XAVIER UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Application for Approval of Research Involving Human Subjects

GENERAL INSTRUCTIONS

1. Review the guidelines and definitions for the protection of human subjects in research at www.xu.edu/IRB.
2. Send a copy of Determining Whether Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions http://www.xavier.edu/irb/documents/1DeterminingHumanResearchForm10-9-12.pdf to the IRB office. IMPORTANT NOTE: If you are confident that your study constitutes "Research" as defined by the Determining Research form, the form may be submitted as part of, rather than in advance of, the full application.
3. 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.
4. Attach a summary of the study that includes the following information, with appropriate headings for each topic. Please note that most Exempt and Expedited summaries should be no longer than three (3) single-spaced pages (generally 1200-1800 words). For complicated Expedited protocols, or most Full-Board protocols, longer summaries are often appropriate in order to provide the IRB with all relevant procedural details (point b, below).
    a. statement of the research, purpose and significance of the study (should be no longer than 2-3 paragraphs, regardless of submission type)
    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
5. 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.
6. Attach a copy of all research instruments (e.g., questionnaire, survey, semi-structured interview guide).
7. 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.
8. Attach letters of permission of study/recruitment sites as appropriate.
9. Attach completed HIPAA form if you answer "Yes" to Question 1 in Section IV of the application.
10. Attach a copy of NIH training certificate. NIH training web site: http://phrp.nihtraining.com/users/login.php

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.

Electronic submission is encouraged to the IRB at irb@xavier.edu. However, a typed signature will not be accepted; therefore sign the application and either scan and email or fax to 513-745-4267. If you prefer to send a hard copy, complete the submission form electronically or manually, 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.

Determining Whether Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions

Investigators: Please complete the top text boxes. Submit the form to Xavier University's IRB office at ML 1100, or as an email attachment to irb@xavier.edu. You will be notified in writing of the IRB's determination.

Person Requesting Determination and Contact Information	Name & Degree	Department
	Phone	Mail Location or Mailing Address
	Email	
Title of Project		
Description of Project, Including Whether or Not Findings Will Be Generalizable		

Research for which DHHS regulations or XU Policies may apply

BOTH "Research" and "Human participants" categories OR "FDA" (next page) must be true for IRB review to be required.

☐ The activity involves **RESEARCH** because BOTH of the following are true.
- ☐ The activity is a systematic investigation, including a systematic collection of data.
- ☐ The activity is designed to develop or contribute to generalizable knowledge.

☐ The activity involves intervention or interaction with **HUMAN PARTICIPANTS** because BOTH of the following are true.

☐ Human participants are involved because EITHER of the following is true.
- ☐ The data being collected are about living individuals.
- ☐ The data being collected include genetic/biological material (sputum, tissue, swab, blood, body fluids, etc.).

☐ Intervention or interaction is involved because EITHER of the following is true.

☐ The investigator plans to obtain the data through ANY of the following (select all that apply).
- ☐ Physical procedures performed on or by participants.
- ☐ Manipulation of participants.
- ☐ Manipulation of participants' environment.
- ☐ Communication with participants.
- ☐ Interpersonal contact with participants.

☐ The information collected is BOTH of the following.

☐ Private, because EITHER of the following is true.
- ☐ The information is about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (such as in a home or a private office).
- ☐ The information is provided by the individual for a specific purpose which the individual can reasonably expect will not be made public (such as class assignments or medical records).

☐ Individually identifiable, because EITHER of the following is true.
- ☐ The identity of the individual is or may readily be ascertained by the investigator.
- ☐ The identity of the individual is or may readily be associated with the information (including a master list linking identity and study ID#).

Research for which FDA regulations or XU policies may apply.

AT LEAST ONE of the following three categories must be true for IRB review to be required.

☐ The activity involves the use of an investigational **DRUG** because ALL of the following are true

- ☐ At least ONE of the following is true (select all that apply).
  - ☐ The article is recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to them.
  - ☐ The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
  - ☐ The article (other than food) is intended to affect the structure or any function of the body of humans or other animals.
  - ☐ The article is intended for use as a component of any article specified in the above items.
- ☐ EITHER of the following is true.
  - ☐ The article is NOT approved by the FDA for marketing.
  - ☐ The article is NOT being used in the course of medical practice.
- ☐ The article or activity will be used on one or more humans.

☐ The activity involves the use of an investigational **MEDICAL DEVICE** because ALL of the following are true.

