The Informed Consent Process

General Requirements

The informed consent process constitutes an invitation to volunteer to participate in a research project. Every researcher (faculty, staff, or student) at Xavier University must obtain the informed consent of any human subject participating in research. Sample letters of informed consent are included in IRB Forms. **The IRB must approve all informed consent forms to be used for research that requires expedited or full board review. Data collection may not begin until the researcher has received consent forms that have been stamped as approved by the IRB.**

***Obtaining Informed Consent*:** The investigator must ensure that the circumstances under which consent is sought will provide the subject (or his/her representative) with sufficient opportunity to consider whether or not to participate. The circumstances must also minimize the possibility of coercion or undue influence that might be experienced by the subjects. Often the situation of the subjects may be inherently coercive; i.e., their freedom of choice may be restricted by the nature of their employment, their age, associations with certain groups, their mental or physical capacities, or due to confinement in a mental hospital or correctional institution. Subjects in any of these categories are not excluded from research; rather, the investigator must make special efforts to ensure that potential subjects are given every opportunity to exercise free choices in consenting to participate in a research project (see next section).

Broadly, the informed consent document communicates to the prospective research subject the purpose, procedures including time commitment of the subject, risks and benefits of the study, a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, the subject's rights in participating in the research, and the freedom to decline to participate without jeopardy. If applicable, alternative treatments available will be explained. The individual will also be given the opportunity to obtain further information and answers to questions related to the study before signing. The consent form will provide contact information for the primary investigator and the IRB Chair to enable the subject to ask questions after the consent form has been signed. The informed consent document is valid for one year. The subject should receive a copy of the informed consent.

In the informed consent document, the description of how confidentiality will be maintained should include an explanation of how identifying data will be securely stored and when they will be destroyed, particularly if the study involves greater than minimal risk to subjects. Studies in which subjects are interviewed, including oral history and ethnography studies, may utilize electronic voice/video recordings. Although these studies generally involve no more than minimal risk to subjects, the use of recording as part of the research procedure and the plans for storage and destruction of the recorded interviews and their associated identifiers should be disclosed in the informed consent document.

Notable Risk Project: When research involves greater than minimal risk, the subject needs a reasonable enumeration of the risk in order to decide whether or not to participate. The list should not be constructed either to minimize real risks or to overstate them. Projects with risks should also list protective measures used to lower the risk potential or to ensure safety while the subject encounters the risk(s). If a project presents one or more risks, an injury clause needs to be included in the consent document.

***Obtaining Oral Consent*:** If oral consent is necessary due to limited literacy or language comprehension, the subject or his/her legal representative will be asked to sign a consent form stating that the basic consent form elements have been orally presented. Both the consent form and the outline of the oral

presentation must be approved by the IRB. A witness must also be present for this presentation and must sign both the consent form and a written summary of the oral presentation.

***Obtaining Assent*:** Parents or legal representatives typically sign consent forms permitting minors or adults incapable of giving adult informed consent to participate in research projects. If the subject is a minor or an adult incapable of giving informed consent, the IRB may require him/her to sign an "assent" form if it has been determined that the subject is able to read and understand a simplified version of the adult consent form. Language must be simplified as appropriate for the age group. A copy of the assent form to be used should be included with other materials submitted to the IRB for approval.

Informed Consent and Special Populations

Every potential subject who is a physically and mentally able adult (defined as anyone age 18 or over) must provide consent to participate in research prior to the conduct of any activities that constitute the research encounter. This is the most general case and applies to all research. Minors or special adult populations who are being recruited as research subjects may be compromised in their ability to provide truly informed and voluntary consent and therefore require special safeguards to ensure that their rights are protected in the informed consent process.

