



## Bharathidasan University Institutional Ethics Committee

### Initial Review Submission Form for Ethical Clearance

#### BDU-IEC Form 1

S.No.	Submission Date	Approved Date	Resubmission Date	Not Approved Date

S.No.	Title	Particulars
1	Title of the research proposal	
2	Name of the Principal Investigator (PI) with Qualification and Designation	
3	Name of the Co-Investigator(s) Co-PI) with Qualification and Designation	
4	Is the study in collaboration with a Medical Institute/Hospital/Practitioner? If yes, give details	
5	Source of funding & financial allocation for the project / trial	
6	Duration of the project / trial	
7	Name of the Institute/ Dept. where the research is to be conducted	
8	Is approval by other Ethics Committees required?	
9	Will the research proposal be submitted to any Ministry Screening Committee for International Collaboration?	
10	Research Proposal: Relevant background Information	
11	Research Proposal: Main objectives	
12	Methodology and Technical approach of the proposal	
13	Justify why a study with human participants is needed to answer the research questions. Also justify the number of participants required.	

14	Participant recruitment process, inclusion and exclusion criteria for selection of participants.	
15	Usefulness of the project / trial	
16	Research Subject Information form	
17	Describe the Informed Consent Process	
18	Explain the plans to maintain confidentiality of records / data	
19	Explain all anticipated 'risks' (adverse events, injury, discomfort...) of the project	
20	Efforts taken to minimize the 'risks'	
21	Whether 'wage compensation' for the research subjects will be provided?	
22	Expected 'benefits' to volunteer / community	
23	Explain the plans of publication of results (positive or negative) while maintaining confidentiality of personal information/identity	
24	How does the PI propose to store and maintain the human material or data obtained from the study.	
25	List of documents enclosed for ethical review	
26	Disclose Conflict of Interest, if any.	
27	Specific ethical issues, as identified by the investigating team	
28	Signature of the Principal Investigator with date	