Guidelines

1. Before beginning the application, review pertinent materials concerning harm, risk, and informed consent available under Overview. Templates for consent form, assent form and participation Information sheet will be available to you under Resources. If your research involves minors or vulnerable population, check the relevant section under Categories of Review for additional regulations.

2. Review the criteria listed under Categories of Review to determine your eligibility for the Exempt, Expedited or Full Review.

3. Complete the appropriate form and submit it. Even projects that the applicant believes to be covered under the Exempt category need to apply for IRB review.

4. Your submission to the IRB must include the application form and supporting documents (if any). Please note that the IRB may request applicants to provide additional information. This will be determined by the IRB on a case-by-case basis.

5. Please note that for Exempt reviews you must allow 2 weeks for a response from the IRB. For Expedited reviews, 3 weeks and projects requiring a Full Review will receive a response within 4 weeks. For some applications, the committee may require more time to complete the review and approval process.

☐ I have carefully read the guidelines mentioned above.

Yes

Personal Details

Please fill in all mandatory fields. If a mandatory field is not relevant to you, please write N/A in the textbox

First Name *

Middle Name

Last Name

Email ID *

HSR training completed? *

Yes No

What is the title of your study ? *

Name of your thesis advisor*

Department*

State the expected duration of this study. Indicate the approximate start and end date *

Protocol Summary

1. Provide a summary of the study, including the objectives, research questions, hypotheses and broad information areas. *

2. Describe briefly how this study will add to existing knowledge in the field. *

3. Will you use only secondary data? If yes, state the data source here? Please write NA for subsequent questions that do not apply to your study? *

4. Describe briefly the profile of the study population. *

5. Describe the data you want to gather from human participants. *

6. Describe how data will be collected from human participants and provide an explanation for the methodologies selected with specific reference to the proposed research. *

7. 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 an extension. *

Participants & Informed Consent

1. Describe how study participants will be recruited for this study. *

2. Describe the process for obtaining informed consent of research participants. *

3. 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. *

4. Please indicate if the study subjects will include minors (those less than 18 years old). *
Yes
No

5. If the study subjects are more than 8 years of age, will you obtain written assent from the child? *
Yes
No

6. 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

7. Please state whether study participants will be told the true purpose of the study on completion. If not, why not? *
Yes
No

8. 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. *

9. Is your research expected to directly or indirectly benefit the participants? If yes, describe any benefits that individuals may expect from participation. *

10. 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. *

11. 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. *
12. 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. *

Risk(s)

1. Describe your strategy for minimizing potential risks described above. *

2. 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 . *

3. Describe the potentials risks (physical or psychological) that study participants may face as a result of participation in this study. *

4. Are there any potential risks that the study personnel may face? If so please describe them. *

5. Describe measures to address any potential risks that study personnel may face. *

Data safety

1.Describe how you will protect the privacy and confidentiality of the study subjects. *

2. Does your study involve recording the participants in any manner – audio or video? Y/N *

3. Who will have access to the server on which you are storing the study data? *

4. How do you plan ensure a safe and secure backup of your data? *

5. Describe your plans for post-research data storage and/or disposal. *

6. Will you collect any personal information during the course of this research project? *
Yes
No

7. Describe how the personal identification information will be kept separate from the substantive data collected from study subjects. *

8. Please describe the nature and frequency of security check-ups (e.g. anti-virus and password updates) performed for your device. *

Dissemination

1. If you intend to share the research findings with the study subjects, please explain your communication strategy for doing so. *

2. 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)

Checklist*

Along with this application, I am submitting: *

1.Completion certificate for human subjects research training for myself
2.Completion certificate for research training for co-investigators and staff, if relevant
3.Participation information sheet
4.Consent form
5.Assent form

If you do not have informed consent procedures in place, please explain why you are requesting a waiver. (Max 250 words)

Declaration *

I understand Ashoka University's policies concerning research involving human subjects and I:

- 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.

Principal Investigator's name. *
Principal Investigator's email id. *