- ☐ At least ONE of the following is true (select all that apply).
  - ☐ The article is recognized in the official United States Pharmacopoeia, or official National Formulary, or any supplement to them.
  - ☐ The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
  - ☐ ALL of the following are true.
    - ☐ The article is intended to affect the structure or any function of the body of humans or other animals.
    - ☐ The article does NOT achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals.
    - ☐ The article is NOT dependent upon being metabolized for the achievement of any of its primary intended purposes.
- ☐ EITHER of the following is true.
  - ☐ The article is NOT approved by the FDA for marketing.
  - ☐ The article is NOT being used in the course of medical practice.
- ☐ The article or activity will be used on one or more humans.

☐ The activity is **OTHERWISE** subject to FDA regulation because AT LEAST ONE of the following is true.

- ☐ Data from the activity will be submitted to or be held for inspection by the FDA.
- ☐ The activity involves at least ONE of the following FDA regulated articles (select all that apply).
  - ☐ Food or dietary supplement that bears a nutrient content or a health claim.
  - ☐ Food or color additive for human consumption.
  - ☐ Infant formula.
  - ☐ Biological product for human use.
  - ☐ Electronic product for human use.
  - ☐ Other article subject to the Food, Drug & Cosmetic Act.
- ☐ The activity is being done to determine the safety or effectiveness of the drug or device.

For IRB Office Use Only

Determined to be human research requiring IRB review, submission to the IRB is required. ☐

Determined NOT to be human research requiring IRB review, submission to the IRB is NOT required. ☐

_____ _____

Signature of IRB Chair or Designee | Date

For IRB Office Use Reviewers: _____ _____

Date of Submission: _____ Protocol Number: _____ Review Category: ❑ **Exempt** ❑ **Expedited** ❑ **Full Board Review**

XAVIER UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Application for Approval of Research Involving Human Subjects

(The most current version of this application is available online at www.xu.edu/IRB)

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:

Intended sponsor/funding agency (if applicable):

Protocol submitted to another IRB? Provide the following information and attach approval letter (if applicable):

Name of institution: Date Submitted:

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).

II. Additional Study-related Information

Check all that apply

☐ Subjects less than 18 years old. Indicate which of the following categories most accurately describe this protocol
- ☐ minimal risk
- ☐ greater than minimal risk (§46.404)
- ☐ greater than minimal risk but of direct benefit to individual (§46.405)
- ☐ greater than minimal risk with no direct benefit to individual, but likely to yield generalizable knowledge (§46.406)
- ☐ research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of minors (§46.407)

☐ Pregnant women subjects

☐ Disadvantaged subjects (e.g. impaired elderly, disabled, mentally/cognitively impaired, individuals with language barriers)

☐ Incarcerated subjects or persons under a correctional sentence (parolees)

☐ Subject(s) may experience emotional stress as a result of participation

☐ Subject(s) may be identified as possibly needing additional services as a result of participation

☐ Subjects will be deceived or incompletely informed regarding an aspect of the study (*debriefing may be necessary – include text if appropriate*)

☐ More than minimal risk to subjects (*provide risk/benefit analysis*)

☐ Audio or videotaping of subjects (*address additional confidentiality and consent issues if applicable*)

Additional safeguards are necessary for vulnerable populations, in special situations that develop during a study, and in certain research designs. Consideration of these factors may require a higher level of review than may otherwise be necessary. *Explain in your summary the safeguards you will employ for identified vulnerable populations and measures you will incorporate to address identified study related special situations.* Review the expedited and full board review categories with these issues in mind to determine which category seems to be appropriate for the review of your research.

III. (a) Review Level for which you are applying

☐ Exempt Review (complete checklist III (b) if you believe your study qualifies as Exempt)

☐ Expedited Review (read III (d))

☐ Full Committee Review (if your study meets neither exempt nor expedited criteria)

III. (b) If seeking Exemption, complete this section.

☐ The research is being conducted in established or commonly accepted educational settings, involving **normal educational practices**, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **Research is exempt. Go to Section IV.**

☐ The research involves only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Such research may be exempt depending upon other factors. **Continue.**

- ☐ All subjects are elected or appointed officials or candidates for office. **Research is exempt. Go to Section IV.**
- ☐ Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects. If the subjects are children, the investigator does not participate in the activities being observed. **Research is exempt. Go to Section IV.**
- ☐ Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research does not reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Research is exempt. Go to Section IV.**

☐ The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens which are (i) publicly available or (ii) recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **Research is exempt. Go to Section III(c).**

☐ The research or demonstration project is conducted or approved by a federal department or agency head and is designed to study, evaluate, or examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. **Research is exempt. Go to Section IV.**

☐ The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives are consumed, or (ii) food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture. **Research is exempt. Go to Section IV.**

III. (c) For existing data sets please include the following information in your summary:

1) Source of data set; 2) brief description of contents of the data set including whether or not the data set you receive will contain identifiers and if so, how you will protect the confidentiality of subjects; and
3) whether the data are from a public or protected data set. If protected, (a) explain how you will obtain access to the information (written documentation of this permission – email or hard copy from person authorized to provide access – will be required as a condition of approval) and (b) advise as to whether or not the respondents gave permission for the information to be used for research purposes.

