**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):**

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| --- | --- | --- | --- | --- | --- |
| **S.****No** | **Name/part of the document (Specify)** | **Original approved content** | **Amendment proposed**  | **Justification** | **Reviewer’s comment: Acceptable/ Not acceptable/ More information needed** |
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| **Part B (Additional ethical considerations): (Use separate sheet if required)**

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|  |  | 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 dateSignature 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*
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