

XAVIER UNIVERSITY
INSTITUTIONAL REVIEW BOARD
Application for Approval of Research Involving Human Subjects
that will be approved with an agency via an Authorization Agreement
GENERAL INSTRUCTIONS

1. Review the guidelines and definitions for the protection of human subjects in research at www.xu.edu/IRB.
2. Complete this application submission form by answering all questions, providing your signature at the end. If this is a student research project, also include Faculty Advisor Assurance.
3. Attach a summary (no longer than three typed pages) of the study that includes the following information with appropriate headings for each topic:
 - a. statement of the research, purpose and significance of the study
 - b. research methodology and procedures including sample selection and size, recruitment of subjects (who and why, total number, inclusion/exclusion criteria, source, initial contact method), and data collection, analysis, and storage/destruction procedure (less detail required for exempt studies than expedited or full review studies)
 - c. Informed Consent Procedures Informed consent is a process, not just a form. Potential subjects must be given information they need to make an informed decision to participate in this research
4. Attach a copy of all consent forms and assent forms. Consent forms must include the following: purpose; procedures including details about what subjects will be expected to do and how long it will take; alternative procedures (usually not applicable); anonymity/confidentiality (state if anonymous or if collecting identifying information, state plan for protecting subjects' identity including identifying record storage/destruction plans); compensation, if any; risks and benefits; right to refuse or end participation; and whom to contact (PI for study-related questions, IRB regarding rights). See sample consent (adults) and assent (children) forms on the [IRB web site](#).
5. Attach a copy of all research instruments (e.g., questionnaire, survey, semi-structured interview guide).
6. Attach a copy of any announcements or instructions relating to subject solicitation, such as announcements publicly posted or instructions to others who will be asked to contact potential subjects.
7. Attach letters of permission of study/recruitment sites as appropriate.
8. Attach completed HIPAA form if you answer "Yes" to Question 1 in Section IV of the application.
9. Attach copy of NIH training certificate. NIH training web site: <http://phrp.nihtraining.com/users/login.php>
10. Once the authorized agency has approved the protocol, send a copy of the approval letter to Xavier's IRB office.

All forms are available at <http://www.xavier.edu/irb>. If you have questions, call the IRB office at (513) 745-2870 or email irb@xavier.edu.

Complete the submission form electronically or manually, then sign it and send it with the attachments as a packet to the IRB by campus mail at ML 1100 or by regular mail at Xavier University, IRB, 3800 Victory Parkway, Cincinnati, OH 45207-7351.

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I. General Information

Title of Study: _____

 Principal Investigator: Name _____ Department _____
 Investigator is Faculty Staff Undergraduate Student Graduate Student Other
 Mailing Address of Investigator: _____
 Phone: _____ E-mail: _____
 Names of Co-Investigators: _____
 Name of Faculty Advisor: (if applicable): _____
 Phone: _____ E-mail: _____ Campus Mail Location: _____
 Authorization Agreement Agency: _____

Have you completed Human Subjects Training? Yes Please include author's and co-author's certificate of completion.

Has your advisor completed Human Subjects Training? Yes (IRB will confirm that certificate is on file).

Investigator Assurance

- I certify that the information provided is complete and correct.
- I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the study.
- I have reviewed and agree to comply with Xavier University policies on research involving human subjects.
- Informed consent will be obtained from human subjects if applicable.
- Adverse events will be reported to the XU IRB promptly via the Adverse Event Report Form.
- I am aware that all protocols approved in the expedited or full board review category are approved for one year. All subject recruitment must stop at the end of that approval period unless the protocol is re-approved for another year. Submission of a Progress Report Form is required for re-approval.

Principal Investigator Signature _____ Date _____