Title: Continuing Review of Study Protocols

SOP Code: SOP 10/V2
Effective Date: 21-10-2019

SOP Constitution and Approval:

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the Institutional Human Ethics Committee (IHEC), MGMCRI. The purpose of continuing review is to periodically monitor the progress of study, to ensure continuous protection of rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals by IHEC, MGMCRI. All the projects approved by the IHEC 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 IHEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IHEC Secretariat to remind the PIs and Member Secretary/Additional Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary/Additional Member Secretary to ensure a decision regarding whether the project needs to be reviewed more frequently is taken during the IHEC meeting in which the project is finally approved. This must be recorded in the minutes. A fresh decision to increase review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. This is responsibility of the SAE subcommittee and Member Secretary/Additional Member Secretary.

The IHEC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IHEC communication.

4. Detailed instructions

4.1 Determining the date of continuing review

- The date of the continuing review will always be at least once in the year.
- The IHEC may recommend more reviews during the approval process depending on the

level of risk. This will be documented in the minutes.

- The Secretariat will inspect the minutes of meeting to set a timetable for continuing review.
- The Secretariat will identify and record the due dates for each project

4.2 Notifying the PI or the study team

The Secretariat will send a reminder to the PI as per the format *AX 01/*SOP 10/V2 two month prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

4.3 Managing the continuing review package upon receipt

- Secretariat will receive a package (soft and hard copy) submitted by the PI for continuing review of each approved protocol. Only one set (soft and hard copy) of continuing review report shall be submitted by PI to IHEC as per format continuing Review Application Form (AX 02/ SOP10/V2*)*.

4.4 Verifying the contents of the package

- Secretariat will ensure that the contents of the package include the following documents:
  - Continuing Review Application Form (AX 02/ SOP10/V2*)*
  - Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (AX 02/ SOP10/V2*)* answers on the application form and a discussion of scientific developments, 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. must have been discussed in the attached narrative.
- The Secretariat will confirm complete information is appended and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (AX 02/ SOP 10/V2).

4.5 Review process

- The Continuing review submission may undergo expedited review (as per the procedure described in SOP 7B/V2) or full board review (as per the procedure described in SOP 7A/V2) as deemed appropriate by the IHEC Chairperson/Member Secretary/Additional Member Secretary.
- The IHEC Chairperson/ Member Secretary/Additional Member Secretary / Member/s will use the Continuing Review Application Form (AX 02/ SOP10/V2*)* to guide the review and deliberation process.
- The Secretariat will send the Continuing Review Application Form (AX 02/ SOP10/V2*)* to the designated IHEC members.
- The IHEC Chairperson/ Member Secretary/Additional Member Secretary / Member/s could reach one of the following decisions after review:

  1. **Noted** - The IHEC approves the continuation of the project without any modifications.
  2. **Modifications recommended**: Study protocols that have been suggested modifications by IHEC may not proceed until the conditions set by IHEC in the decision have been met. The amendments and the required documents should be amended and submitted to the IHEC within one month for re-review.
  3. **Project cannot be continued**: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary/Additional Member Secretary on AX 02/ SOP10/V2.

- The IHEC Chairperson will sign and date the IHEC decision on Continuing Review Report after a decision has been reached.
- The decision on continuing review taken by the Chairperson/ Member Secretary/Additional Member Secretary / Member/s will be informed to all IHEC members at the next full board meeting.
- The continuing review report may be discussed at full board if deemed necessary by Chairperson/Member Secretary/Additional Member Secretary.
- IHEC Secretariat will maintain and keep the IHEC Decision forms and minutes of the

meeting relevant to the continuing review as part of the official record of the review process in the project file.

4.6 Communicating IHEC Decision to PI

- The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson/ Member Secretary/Additional Member Secretary / IHEC Member/s.

4.7 Non-submission of continuing review report by principal investigator before due date

- If a PI fails to submit continuing review report within one month of the due date (ie.11 months from the date of approval, or earlier on the dates as specified), Secretariat will send a email reminder at least 1 month prior to due date of review.

  If there is no response, IHEC secretariat will put up the matter for discussion at forthcoming full board meeting for appropriate action which may consist of but not limited to sending:
  - A reminder letter again
  - A letter asking explanation for non-submission
  - A letter asking PI to put recruitment of new participants on hold till report is submitted
  - Any other action as deemed appropriate by IHEC

5. Annexures

Annexure 1: AX 01/ SOP10/V2- Reminder letter by the IHEC to Principal Investigator

Annexure 2: AX 02/ SOP10/V2- Continuing Review Application Form

Annexure 1: AX 01/ SOP10/V2

Reminder letter by the IHEC to Principal Investigator

Date:

Name of Principal Investigator:

Department:

Ref: - Project no. **Title:**

The above referenced project was approved by the IHEC on …… and is due for Continuing Annual/ Periodic Review by the IHEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed (AX 02/SOP 10/V2) at the earliest, on or before …….. (1 month period)

Signature with date _____

Member Secretary/Additional Member Secretary / Chairperson

_____

Project No.: **Date of IHEC approval:**

Project Title:

Principal Investigator:

Department:

Annexure 2: AX 02/ SOP 10/V2

Continuing Review Application Form

MGMCRI-IHEC Ref. No. (for office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Validity of approval:
2. Date of Start of study: Proposed date of Completion:

   Period of Continuing Report: - to -
3. Does the study involve recruitment of participants?

a. If yes, Total number expected…… Number Screened: …… Number Enrolled: ……..

