Date:

From:

Dr…
Principal Investigator
Designation: ….
Department of ….
NDCH

To

The Member Secretary
IEC, NDCH

Sir/ Madam,

I request for an extension of ethical clearance validity for the sanctioned study, "……..……
……". I have enclosed the documents as per the check list stipulated by IEC, NDCH guidelines.

Principal Investigator Details:

Email id:
Contact No.:

Thanking you,
Yours sincerely,

Signature of PI

……

To be filled by IEC NDCH Office

Received on:

Signature:
IEC NDCH

INSTITUTIONAL ETHICAL COMMITTEE, NDCH (IEC, NDCH)

PROFORMA III

(CONTINUING REVIEW FORM)

(Applicable for Dissertation /Short Studies / Research exceeding 6 months / one year as per IEC Clearance Certificate)

Name of the Principal Investigator:

Department:

Title:

IECC Reference No.:

Date issued:

A	**Summary of protocol participants:**	
1.	No. of participants screened: (*No. of participants that you have considered for including in your research study but may or may not have got recruited for your study for various reason*)	
2.	No. of participants approved by IEC, NDCH : (*This is the No. of participants as approved by the YUEC and as mentioned in your approved protocol and in the EC clearance letter*)	
3.	No. of recruited participants: *(No. of participants on which the research has been conducted so far) Please note the no. of recruited participants should not be more than no. of participants approved by IEC, NDCH. Also note that the no. of recruited participants will never be more than the total no. of participants.* *No. of recruited participants =No. of ongoing participants + No. of completed participants + No. of participants who have withdrawn from the study*	
4.	No. of ongoing participants: (*The no. of participant on which the research is actively being conducted at the movement. Example: intervention /questionnaire /observation etc. Please note this does not include the no. of participants on whom the research is already completed. Also note that this is not more than the no. of recruited participants*.)	
5.	No. of completed participants:	
6.	No. of participants who refused to consent: (*This includes the no. of participants screened for the research but were not recruited because they refused to consent*)	
7.	Have any participants been withdrawn from this study? (*This includes the no. participants who withdrew their consent during the conduct of the study*)	

8.	If Yes, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)	
B	**Amendments in the protocol**	
9.	Have there been any amendments in the protocol or informed consent document since the last review	
10.	Were these protocol/Informed Consent Document (ICD) amendments approved by the IEC, NDCH	
11.	If no, mention the amendments not approved	(Attach separate sheet)
12.	Which protocol amendment is being followed at present?	
13.	Which Informed consent amendment is being followed at present?	
14.	Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC, NDCH evaluation of the risk/benefit analysis of participants involved in the protocol?	
15.	Whether reports of Serious Adverse Events/Adverse Events (SAE/AEs) so far have been reviewed by the IEC, NDCH	
16.	Have any participating investigators been added or withdrawn since last review	
17.	Is report of interim data analysis available?	
18.	Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	
19.	Brief Status of the Study report (*Use blank sheet and attach if required*)	
	Signature of the Principal Investigator with Date:	
	Signature of the Guide with Date:	