



YEC2/SOP10/v2
Effective Date: 25.02.2023

Title: Continuing review

SOP Code: YEC2/SOP10/v2

Prepared by:

Dr. K. Leena Pramod Convenor, YEC2 SOP committee	Signature with date <i>Leena</i>
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Reviewed by:

Dr. Pradeep M D Member, YEC2 SOP committee	Signature with Date <i>Pradeep</i>
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Approved by:

Dr. Animesh Jain Chairperson, YEC2	Signature with Date <i>Animesh Jain 25/02/2023</i>
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Notified by:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>K. S. Somayajhi</i> 25/04/23 Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore - 575 018
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Details of superseded SOP 10/v1

Subcommittee Convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr.H.Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP 10/v2

SOP subcommittee convenor name	Version 02	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. K. Leena Pramod	v2	25.02.2023	Added Definiton Added Responsibility Added detailed instruction Modified in the Annexure



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1. Purpose:



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- a. The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed by the YEC 2 for conducting continuing review of protocols which have been previously approved by the YEC 2.
- b. The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants

2. Scope:

2.1. This SOP applies to continuing review of all the already approved study protocols

- Approved protocols
- Resubmission of protocols
- Amended protocols
- Protocols with SAE reports
- Protocols with reports of deviations
- Other protocol reports as determined by the YEC 2

2.2. It applies to the continuing review conducted at pre-specified intervals, at least once a year, as determined by the YEC 2 for each protocol depending on

- The degree of risk to the participants
- The nature of the study
- The studies on vulnerable participants
- Duration of the study
- Other factors as determined by the YEC 2 members

3. Definitions

3.1. Periodic review: The ongoing review of the status of the study conducted during the validity period of the YEC2 clearance at predetermined intervals.

3.2. Extension of EC approval: The PI requests extension of validity period of the EC approval if



the study is not completed .

Responsibilities:

4.1. The YEC2 Chairperson will

- 4.1.1. Ensure that periodic review of protocols takes place as determined by the YEC2.
- 4.1.2. Recommend modifying the frequency of the periodic review, if required, based on the perceived change in risk-benefit for the participant in an ongoing study.

4.2. The YEC2 Member-Secretary will

- 4.2.1. Ensure that the frequency of periodic review is determined and noted in the decision form for each protocol at the time of approval.
- 4.2.2. Ensure that the assessment of periodic review forms is done as per schedule and in a timely manner.
- 4.2.3. Categorize the filled periodic review form of the ongoing protocol based on the risk as full review or expedited review .
- 4.2.4. Assign reviewers for the periodic review.
- 4.2.5. Initiate appropriate action, with the approval of the Chairperson, if periodic review forms are not submitted by the PI in a timely manner.
- 4.2.6. Recommend modifying the frequency of the periodic review based on the perceived change in risk-benefit for the participant.

4.3. The YEC2 Secretariat will

- 4.3.1. Maintain a calendar for periodic review of protocols as determined by the YEC2 at the time of approval or subsequently based on post-approval events.
- 4.3.2. Send an email reminder to the PI for submission of the periodic review forms one month before the scheduled date. If necessary, one or more reminders may be sent, if delayed.
- 4.3.3. Enter the list of protocols for which periodic review is scheduled every month in the meeting agenda
- 4.3.4. Provide a list of protocols to the Member-Secretary for which the periodic review form is not received as per the schedule.



5. Detailed instructions:

5.1. Determining the periodic review schedule at the time of approval of a protocol

5.1.1. For regulatory clinical trials, the periodic review will occur as per the rules laid down by the Government of India, from time to time.

5.1.2. For other full review protocols, the YEC2 will determine the frequency of periodic review at the time of approval, in the meeting.

5.1.3. For expedited review protocols, the YEC2 Member-Secretary will determine the frequency of periodic review at the time of approval based on the decision of the reviewers.

5.1.4. Protocols considered for exemption from review will generally not be considered for periodic review

5.1.5. In addition, for all protocols, if the PI desires to renew the YEC2 approval validity, the PI must initiate the process of periodic review in the last month of the validity of the protocol. For example, if the validity of the YEC2 clearance is for 12 months, the PI should submit the periodic review request in the 11th month.

