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

Due date

1. IEC UoH Office: iecuohoffice@uohyd.ac.in
2. Member Secretary IEC - iecmembersecretary@uohyd.ac.in
3. Member Convenor IEC - iecconvenor@uohyd.ac.in

1.	**Date:**	
2.	**Name of the Principal Investigator:**	
3.	**School/Department/Centre:**	
4.	**Institution**	
5.	**Prior IEC ID Number/s:**	
6.	**Protocol title:**	
7.	**Date of UOH-IEC initial approval**	**From** **To**
8.	**Dates of Approval of amendments if any:**	**From** **To**
9.	**Dates of previous extension of IEC clearance if any**	**From** **To**
10.	**Date of submission of the last continuing review application form:**	
11.	**Any lapse in UOH-IEC clearance validity:**	
12.	**Sample size approved at this site**	
13.	**Number of participants screened so far**	
14.	**Number of participants recruited so far**	
15.	**Number of participants who are ongoing**	
16.	**Number of participants who have completed the study**	
17.	**Projected duration of study at the time of first UOH-IEC approval**	
18.	**Duration of study completed so far**	
19.	**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 by due date.
1. IEC UoH Office: iecuohoffice@uohyd.ac.in
2. Member Secretary IEC - iecmembersecretary@uohyd.ac.in
3. Member Convenor IEC - iecconvenor@uohyd.ac.in

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):

1.
2.
3.

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
1.					
2.					
3.					

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.*

Mandatory requirement for both extension and amendment

Human Research during COVID-19 pandemic times
1. Highlight the steps of how you will take to ensure health/safety/wellbeing/protection of stakeholders of this research during COVID – 2019 times. Also clearly indicate whether you also seek approval for virtual modes of primary data collection.