any modifications (as per the format *AX 03/SOP 10/V3.2*)
2. Modifications recommended: Protocols that have been suggested modifications by the IRB may not proceed until the conditions set by the IRB in the decision have been met. Protocols should be amended and submitted to the IRB within one month for re-review.
3. The project cannot be continued: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary on *AX 02/SOP 10/V3.2.*
   - The IRB Chairperson will sign and date the IRB decision on Continuing Review Report after a decision has been reached.
   - The IRB Secretariat will maintain and keep the IRB Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.6 ***Storing the original documents.***

Place the original completed documents *AX 01/SOP 10/V3.2* with the other documents in the Continuing Review Package in the protocol file.

5.7 Communicating the IRB Decision to the Principal Investigator

The Secretariat will notify the Principal Investigator of the decision. The letter must be sent to the Principal Investigator within 14 days of the Meeting at which the report was discussed or the decision taken earlier by the Chairperson regarding the Continuing review was informed to the IRB members.

6. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 24th September 2008)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 24th September 2008)

7. Annexure

Annexure 1	*AX 01/SOP 10/V3.2*	Reminder letter by the IRB to investigator
Annexure 2	*AX 02/SOP 10/V3.2*	Continuing Review Application Form
Annexure 3	*AX 03/SOP 10/V3.2*	Project Report Approval letter

Annexure 1

AX 01/SOP 10/V3.2

Reminder letter by the IRB to Investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project Title: XXXXXX

The above referenced project was approved by the IRB on XXXXXXX and was due for Continuing Annual/ Periodic Review by the IRB. You are requested to submit an Annual/ Periodic status report in the prescribed format (Continuing Review Application Form *AX 02/SOP 10/V3.2*) at the earliest, on or before XXXXX.

Signature with date _____

Member Secretary/ Chairperson _____

Annexure 2

AX 02/SOP 10/V3.2

Continuing Review Application Form

Date: _____

Protocol No.:	**Date of IRB approval:**
Protocol Title:	
Principal Investigator : **Department :**	

Summary of protocol participants:

_____ number of participants approved by IRB

_____ New participants recruited so far

_____ Number of ongoing patients

_____ Number of patients who have already Completed the study

Have any participants been withdrawn from this study?

- ❑ No
- ❑ Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)

_____

Impaired participants

- ❑ None
- ❑ Physically
- ❑ Cognitively
- ❑ Both

Have there been any amendments in protocol/ Informed Consent Document since the last review?

- ❑ NO
- ❑ YES

Were these protocol/ Informed Consent Document (ICD) amendments approved by IRB?

- ❑ No
- ❑ Yes

If no, mention the amendments not approved

_____

Has any information appeared in the literature, or evolved from this or similar research that might affect the IRB/IRB's evaluation of the risk/benefit analysis of participants involved in this protocol?

- ❑ No
- ❑ Yes (attach separate sheet if needed)

_____

Have any unexpected complications or SAEs been noted since last review at our site?

- ❑ No
- ❑ Yes (attach separate sheet if needed)
- ❑ No. of patients who had SAEs- _____
- ❑ Whether reports of SAEs at have been submitted to the IRB- _____
- ❑ Whether reports of SAEs at other sites have been submitted to the IRB-_____
- ❑ Types of adverse events with nos. of participants- _____ _____
- ❑ Number of unexpected AE

Have any participating investigators been added or withdrawn since last review?

- ❑ No
- ❑ Yes (Identify all changes in the attached narrative)

Is report of interim data analysis available?

- ❑ No
- ❑ Yes (submit as an attachment)

Is report of the data safety and monitoring board

_____ **Which protocol amendment is the site following at this date** _____ **Which ICD amendment is the site following at this date** _____	**available?** ❑ No ❑ Yes (submit as an attachment) **Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?** ❑ No ❑ Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date: _____

Assessment of Continuing Review Report by the IRB

To be reviewed by

- Chairperson / Member Secretary only and informed to the IRB members at Full Board ☐
- Full Board ☐
- Any 2 IRB members and informed to the IRB members at Full Board ☐

1. Names of IRB members: _____

_____

_____

_____
Signature with date
Chairperson

<u>IRB Decision on the Continue Review Report</u>

Decision

Approved and the project can be continued without any modifications ☐

Modifications recommended - requiring protocol resubmission ☐

<u>State the recommendations</u>:

Protocol should be discontinued ☐

State the reasons for discontinuation

Full Board discussion ☐

Any Other ☐

Signature of reviewer/s with date: _____

Final Decision on the Continue Review Report: _____

_____

Signature with date
Chairperson

Annexure 3

AX 03/SOP 10/V3.2

Project Report Approval Letter

Name of the Principal Investigator:-
Department :-
Ref: - Project Title: _____
Sub: - Letter dated: _____

This is with reference to the above stated letter regarding the continuing review report of the above mentioned project. The Continuing Review Report was reviewed in the IRB meeting held on XXXXXXXX and was noted.

The IRB allows continuation of the above mentioned project without any modifications.
You are requested to submit the next continuing review report within 1 month of the due date i.e. on or before XXXXX.

_____

Signature with date
Member Secretary / Chairperson

Date of approval: