



BHARATHIDASAN UNIVERSITY INSTITUTIONAL ETHICS COMMITTEE
ONGOING PROTOCOL REVIEW SUBMISSION FORM

BDU-IEC Form 2

S.No.	Title	Particulars
1a	BDU-IEC Protocol Number	
1b	Month/ Year of approval	
1c	Number of ongoing review	One / two / three / four / five / six / other
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-Investigator(s) Co-PI with Qualification and Designation	
5	Duration of the project / trial	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute/ Dept. where research is to be conducted	
8a	Has subject recruitment begun?	Yes/ No (If Yes, proceed to S.No. 9)
8b	If subject recruitment has not begun, give reasons and proceed to S.No. 18	
9	How many subjects have been screened?	_____ (give a brief demographic profile of subjects screened)
10	How many subjects have been recruited?	_____ (give a brief demographic profile of subjects screened)
11	What is the sample size required	
12	Is subject recruitment continuing?	Yes/ No (If No, Provide a 'project report' as attachment)
13	Is there any 'drop outs'?	Yes/ No (If Yes, Provide details)
14	Are subjects still receiving active intervention?	Yes/ No (If Yes, Provide details)
15	Have there been any adverse events ? If yes, give details	Yes/ No (If Yes, Provide details)
16	Have there been any unexpected adverse events ? If yes, give details	Yes/ No (If Yes, Provide details)

17	Have there been any <u>unanticipated study-related problems</u> ? If yes, give details	Yes/ No (If Yes, Provide details)
18	Is there any new Risk/ Benefit information? If yes, give details	Yes/ No (If Yes, Provide details)
19	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval.	Yes/ No (If Yes, Provide details)
20	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?	Yes/ No (If Yes, give a brief summary as attachment)
21	List of attachments for review, if any	
22	Remarks, if any	
23	Signature of the Principal Investigator with date	