5.1.6. The date for initiation of planned periodic review process will be stated in the YEC2 approval letter (one month before expiry of approval).

5.2. Determining the periodic review schedule based on post-approval events of a protocol:

5.2.1. For ongoing protocols in which SAEs, protocol deviations/violations are reported or when the reports of site monitoring or audits or any other received from any individual/party about a protocol, an initiation or modification in the frequency of the periodic review may be considered

5.2.2. The schedule previously determined may be modified by increasing or decreasing the



frequency of periodic review or asking for an immediate submission of periodic review form.

5.2.3. Modification of the periodic review schedule may be called by the Member-Secretary/Chairperson/ concerned reviewers/YEC2 meeting depending on the post-approval event

5.3. Assessment of the risk: The risk may be assessed as per ICMR guidelines by considering the following

5.3.1. The risk-benefit analysis

5.3.2. The inclusion of vulnerable participants

5.3.3. The type of study

5.4. Recording of the decision

5.4.1. For those protocols where a periodic review is decided at the time of approval, the decision will be recorded in the decision form.

5.4.2. The decision will be included in the YEC2 approval letter

5.6. Maintaining the calendar for periodic review of protocols

5.6.1. The Secretariat will maintain a calendar for periodic review schedules of all the protocols in an Excel spreadsheet in the YEC2 computer (Ann01/SOP10/v2)

5.6.2. The Secretariat will update the calendar as and when protocols are approved

5.6.3. The Secretariat will identify all protocols which are due for periodic review in the coming month in order to send reminders to the PI

5.6.4. The Secretariat will identify all the protocols which are due for periodic review in the current month and inform the Member-Secretary

5.7. Reminders to the PI:

5.7.1. The Secretariat will send notification to the Principal Investigator and other research team members, one month before the scheduled date for periodic review.



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5.7.2. The Secretariat will send a reminder by individual emails to the PIs of all the protocols which are due for periodic review in the subsequent month as per the format

5.7.3. A second reminder may be sent within 7 calendar days after the due date if the PI does not submit the period review application form in the scheduled month

5.8. Submission of periodic review report by the Principal Investigator:

5.8.1. The Principal Investigator will submit the filled, signed and dated periodic review form as per the format

5.8.2. The Principal Investigator will make the submission on or before the scheduled date as mentioned in the approval letter.

5.9. Components of the periodic review:

5.9.1. The components of the periodic review form will be as per annexure

5.10. Receipt of the submission for periodic review:

5.10.1. The Secretariat will ensure that the contents of the periodic review form are complete with signature and date of the PI and any attachments, if applicable

5.11. Categorization of the periodic review form:

5.11.1. Initial screening: The Member-Secretary will do an initial screening and decide on the review process based on the issues identified in the periodic review application form as in SOP07/v2.

5.11.2. Full review: If serious ethical or scientific issues are identified, the Member Secretary will categorize the form for full review. The submission for periodic review listed under full review will be managed as per SOP7A/v2.

5.11.3. Expedited review: If no serious ethical or scientific issues are identified, the Member-Secretary may categorize it for expedited review. The submission for periodic review listed under expedited review will be managed as per SOP7B/v2.

5.12. Review of the periodic review form:



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5.12.1. The Member-Secretary will identify reviewers for the periodic review depending on the categorisation

5.12.2. For expedited review, one YEC2 member/Member-Secretary will be assigned to review

5.12.3. For full review, two YEC2 members will be assigned to review the periodic review

5.12.4. The reviewers will review the contents of the periodic review application form

(Ann05/SOP10/v2) 5.12.5. Any subsequent clarifications/ responses from the PI following YEC2 communication after the periodic review will also be reviewed as above.

5.13. The provisional decision by the reviewers: 5.13.1. Noted and the study can continue without any changes

5.13.2. Noted and the PI has to provide more details/ provide clarifications within 30 calendar days.

5.13.3. Decision in the full review meeting

5.14. The final decision on periodic or periodic review:

The final decision in the YEC2 can be recorded in one of the following (Ann06/SOP10/v2):

5.14.1. Approved

5.14.2. Request information

5.14.3. Further action recommended which may include Audit or Site Monitoring, amendment, suspension or termination of the study.

