**Yenepoya Ethics Commitee-1**

**Ann01/SOP9B/v4**

**Application for Protocol Amendment**

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

|  |
| --- |
| **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*
 |