1) **Children:** Obtaining permission to conduct research involving children (persons under age 18) requires special attention to the child's age, his/her ability to understand what is asked of him/her, and his/her relationship to parents/guardians. If research subjects are wards of the state, further safeguards are required as outlined in 45CFR46. In all cases, the investigator must demonstrate respect for the rights of the subject within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the child (see IRB Forms for Sample Child Assent Form).
    a. **Parental Consent:** Parental permission or consent in writing is required for all minors under the age of 18 who participate in research except for emancipated minors.
    b. **Adolescent's Written Assent:** From about junior high or middle school onward, a child's written assent is needed (in addition to parental consent), because children in this age group usually can read and comprehend a well-constructed assent form. However, the investigator should use supplementary verbal explanations whenever needed.
    c. **Child's Assent:** For elementary school aged children, the investigator should obtain (in addition to parental consent) the child's assent to participate. The explanation to the child should contain elements of consent expressed in a form the child can understand. A conversational question-and-answer setting is often necessary to achieve this goal. In addition, the child's assent should be positive, that is, not merely lacking of dissent. If the child is old enough to render a signature, investigators are required to obtain a signed assent form.
    d. **Very Young Child's Assent:** For children below school age (e.g., infants, toddlers, and preschoolers) the investigator should give explanations that match the level of understanding. In many instances, the children's nonresistant behavior may be interpreted as assent, but the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. A verbal script must be submitted as part of the protocol.

2) **Other Special Types of Subjects**: Besides children, numerous other types of subjects require special attention when obtaining informed consent. In all cases, the guiding principle is respect for the rights of the potential subject.

a. **Prisoners:** Obtaining the informed consent of prisoners to participate in research requires attention to their circumstances. The research should not provide the prisoners with advantages that would unduly influence their ability to weigh the risks involved in the research. Moreover, the consent form should make it clear to prisoners that participation would have no direct effect upon their parole or treatment. An advocate is required. See 45CFR46.
b. **Individuals with mental disabilities:** In obtaining informed consent from individuals who are mentally disabled, additional protection is necessary. The research protocol must clearly demonstrate how the research intends to ensure that the interests of patients are protected.
c. **Fetuses, pregnant women, and human in-vitro fertilization:** Special safeguards may be required depending upon the research. See 45CFR46 for details.
d. **Other groups:** Vulnerable and special populations include subjects who, as outlined in federal regulations, must be provided extra protection. Other groups such as racial minorities, the elderly, the economically disadvantaged and the very sick are described as vulnerable populations by The Belmont Report, and are therefore provided similar protection when sought as research subjects.

Although the regulations specifically mention only these special categories of subjects, the overall intent is clear. Whenever the potential subjects of research have special features or circumstances that might alter their ability to render informed and voluntary consent to participate in research, the researcher has special responsibilities. There is no way to anticipate every situation. Therefore, researchers must use extreme care to respect the rights of potential subjects in developing the means of obtaining their informed consent.

Alteration or Waiver of Informed Consent

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1) The research is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (1) 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 payments for benefits or services under those programs;

   AND

2) The research could not practicably be carried out without the waiver or alteration

   OR

1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration;

   AND

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

An alteration of the consent procedure may be considered if the research meets all four criteria.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either

1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality
OR
2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Waiver of signed consent does not imply waiver of the researcher's responsibility to obtain consent from subjects. Projects that may benefit from a waiver of the requirement for a signed consent form may include 1) **anonymous** interviews including face-to-face and telephone interviews in which the investigator's sole knowledge of the identity of the interviewee would come from the signed consent document or 2) **anonymous** survey research that involves no more than minimal risk. In either case the consent document which can be read to or read by the subjects would include a statement informing them that they are indicating their consent by participating in the interview or completing the survey.

NOTE: A subject is *anonymous* only if his/her identity remains individually unknown to the investigator. When the identity is known, but held secure from being known by others, the researcher is maintaining the *confidentiality* of the identity.

Retaining and Storing Signed Informed Consent Documents

Signed informed consent forms are legal documents, and the researcher has the legal responsibilities in handling them. They should be stored in a secure location that is accessible to the University in the event that an inquiry should require their examination. Access to these documents should be limited to those persons who have a right to know their contents, ordinarily, the investigator (and co-investigators), a representative of the IRB (usually the chair), and authorized federal officials. In compliance with federal regulations, consent documents must be retained for a period of *three years following the completion of the research.* Consent documents become part of the IRB file of a project and as such, are subject to Federal Audit. Therefore, the IRB will review carefully both the content of and the storage provisions for all consent forms.

The Progress Report Form requires an account of the exact location, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. The IRB cannot approve the continuation of projects that omit this information.