5.15. The decision letter is signed and dated by the Chairperson/ Member-Secretary

5.16. The follow-up action after the final decision

5.16.1. Decision will be communicated to PI within 7 calendar days

5.16.2. The decision will be communicated to the Head of the Institution/ Sponsor/ Regulatory bodies if required

5.16.3. If the PI does not submit periodic review application as per the schedule or if the PI does not respond to the queries by the YEC2 within 30 calendar days, then the same will be considered as protocol deviation/ violation and action will be initiated as per

5.16.4. If any other protocol deviations/violations are identified action will be taken as per SOP11/v2

5.16.5. If audit/site monitoring is planned, action will be initiated as per SOP20/v2.

5.16.6. If amendment in protocol is recommended, action will be initiated as per SOP09/v2.



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5.16.7. If suspension/ termination of the study is recommended, action will be initiated as per SOP14/v2.

5.16.8. If change in frequency of periodic review is recommended, the same will be done as per SOP10/v2

5.16.9. A copy of the submitted form, review forms and the decision letter will be filed in the respective protocol file

5.17. Non submission of report for periodic review:

5.17.1. The PI is expected to submit the periodic review form at the scheduled time as determined by the YEC2 at the time of approval or after approval following a post-approval decision.

5.17.2. The PI will be reminded by email one month before the scheduled date for periodic review.

5.17.3. A second reminder will be sent if the deadline is missed within 7 calendar days of expiry of the validity of the YEC2 approval letter.

5.17.4. The PI is expected to submit the periodic review form as per the schedule with a grace period of one week extended to a maximum of one month on the written request by the PI.

5.17.5. If the PI does not submit periodic review application as per the schedule or if the PI does not respond to the queries by the YEC2 within 30 calendar days, then the same is considered as protocol deviation/ violation and action is initiated as per SOP11/v2

5.17.6. If the PI fails to submit the periodic review application form, one month before the end of the validity period of the EC approval, the PI must not include the data collected in the interim period between expiry of the initial approval and commencement of the continuation of approval.

5.17.7. Any data collected in this interim period will constitute a protocol deviation/ violation and will be treated as such as per SOP11/v2. Moreover, such data will need to be discarded and not included in the analysis.

5.17.8. The Member-Secretary may include failure to submit a periodic review form of the protocol, for discussion in the YEC2 meeting and YEC2 can decide regarding the status of the ethics committee approval and future submissions by the Principal Investigator.



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6. References:

6.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

7. Annexures:

7.1.1. Ann01/SOP10/v2 : Reminder to the Principal Investigator to submit periodic review form

7.1.2. Ann02/SOP10/v2 : Second reminder to the Principal Investigator to submit periodic review form

7.1.3. Ann03/SOP10/v2: Application for extension of the study.

7.1.4. Ann04/SOP10/v2: Assesment for periodic review

7.1.5. Ann05/SOP10/v2: Approval letter for extension of the study

Ann02/SOP10/v2

Reminder to the Principal Investigator to submit periodic review form

Date:

Name of the Principal Investigator:

Department:

Reference:

Protocol Number:

Protocol title:

Date of YEC2 approval:

Date of YEC2 approval validity: Frequency of Periodic review:

Subject: Reminder to submit periodic review form Dear Dr./Mr./Ms. _____ You are requested to submit the duly filled and signed periodic review application form to YEC2 on or before _____. Any lapse or delay in submission of the periodic review application form will be considered as protocol deviation/violation. If you are submitting the periodic review application form and requesting for extension of the EC clearance validity, then delay will result in a lapse of ethics committee approval. Please note that data collected in the interim period where the ethics committee approval is not renewed, cannot be included in your final analysis. and if done, will constitute a protocol violation.

Thank you,



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Yours sincerely, Member-Secretary/Chairperson, YEC2

Ann03/SOP10/v2:

Second reminder to the Principal Investigator to submit periodic review form

Date: Name of the Principal Investigator:

Department:

Reference:

Protocol Number:

Protocol title:

Date of YEC2 approval:

Date of YEC2 approval validity:

Frequency of Periodic review:

Subject: Second reminder to submit periodic review form Dear Dr./Mr./Ms. _____ We have not received the periodic review application form from you despite the reminder sent to you by email on _____. You are requested to submit the duly filled and signed periodic review form to YEC2 within 7 calendar days failing which, this will be considered as protocol deviation/violation, and will be suitably dealt with as outlined in SOP11/v2..

