ASHOKA University IRB

Application for FULL Review for Research Studies involving Human Subjects

Please send the completed application along with all the supporting documents in a single PDF to **IRB@Ashoka.edu.in**. If the IRB committee is in agreement of your assessment that the project meets the full review criteria (as determined by the categories of IRB review document) , it will give your project an approval number that may be helpful in case a manuscript based on the study is submitted for peer review. If the committee determines that the study does not fulfil these criteria, you will be notified about the relevant application to complete.

Please fill out all the fields in this form. Where the information asked is not applicable please mark NA

SECTION I: STUDY PERSONNEL					
Title of the study:					
Principal Investigator (PI)	Name: Email:		Select ONE: ☐ Student ☐ Staff ☐ Faculty ☐ Other (pls specify)		
Other Study Personnel					
Name	Institutional Affiliation	Position	E-mail Address	Contact number	Mandatory HSR training completed? (Y/N)

Note: Please attach a copy of current certification of HSR training e.g. CITI, PHRP, other as appropriate.

SECTION II: PROTOCOL SUMMARY	
1.	Please provide a brief summary of the study, including the objectives, research questions, hypotheses and broad information areas (500 words max)
2.	Please provide a brief summary of the study, including the objectives, research questions, hypotheses and broad information areas (500 words max)
3.	Please describe briefly how this study will add to existing knowledge in the field. (250 words max)
4	Please describe briefly the profile of the study population (250 words max)
5	Please describe the data you want to gather from human participants. (250 words max)
6	Please describe how data will be collected from human participants and provide an explanation for the methodologies selected with specific reference to the proposed research. (250 words max)
7	Please state the location(s) in which this study will be conducted
8	Please state the expected duration of this study. Indicate the approximate start and end date. Please note that research projects not completed within two years or the stated duration, whichever is shorter, will require an application for extension. - Start date - End Date
SECTION III: PARTICIPANTS & INFORMED CONSENT	
9	Please describe how study participants will be recruited for this study.
10	Please indicate if participants will be given any money for their participation in this study? If yes, please explain the rationale for including monetary compensation.
11	Is your research expected to directly or indirectly benefit the participants? If yes, describe any benefits that individuals may expect from participation.
12	Please describe the process for obtaining informed consent of research participants. Instruction: Include the Consent Form(s) with this application.
13	In case written consent is not being obtained, please explain why not. Describe other consent procedures which will be followed along with the rationale for this approach.
14	Please describe any factors that may inhibit participants' ability to give informed consent i.e. be adequately knowledgeable about the study, adequately comprehend the purpose of the study and exercise their choice free of any perceived coercion. These could be unequal power relations, political or organizational affiliations etc.
15	Please describe if your study will include any vulnerable populations as subjects who may have limited capability to make informed choices in an informed and voluntary manner without feeling coerced in any manner whatsoever. "Vulnerable" populations include prisoners, pregnant women, cognitively impaired persons, mentally ill, individuals with substance abuse issues, or economically or educationally disadvantaged persons.
16	If your study will include vulnerable study subjects, please explain how your informed consent process takes their special needs into account and ensures that there is no coercion whatsoever
17	Please indicate if the study subjects will include minors (those less than 18 years old) Y/N
18	If study will include minors, please describe the process for obtaining consent from the guardian of the child.

19	If the study subjects are more than 8 years of age, will you obtain written assent from the child? Y/N
20	If answer to the above question is no, please explain why. If the answer is Yes, please explain the process.
21	Please state if the research procedures include deception of any nature i.e. not stating or only partially stating the true purpose of the study to the study participants? Yes No
22	Please describe methodological rationale for the necessity of deception in this study
23	Please state whether study participants will be told the true purpose of the study on completion. Yes No If not, why not?
24	Please indicate if fresh/new consent will be obtained from participants after they have been informed about the true nature of the study on its completion.
SECTION IV: RISKS	
25	Please describe the potentials risks (physical or psychological) that study participants may face as a result of participation in this study.
26	Please describe your strategy for minimizing potential risks described above
27	Please describe your plan for addressing any unanticipated adverse outcomes, such as complaints by study subjects or domestic violence reported by study subjects as a result of participating in your study
28	In case of data collection by personnel other than yourself, please explain their functions and how their efforts will be recognized/rewarded.
29	Please describe how research assistants/interviewers will be recruited and the training they will receive
30	Are there any potential risks that the study personnel may face? If so please describe them
31	Please describe measures in place to address any potential risks that study personnel may face.
SECTION V: DATA SAFETY	
32	Will you collect any personal information during the course of this research project? Yes No
33	Describe the nature of this personal information. Check all that apply Name Date of birth Mailing or email address Home GPS coordinates Phone numbers Aadhar Number Medical records or health information License, or Vehicle ID Biometric identifiers Photos/images/audio recording Signatures, handwriting samples Other (specify)
34	Describe how you will protect the privacy and confidentiality of the study subjects?

35	Describe how the personal identification information will be kept separate from the substantive data collected from study subjects?
36	Please describe the nature and frequency of security check-ups (e.g. anti-virus and password updates) performed for your device?
37	Who will have access to the server on which you are storing the study data?
38	How do you plan to ensure a safe and secure backup of your data?
39	Please describe your plans for post-research data storage and/or disposal?
40	If you intend to share the research findings with the study subjects, please explain your communication strategy for doing so
41	Please describe how you intend to disseminate the study results with the larger academic, research, development and general community. Mark all that apply • Peer Reviewed paper(s) • Conference Presentation(s) • Newspaper article(s) • Meetings with relevant stakeholder(s) • Social Media • Online platforms/repository • Other (please specify)
SECTION VII: FUNDING AND CONFLICT OF INTEREST	
42	Please state the source of funding for this project?
43	Please describe procedures to ensure that the study is not influenced/biased by the funder/funding organization?
44	Please provide details of any financial or other conflict of interest that may exist for any of the researcher(s). Mark NA if not applicable *Note: Financial Conflicts of Interest (FCOI) in research may occur when outside financial interests compromise, or have the appearance of compromising, the professional judgment of a researcher when designing, conducting, or reporting research.*
SECTION VIII: CHECKLIST OF APPPLICATION MATERIALS	
45	CHECKLIST: Along with this application I am submitting: ☐ Completion certificate for human subjects research training for myself ☐ Completion certificate for research training for co-investigators and staff, if relevant ☐ Participation information sheet ☒ Consent form* ☒ Assent form* If you do not have informed consent/assent procedures in place, please explain why you are requesting a waiver? (Max 250 words)
SECTION IX: DECLARATION BY THE PRINCIPAL INVESTIGATOR	
I understand the Ashoka University's policies concerning research involving human subjects and I: • Declare that I have read and understood the ICMR guidelines (for biomedical research) or the Common Federal Code (CFR) or the UNESCO Universal Declaration on Bioethics and Human Rights (or any other detailed guidelines for ethical research with human subjects). • Agree to comply with all of ASHOKA University IRB's policies, decisions, conditions, and requirements; • Agree to accept responsibility for the scientific and ethical conduct of this research study;	

- Declare that I have the requisite qualifications and experience to perform the research described in this document.
- Assure that all personnel who will work on this project have been completed the appropriate training for conducting research with human subjects and are fully conversant with the relevant procedures on ethical considerations.
- Undertake to keep the ASHOKA University IRB fully informed on any changes to the proposed research or its details given in this application form subsequent to its submission (including change of contact details and changes in study personnel).
- Agree to submit a Research Closure form to the ASHOKA University IRB upon completion of the research procedures outlined in this proposal.

PI Name:	**PI's Signature**	**Date**