An investigator who leaves the University prior to the end of the three-year retention period for consent forms should notify the IRB of this fact, specifying the new location of the consent documents. Signed consent documents must be turned over to the responsible faculty member after data collection is completed if a student or research assistant maintained the consent documents. Any change of storage location for consent forms should be reported to the IRB.

XAVIER UNIVERSITY

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INFORMED CONSENT FORM (Template)

Include this information (sample wording) in all consent forms:

You are being given the opportunity to volunteer to participate in a project conducted through Xavier University [and, if applicable, any other co-operating institution].

[Explain #1-#8 in simplified language.] If you decide to participate in the project, please sign this form. You will be given a copy of this form to keep. [There are situations in which subjects may not be given a copy and situations in which subjects will be informed but will not be required to sign a consent form, thus wording may differ – see Informed Consent section of IRB Policies & Procedures.]

If you have any questions at any time during the study, you may contact [name of PI] at [contact info] [also include name & # of your dissertation chair if you are a student]. [For expedited or full board review research, also include statement: "Questions about your rights as a research subject should be directed to Xavier University's Institutional Review Board at (513) 745-2870."]

Include the following in the description of your study:

1. Nature and purpose of the project
2. Why subject was selected
3. Explanation of procedures including explanation of what is required of subjects (complete 3 surveys about *x* topic that is expected to take *x* amount of time)
4. Discomfort/Risks including the time commitment expected of the subject – amount and length of time. Recognize unpredictable risks if appropriate. If there are no known risks, so indicate.
5. Benefits (if any) to the volunteer and to the broader community if appropriate
6. Confidentiality – explain how privacy will be maintained, if and when the data will become anonymous, how data will be stored, and when it will be destroyed. Explain the legal limits of confidentiality if they apply to the study. **Note:** This section does not apply if data are collected anonymously. Subjects should then be informed that data will be collected anonymously and therefore their answers cannot be linked to them.
7. Compensation to be expected, if any
8. Refusal/Withdrawal (Example: Refusal to participate in this study will have NO EFFECT ON ANY FUTURE SERVICES you may be entitled to from the University. You are FREE TO WITHDRAW FROM THE STUDY AT ANY TIME WITHOUT PENALTY.)

I have been given information about this research study and its risks and benefits and have had the opportunity to ask questions and to have my questions answered to my satisfaction. I freely give my consent to participate in this research project.

_____ _____

Signature Date

_____ _____

Witness [Witness signature is not always necessary] Date

THE DATE APPROVAL STAMP ON THIS CONSENT FORM INDICATES THAT THIS PROJECT HAS BEEN REVIEWED AND APPROVED BY XAVIER UNIVERSITY'S INSTITUTIONAL REVIEW BOARD.

XAVIER UNIVERSITY

Institutional Review Board

Obtaining Assent from Minors and Adults Incapable of Giving Informed Consent

Parents or legal representatives typically sign consent forms permitting minors or adults incapable of giving adult informed consent to participate in research projects. [The Informed Consent Process section of the IRB Policies and Procedures Manual provides information about situations in which signed informed consent may be waived.]

If the subject is a minor or an adult incapable of giving adult informed consent, the IRB may require him/her to sign an "assent" form if it has been determined that the subject is able to read and understand a simplified version of the adult consent form. Language must be simplified as appropriate for the age group used as subjects.

CHILD/MINOR ASSENT FORM (Template)

I, _____ understand that my parents (mom and dad) have given permission (said it's okay) for me to take part in a project about _____ under the direction of _____.
I am taking part because I want to. I have been told that I can stop at any time I want to and that nothing will happen to me if I want to stop.

[NOTE: All the elements of adult informed consent must be presented in simplified language and congruent with the age of the minor or the adult who is incapable of adult informed consent.]

_____ _____
Signature Date

_____ _____
Witness (someone other than parent/guardian) Date
[Witness signature not always necessary]

THE DATE APPROVAL STAMP ON THIS CONSENT FORM INDICATES THAT THIS PROJECT HAS BEEN APPROVED BY XAVIER UNIVERSITY'S INSTITUTIONAL REVIEW BOARD.