If you are requesting for extension of the EC approval, then delay will result in a lapse of a seamless ethics committee approval. Please note that data collected in the interim period where the ethics committee approval is not renewed, cannot be included in your final analysis. and if done, will be considered as a protocol violation. Thank you, Yours sincerely, Member-Secretary/Chairperson, YEC2

Yenepoya Ethics Committee 2



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Ann03/SOP10/v2

Periodic/Continuing Review Application Form

(Download the form, type the details, print, sign, scan and send to YEC2 at yec2@yenepoya.edu.in. Please do not delete any of the text typed in the form)

A. Protocol details			
1	YEC2 Protocol No.		
2	Title:		
3	Type of Study		
4	Name of the Principal Investigator: Department and Institution:		
5	Names of all the Co-Is (guides): Department and Institution:		
6	Names of Research Assistants/Data Coordinators		
6	Validity of approval by YEC2	From:	To:
7	Extensions of approval (<i>add rows for each extension</i>)	From:	To:
8	Protocol amendment (<i>add rows for each amendment</i>)	From:	To:
9	Date for periodic review (as per YEC2 communication)		
2. Protocol timelines			
1	Date of first recruitment:		
2	Date of the last recruitment:		
3. Participant details		Number	Date
1	Sample size approved		
2	Number of participants screened/date of last screened (or samples/data selected)		



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3	Number of screen failures/date of last screen failure		
4	<i>Number of participants/biological samples/data recruited/ collected</i>		
5	<i>Number of ongoing participants/biological samples</i>		
6	<i>Completed participants/date when last participant completed</i>		
7	<i>Participants who withdrew the consent/date of last withdrawal/or samples/data rejected</i> <i>(Provide reasons for withdrawal/rejection)</i>		
8	<i>Participants who were discontinued from the study by PI or sponsor/date of last discontinuation</i> <i>(Provide reasons for discontinuation)</i>		
9	<i>Participants with adverse events/dates for all adverse events</i> <i>(Provide details of each adverse event – attach separate sheet if necessary)</i>		
10	<i>Number of SAE reported</i> <i>Dates for all SAEs reported (details)</i>		
4. Changes in the protocol/ risk to participants:			
1	Whether approved protocol version followed (provide protocol number):	Yes / No Protocol version number:	
2	Any changes made in the selection criteria of participants	Yes / No (If yes, please provide details)	
3	Any changes made in the protocol	Yes / No (If yes, please provide details)	



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4	Any changes made in the study team; any change in guide	Yes / No (If yes, please provide details)
5	Any changes in the sample size	Yes / No (If yes, please provide details)
6	Any changes in the funding status	Yes / No (If yes, please provide details)
7	Whether approved version followed: a. PIS b. ICF c. Data collection form:	Yes / No Version number
8	Any increase in risk to participants based on the findings of the current study/new information in literature	Yes / No (If yes, please provide details)
9	Any protocol deviations noted	Yes / No (If yes, please provide details)
5. Monitoring/ data analysis		
1	Has interim data analysis been done?	Yes / No (If yes, provide the report)
2	Has the data safety and monitoring board reported?	Yes / No (If yes, provide the report)
3	Has YEC2/ regulatory authorities conducted a site monitoring/ audit?	Yes / No (If yes, provide the report)
6. Any other:		
1	Have any investigator(s) developed a CoI during the conduct of the study:	Yes / No (If yes, provide the report)



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2	Have any research team members faced any difficulties/events during the study	Yes / No (If yes, provide the report)
3	Any other information you would like to share with the YEC2	

Signature of the PI: (with name and date)

Signature of the guide (if any): (with name and date)

Ann04/SOP10/v2

Assessment form for periodic reviewer

Categorization of the periodic review application

form:

Protocol No:

Title:

Principal investigator:

Full review /Expedited review:

Assignment of reviewers with dates of communication

Name of the reviewer 1:

Name of the reviewer 2:

Signature with date:

Chairperson/ Member-Secretary

Reviewer's assessment:

