**PART 1 - Application for extension of the research study**

*Please download the form, fill the details, sign, scan and send by email or submit at by*

***5th February, 2021 before 5:00 pm to:***

***1. Member Secretary IEC - iecmembersecretary@uohyd.ac.in***

***2. Member Convenor IEC - iecconvenor@uohyd.ac.***

|  |  |  |
| --- | --- | --- |
|  | **Date:** |  |
|  | **Name of the Principal Investigator:** |  |
|  | **School/Department/Centre:** |  |
|  | **Institution** |  |
|  | **Protocol Number:** |  |
|  | **Protocol title:** |  |
|  | **Date of UOH-IEC initial approval** | **From**  **To** |
|  | **Dates of Approval of amendments if any:** | **From**  **To** |
|  | **Dates of previous extension of IEC clearance if any** | **From**  **To** |
|  | **Date of submission of the last continuing review application form:** |  |
|  | **Any lapse in UOH-IEC clearance validity:** |  |
|  | **Sample size approved at this site** |  |
|  | **Number of participants screened so far** |  |
|  | **Number of participants recruited so far** |  |
|  | **Number of participants who are ongoing** |  |
|  | **Number of participants who have completed the study** |  |
|  | **Projected duration of study at the time of first UOH-IEC approval** |  |
|  | **Duration of study completed so far** |  |
|  | **Expected duration in months to complete the study** |  |

I declare that the above information is accurate and true. I request UOH-IEC Ethics Committee to grant me extension of approval to conduct the study, with all the other terms of reference and conditions remaining unchanged.

**Signature of the PI**

**Date:**

**Signature of the co-investigator/research supervisor in case of student**

**PART 2 - Form for Approval of Protocol Amendment**

**Please download the form, fill the details, sign, scan and send by email or submit at by 5th February, 2021 before 5:00 pm to:**

**1. Member Secretary IEC - iecmembersecretary@uohyd.ac.in**

**2. Member Convenor IEC - iecconvenor@uohyd.ac.**

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| --- |
| **Protocol Number (assigned by UOH-IEC):**  **Protocol title (as approved by UOH-IEC):**  **Name of the PI:**  **School/Department/Centre:**  **Names of all the research team members:**  **Issue and expiry dates of UOH-IEC initial approval:**  **Issue and expiry date(s) of UOH-IEC 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 supervisor (for MPhil/Ph.D. 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 |  |  | | P.I Proposed changes 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 of the PI with date:  Signature of the supervisor with date for MPhil and Ph. D studies: |
| **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. *Include every change in the protocol clearly in the application form for amendment point by point* 4. *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.* 5. *Other research team members (or supervisor where applicable) should be informed about all the changes made in the documents and seek their approval before submitting to UOH-IEC.* 6. *Implement the amended version of the protocol only after it is approved by UOH-IEC.* 7. *Any changes made in the protocol without prior UOH-IEC approval will be considered as protocol deviation/violation and is therefore strongly discouraged.* |