**Yenepoya Ethics Commitee-1**

**Ann01/SOP9B/v4**

**Application for Protocol Amendment**

*Principal Investigator, please submit a continuing review application form along with this application*

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| **Protocol Number (as assigned by YEC-1):**  **Protocol title (as approved by YEC-1):**  **Name of the PI:**  **Department:**  **Names of all the research team members:**  **Issue and expiry dates of YEC-1 initial approval:**  **Issue and expiry date(s) of YEC-1 extensions of approval (list all):**  **Date(s) of previous amendment approvals, if any:**  **Continuing review application form submitted along with this amendment application to update the study status: Yes/No** | | | | | |
| **List of documents (with version numbers) previously approved (keep adding numbered rows):** | | | | | |
| **Overview of section/document in which the amendment is proposed:**  **Protocol:**  Change in title:                                                                                                     Yes/No            Change in research team members (persons or order of investigators):              Yes/No            Change in guide (for postgraduate studies):                                                         Yes/No            Change in sample size:                                                                                         Yes/No            Change in sampling technique:                                                                            Yes/No            Change in inclusion/exclusion criteria:                                                                Yes/No            Change in data collection/analysis/storage                                                           Yes/No            Change in any other part of the methodology:                                                    Yes/No  **Case record form:**                                                                                                        Yes/No  **Participant Information Sheet:**                                                                                   Yes/No  **Informed Consent Form:**                                                                                             Yes/No  **Questionnaire (if any):**                                                                                                 Yes/No  **Any other (specify):**                                                                                                      Yes/No | | | | | |
| **Detailed description of the amendment(s) (add rows as necessary):** | | | | | |
| **S. No.** | **Name/part of the document (Specify)** | **Original approved content** | **Amendment proposed** | **Justification** | **Reviewer’s comment: Acceptable/ Not acceptable/ More information needed** |
|  |  |  |  |  |  |
| **Part B (Additional ethical considerations):**   |  |  |  |  | | --- | --- | --- | --- | |  |  | Details/justification (Provide separate sheet if required) | Reviewers’ assessment -each item | | Will the amendment affect the scientific integrity of the study? | Yes/ No |  |  | | Will the amendment change the risk to the participants? | (Increase/ decrease/ no change) |  |  | | Will the amendment change the benefits to participants? | (Increase/ decrease/ no change) |  |  | | Will the amendment require change in the content of the participant information sheet and/or the informed consent form? | Yes/ No |  |  | | What does the PI propose to do with the samples/data already collected? | Include/ exclude in data analysis |  |  | | If included, how would it impact the consent already provided | No impact/ re-consent will be taken |  |  |   **Signature and date of the PI:**  **Signature and date of the guide** | | | | | |
| **Note to the PI and responsibility of the PI**   1. *Any request for amendment of protocol will only be considered if applied for prospectively* 2. *Submit continuing review application form along with the application for protocol  amendment (Ann04/SOP10/v4)* 3. *Include every change in the protocol/ related document clearly in the application form for amendment point by point* 4. *Submit the application for protocol amendment, at least one week before the YEC-1 meeting, so as  to be included in that meeting.* 5. *Highlight all changes made in the amended protocol documents (soft and hard copy), update the version number, insert page numbers and reflect these changes in the table given above.* 6. *Inform the other research team members (or guide where applicable) about all the changes made in the documents and seek their approval before submitting to YEC-1.* 7. *Implement the amended version of the protocol only after it is approved by YEC-1.* 8. *Any changes made in the protocol without prior YEC-1 approval will be considered as protocol deviation/violation and is therefore strongly discouraged.* 9. *PI should ensure concordance in the application form for amendment and the amended protocol version* | | | | | |