Protocol No:

Title:

Principal investigator:



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- A. Any clarifications required?
 - a. If yes, provide details
 - B. Assessment by the reviewer:
 - a. Any ethical issues noted?
 - b. If yes, provide details:
 - C. Are there any scientific issues noted?
 - a. If yes, provide details:
 - D. Are there any protocol deviations?
 - a. If yes, provide details
 - E. Are there any unreported serious adverse events?
 - a. If yes, provide details:
-

- F. Recommendation of the reviewer:
 - a. Noted and the study can continue without any changes
 - b. Noted and the PI has to provide more details/ provide clarifications within 30 calendar days.
 - c. Decision in the full review meeting
-

Signature of the reviewer Date:

Final Decision form for periodic review

Protocol Number:

**Title of the
protocol:**

Name of the Principal Investigator:

Department:



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Validity of EC clearance: From _____ to _____ Extended validity: From: to _____

- A. Approved
- B. Request information
- C. Further action recommended

Signature of Chairperson/Member-Secretary with date

Ann05/SOP10/v2

Approval letter for extension of the study

Subject: YEC2 Approval stud for extension of

Ref: Protocol no.
titled “

Name of all research team members:

Sl. no	Name	Role in the research team	Designation/ Affiliation
1.			
2.			

The YEC2 has reviewed the continuing review application form dated

YEC2 hereby approves the extension of the study for the protocol no.
and the related documents as listed in the approval letter dated

The extension of the study is valid from:

Any data collected before or beyond the validity period shall be considered
as protocol deviation and liable to action.



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It is the responsibility of the Principal Investigator to:

1. Provide correct, updated contact details and respond to YEC2 communications without delay.
2. Adhere to the current regulatory guidelines.
3. Adhere to the undertaking signed by the PI.
4. Adhere to the approved version of the protocol
 1. Protocol Version :
5. Adhere to the compensation plan as per the approved protocol
6. Restrict recruitment to the approved sample size of
7. Inform the YEC2 at the time of recruitment of the first participant.
8. Obtain written approval of YEC2 before any proposed change in the protocol (amendment) is implemented in the prescribed format .
9. Report to YEC2 any deviation from the guidelines/approved version of the protocol without delay (including change in research team members) in the prescribed format..
10. Submit continuing review form one month before the end of validity of this approval (**Ann02/SOP10/v1**)
11. Report to YEC2 an adverse event/change in risk to participants(excluding SAEs) that may occur during the study in the periodic review
12. Submit a completion report to YEC2 when the data/sample collection is completed in the prescribed format (**Ann01/SOP13/v1**)
13. Submit a summary of the study when the data analysis is completed.
14. Maintain the privacy of the participants/ samples and confidentiality of data.
15. All communications with YEC2 should be by email to yec2@yenepoya.edu.in

YEC2 is registered with Drug Controller General of India (DCGI)

with the registration no ECR/1337/Inst/KA/2020 for a period 5 years from 30.01.2020.



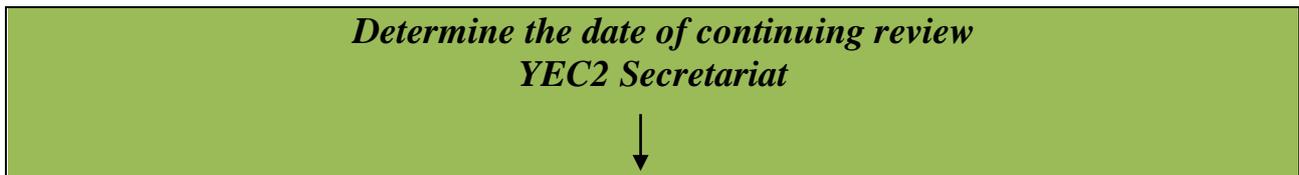
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16. YEC2 is registered with Department of Health Research (DHR)
with the registration no EC/NEW/INST/2020/1216 for a period 2 years from
23.12.2020.

