

SUBMISSION REQUIREMENTS FOR PROTOCOL AMENDMENT AND CONTINUING REVIEW/ANNUAL RENEWAL

Submission requirements for protocol amendment

1.	Application/cover letter addressed to the CIU-REC chairperson requesting the amendment.
2.	Justify and indicate the amendments to be made
3.	Submit a copy of the track changed document and the clean copy/ies (Please note that submission is through the National Research Management System (NRIMS))
4.	proof of payment for protocol amendment fees (refer to the fee structure)
5.	A submission list

Submission requirements for annual renewal

1.	Application/cover letter addressed to the CIU-REC chairperson requesting for study extension
2.	Submit copies of all previously approved and stamped documents
3.	Submit an annual progress report (please see the annex to this document the progress report template)
4.	proof of payment for annual renewal fees (refer to the fee structure)
5.	Attach the previous approval letter and details of the study team (CV)
6.	Submission Face sheet

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ANNUAL PROGRESS REPORT TEMPLATE

1.	Protocol title
2.	Protocol version and dates
3.	Expiry date of the current approval
4.	Period covered by the report (for example, 28 th January 2024-28 th November 2024)
5.	Brief rationale of the study
6.	General objectives
7.	Study design and selection of study participants
8.	Status of participants (initial number of study participants approved, the number enrolled, and the number that dropped out or lost to follow-up)
9.	Specimens description (where applicable) Give the approved sample size, samples analyzed, and withdrawn consent. This may apply to studies of a clinical nature
10.	Current literature
11.	Summary of protocol deviation and violation if any
12.	Summary of Adverse Events if any (in case the study had reported Serious Adverse Events (SAE) during the study, a summary of the SAE should be included in this section.
13.	Summary of site activities (this may include information on; when enrollment of study participants began and stopped and the current stage at which the study has reached)
14.	Challenges experienced during the study
15.	Future Plans (This may be in terms of data cleaning and analysis or any other future plans)
16.	Conclusion

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