



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

13th August, 2021 before 5:00 pm to:

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

2. Member Convenor IEC - ieconvenor@uohyd.ac.

1.	Date:	
2.	Name of the Principal Investigator:	
3.	School/Department/Centre:	
4.	Institution	
5.	Protocol Number:	
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 at by 13th August, 2021 before 5:00 pm to:

1. Member Secretary IEC - iecmembersecretary@uohyd.ac.in
2. Member Convenor IEC - ieccconvenor@uohyd.ac.

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): <ol style="list-style-type: none"> 1. 2. 3. 																															
Overview of documents in which the amendment is proposed: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Protocol:</td> <td style="width: 20%;"></td> </tr> <tr> <td>Change in title:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in research team members (persons or order of investigators):</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in supervisor (for MPhil/Ph.D. studies):</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in sample size:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in sampling technique:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in inclusion/exclusion criteria:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Change in any other part of the methodology:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Case record form:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Participant Information Sheet:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Informed Consent Form:</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Questionnaire (if any):</td> <td style="text-align: right;">Yes/No</td> </tr> <tr> <td>Any other (specify):</td> <td style="text-align: right;">Yes/No</td> </tr> </table>						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
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Detailed description of the amendment(s) (add rows as necessary): <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 5%;">S. No</th> <th style="width: 25%;">Name/part of the document (Specify)</th> <th style="width: 15%;">Original approved content</th> <th style="width: 15%;">Amendment proposed</th> <th style="width: 15%;">Justification</th> <th style="width: 20%;">Reviewer's comment: Acceptable/ Not acceptable/ More information needed</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">2.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">3.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>						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.							
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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. Will you be carrying out this Research during Covid-19 Pandemic times? Yes/No
2. If Yes - highlight the steps of how you will take to ensure health/safety/wellbeing/protection of stakeholders of this research.