Member-Secretary-YEC2 Date: 13.01.2024
Dr. K . Leena Pramod

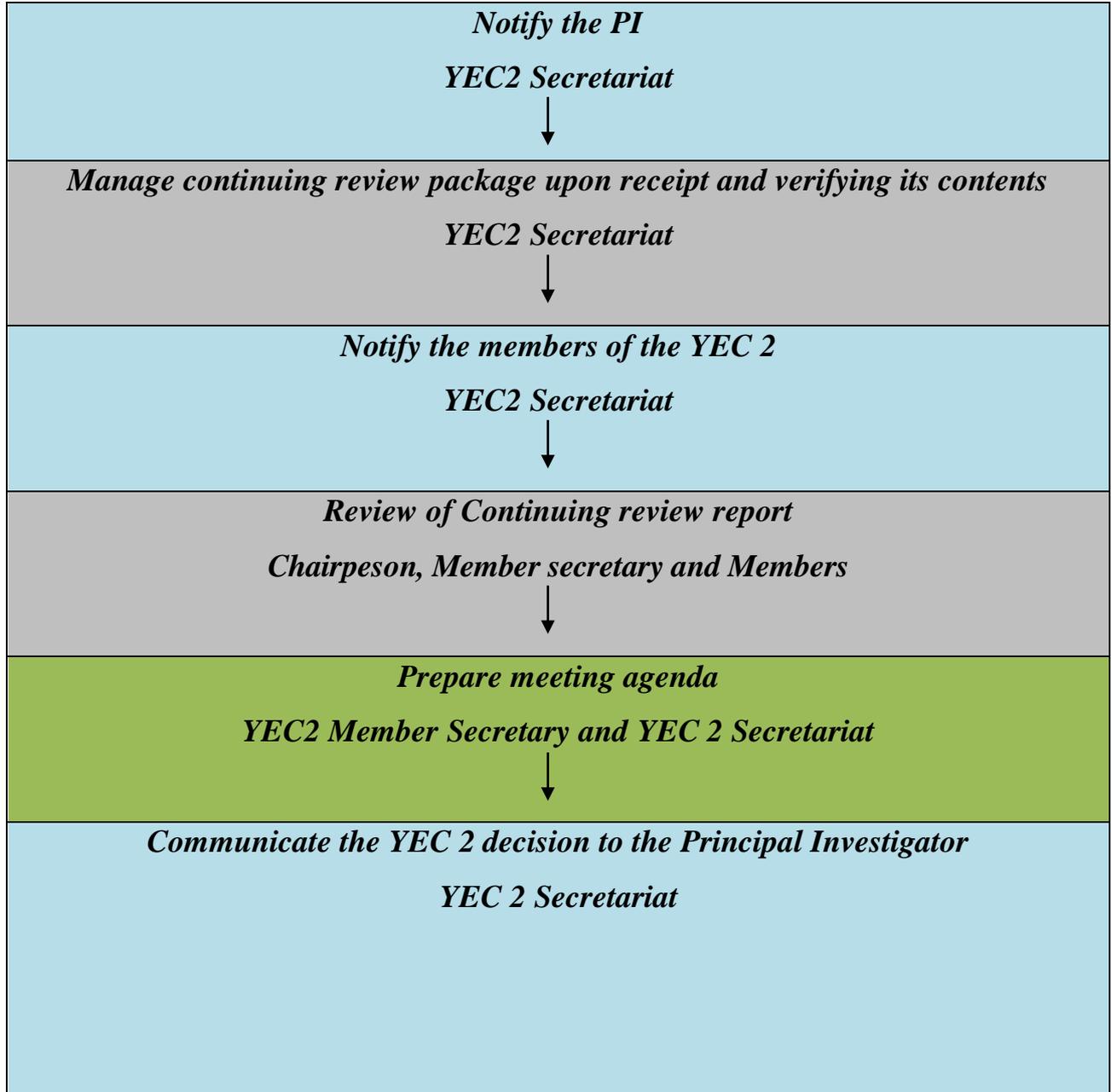
Important Dates:
Date of YEC2 Approval:

Flow Chart





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7. References

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and



YENEPOYA
[DEEMED TO BE UNIVERSITY]
Recognized under Sec 3(A) of the UGC Act 1956
NAAC Accredited A+ with CGPA3.47

YENEPOYA ETHICS COMMITTEE 2
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2020/1216

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health research involving human participants, October 2017 (cited 6 th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf