**YENEPOYA ETHICS COMMITTEE - 1**

**YENEPOYA DEEMED TO BE UNIVERSITY, MANGALORE**

**Form for Approval of Protocol Amendment**

*(Source: Ann01/SOP9B/v3 Effective date: 3 October 2019)*

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| **Protocol Number (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:** |
| **List of documents (with version numbers) previously approved (keep adding numbered rows):** |
| **Overview of documents 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 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): (Use separate sheet if required)**   |  |  |  |  | | --- | --- | --- | --- | |  |  | Details/justification | Reviewers’ assessment | | 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 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 of the PI with date  Signature of the guide with date |
| **Note to the PI and responsibility of the PI**   1. *Incomplete forms will not be accepted.* 2. *Any request for amendment of protocol will only be considered if applied for prospectively* 3. *Submit continuing review application along with application for protocol amendment (Ann04/SOP10/v3)* 4. *Include every change in the protocol clearly in the application form for amendment point by point* 5. *Submit application, at least one week before the YEC-1 meeting, so as to be included in that meeting.* 6. *Highlight all the 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.* 7. *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.* 8. *Implement the amended version of the protocol only after it is approved by YEC-1.* 9. *Any changes made in the protocol without prior YEC-1 approval will be considered as protocol deviation/violation and is therefore strongly discouraged.* 10. *Ensure concordance in the application form for amendment and the amended protocol version* |