III. (d) If your protocol is not exempt, read this section to determine if, in your estimation, your study should be reviewed by Expedited Review. See 45 CFR 46.111 for unabridged text (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Studies reviewed in this category must meet all of the following requirements: 1) Risks to subjects are minimized; 2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be expected to result; 3) Selection of subjects is equitable; 4) Informed consent will be sought to the extent required by §46.116.

IV. Other Considerations:

Yes ☐ No ☐ 1. Will protected health information (PHI) be obtained from a covered entity without authorization for its use by the patients (a health plan, health care clearinghouse or health care provider)? *If so, please complete and attach the Request for HIPAA Alteration to/Waiver of Individual Authorization form.*

Yes ☐ No ☐ 2. Are you conducting only anonymous survey research that involves no more than minimal risk to subjects? If so, while informed consent is still necessary, subjects may be able to be consented by reading or listening to an informed consent document/script which includes a statement that completion of the survey indicates consent to participate in the study. *Provide a modified informed consent document/script that does not require a signature.*

Yes ☐ No ☐ 3. Are you requesting a waiver or alteration of Informed Consent?

An IRB may approve a consent procedure that does not include, or alters, some of the elements of informed consent. *Provide justification for the waiver.* A) Describe how the proposed research presents no more than minimal risk to the subjects. B) Why will a waiver of informed consent not adversely affect the rights and welfare of the subjects? C) Why is it impractical to carry out the research without a waiver or alteration of informed consent? D) How will pertinent information be provided to subjects, if appropriate, at a later date?

V. Conflict of Interest Disclosure

Yes ☐ No ☐ Except for grant-funded compensation and expenses, do you, or does any member of your immediate family, intend or expect to profit financially in any manner from the results of the research undertaken in this study (including but not limited to any patent, royalty, or licensing fees)?

If yes, please provide a detailed description of your financial intentions or expectations:

Yes ☐ No ☐ Do you, or does any member of your immediate family, currently have or expect to have an ownership or other financial interest in, or management position with, any entity whose procedure, technique, product or software is used or tested in this study?

If yes, please provide a detailed description of your financial interest or management position:

VI. Permission for future IRB use

Yes ☐ No ☐

The IRB is interested in compiling a database of sample protocols to use in training new members, and to further educate faculty and students about the IRB review process. Any protocol used for these purposes would be fully anonymized (all identifying information about you and your research team would be removed), and would not be used for a minimum of two (2) years after its completion. Only those studies that are no longer actively collecting data at that time would be made available. In light of this, would you be willing to allow the IRB to use your protocol for training purposes two years after the completion of your project?

Note: Your response to this question has no bearing on the review of your protocol. You may elect not to respond at this time and notify our office at a later date if you would like your anonymized protocol to be included in our training database.

☐ The IRB may include an anonymized version of my protocol in its training database.

☐ I would prefer the IRB not include any version of my protocol in its training database.

☐ I would like the IRB to contact me six months after my protocol is approved to request permission to utilize my protocol in its training database.

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 _____

Checklist of items to include with submission:

- ☐ Completed and signed application with correct number of copies for review category
- ☐ Faculty Advisor Assurance (if applicable)
- ☐ Summary
- ☐ Consent documents – see guidelines and templates on Forms web page
- ☐ Research instruments (if applicable)
- ☐ Recruiting materials (if applicable)
- ☐ Approval letter from other IRB (if applicable)
- ☐ Letter of permission from study/recruitment site, data source (if applicable) – see template on Forms web page
- ☐ Debriefing text (if applicable)
- ☐ HIPAA form (if applicable)
- ☐ Human subject training certificate of completion

THIS PAGE REQUIRED FOR STUDENT RESEARCH ONLY
(Submit with application)

Faculty Advisor Assurance

By my signature as sponsor on this research application, I certify that the primary investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. I also agree to monitor the progress of the study.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Conflict of Interest Disclosure

Yes ☐ No ☐

Except for grant-funded compensation and expenses, do you, or does any member of your immediate family, intend or expect to profit financially in any manner from the results of the research undertaken in this study (including but not limited to any patent, royalty, or licensing fees)?

If yes, please provide a detailed description of your financial intentions or expectations:

Yes ☐ No ☐

Do you, or does any member of your immediate family, currently have or expect to have an ownership or other financial interest in, or management position with, any entity whose procedure, technique, product or software is used or tested in this study?

If yes, please provide a detailed description of your financial interest or management position:

Advisor/Faculty Sponsor Signature _____ Date _____