   Number Completed: ……...…… Number on follow up: ……...……

b. Enrolment status – ongoing / completed/ stopped

c. Report of DSMB Yes☐ No☐ NA ☐

   (In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA)

d. Any other remark

e. Have any participants withdrawn from this study since the last approval?
   If yes, total number withdrawn and reasons:

4. Is the study likely to extend beyond the stated period? *(Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC)*
   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?
   If No, skip to item no. 6 Yes☐ No☐
   a. If yes, date of approval for protocol and ICD :
   b. In case of amendments in the research protocol/ICD, was re-consent sought from ☐ ☐

participants? Yes No
If yes, when / how

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes☐ No☐
If yes, discuss in detail:

7. Have any ethical concerns occurred during this period? Yes☐ No☐
If yes, give details:

8. a. Have any adverse events been noted since the last review? Yes☐ No☐
Describe in brief:

b. Have any SAE's occurred since last review? Yes☐ No☐
If yes, number of SAE's:…… Type of SAE's: ……..

c. Is the SAE related to the study? Yes ☐ No☐
Have you reported the SAE to EC? If no, state reasons Yes ☐ No☐

9. Has there been any protocol deviations/violations that occurred during this period?
If yes, number of deviations …….
Have you reported the deviations to EC? If no, state reasons Yes ☐ No☐

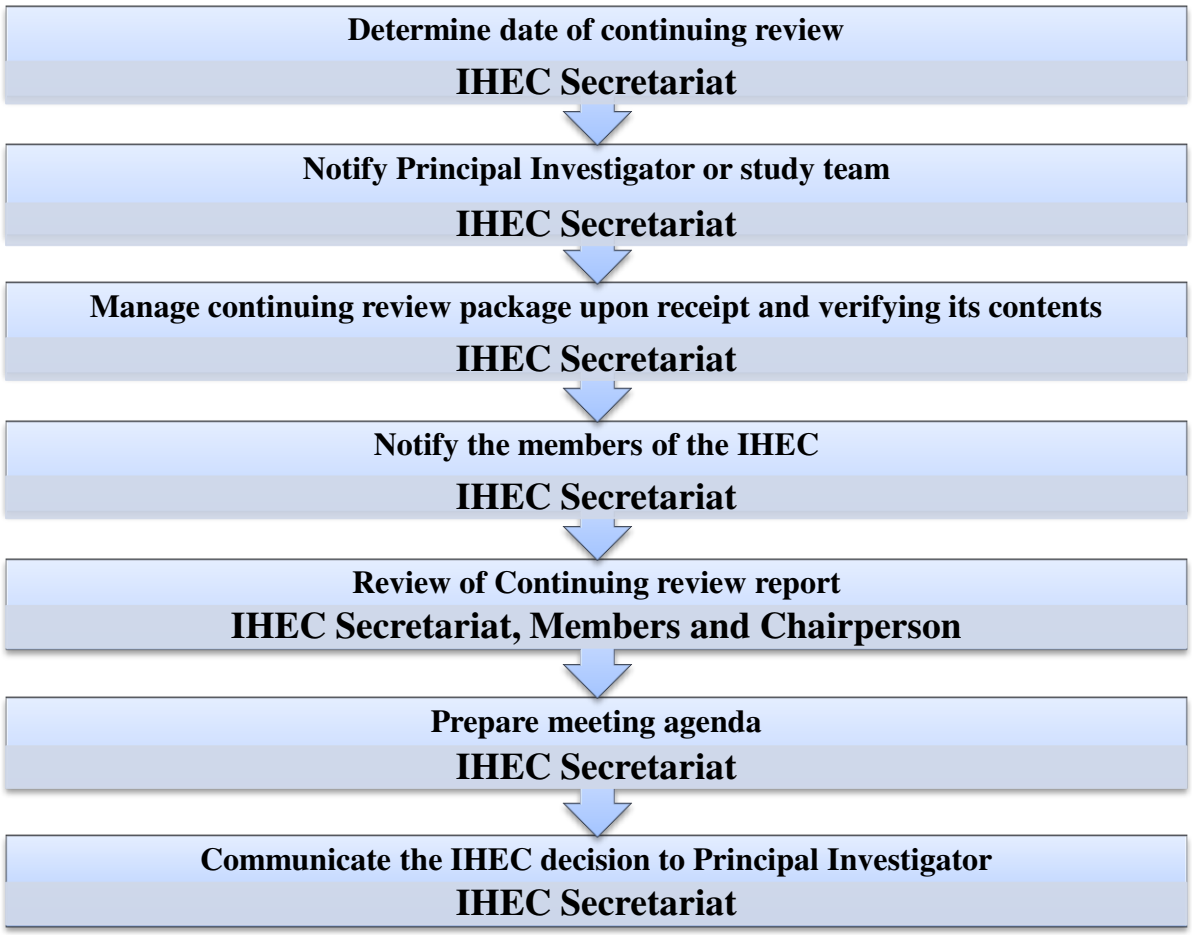
10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ?
Yes☐ No☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes☐ No☐

Any other comments:

Signature of PI with date

6. Flow Chart



7. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*