Policies and Procedures of the Xavier University Institutional Review Board

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Policies and Procedures of the Xavier University Institutional Review Board

Introduction

The Xavier Institutional Review Board (IRB) was founded in 1995 to ensure the protection of human subjects in all research conducted on the Xavier University campus and/or by Xavier University faculty, staff and students.

The Office for Human Research Protection (OHRP) supports, strengthens and provides leadership to the nation's system for protecting volunteers in research that is conducted or supported by the U.S. Department of Health and Human Services (HHS). This policy, referred to as the Common Rule, is incorporated in HHS regulations as Title 45 Part 46 of the Code of Federal Regulations (45CFR46). The Xavier University IRB Policies and Procedures are designed to meet these federal requirements and to guide researchers in the design, submission, and implementation of proposals that appropriately protect human subjects.

Statement of Principles

Xavier University is committed to excellence in teaching and research. Further, the University is committed to the conduct of these activities with the highest possible ethical standards. Xavier University has established an Institutional Review Board (IRB) which will review for approval research involving human subjects. The purpose of the IRB is to protect human subjects and to assist faculty, students, and staff in the pursuit of knowledge through research that reflects the ethical standards of Xavier University and those required by OHRP.

The Institutional Review Board is guided by the ethical principles regarding all research involving humans as subjects set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report*. The Belmont Report includes such principles as respect for autonomy, beneficence, and justice to guide research involving human subjects. In addition, the IRB will attempt to assure compliance with the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations.

Xavier University, as identified in its Mission Statement, is a Catholic institution in the Jesuit tradition, firmly rooted in the principles and convictions of the Judeo-Christian tradition. These convictions include the acceptance both of the existence of God as creator and sustainer of our world and of the unique value and destiny of every human being. These principles and convictions ground a living tradition of personal and social ethics, which, along with the Belmont Report, provide the IRB with a basis for the protection of human subjects in research.

The following broad principles are the basis for the development of Xavier University's policies concerning review of research involving humans:

- The direct or potential benefits to the subject, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.
- Participation in the project must be voluntary and informed consent must be obtained from all subjects, unless the Institutional Review Board waives the requirement.
- A subject has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which the subject would be otherwise entitled.
- Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.
- No distinctions in the approval and monitoring of projects will be drawn between funded and non-funded projects, sponsored and unsponsored projects, or on-campus or off-campus projects, except for requirements concerning reporting information to a funding agency.

Establishment of an Institutional Review Board

I. The Institutional Review Board will consist of at least seven members including a chair and a vice-chair appointed by the President after being recommended by the Academic Vice President in consultation with the Associate Academic Vice President, the Deans, and the Faculty Committee. Appointments will be for a minimum of two years (including the Chair). Members will have various experiences and skills necessary to evaluate research involving human subjects and its institutional, legal, scientific, and social implications and will represent areas of expertise from which protocols are expected to be generated. At least one member should represent the community in which Xavier is located. At least one IRB member must have expertise in ethics. The board will have a Chair and vice-Chair appointed by the Academic Vice President.

   a. Experts can be consulted as necessary to advise the IRB. Consultants will not vote on the disposition of a protocol.
   b. An IRB member who has a conflict of interest with any particular protocol, for any reason, must remove herself or himself from consideration of that protocol.

II. The IRB will establish and review the written procedures that those engaged in research involving human subjects must utilize in applying for committee approval. These include policies and procedures for investigators seeking:

   a. Exemption from IRB oversight.
   b. Expedited review.
   c. Full Board review.
   d. Annual Renewal of protocol approval.
   e. Modification of approved protocol.

III. The Institutional Review Board office will keep written records of proposals received, minutes of meetings, and records of the disposition of proposals and renewal requests. All records will be maintained for three years after the completion of the project. Minutes of all meetings are sent to the University's Vice President of Academic Affairs. A brief annual report is sent to the President, Academic Vice President, and the Chair of the Faculty Committee. The IRB will monitor as appropriate those research situations where human subjects are placed at substantial risk to verify that consent is being properly attained and protocol properly adhered to.

IV. The University will supply adequate space and logistical support for the IRB to accomplish its work expeditiously.

V. The University will recognize the service which members of the IRB give in fulfilling their duties.

The Institutional Review Board will follow federal regulations and the requirements of federal, state, local, and private funding sources. More importantly, the establishment and the conscientious work of the IRB will demonstrate Xavier University's commitment and dedication to research conducted in an ethical manner.

General Guidelines

Safeguarding the rights and welfare of human subjects in research is a general institutional policy delegated by the President through the Academic Vice President to the Institutional Review Board (IRB). Any research project involving human subjects which is conducted by Xavier University faculty, staff, or students, or that takes place on the Xavier University campus, is subject to review and approval by the IRB. In order to approve proposed research protocols, the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized by using tests or procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and whenever appropriate, use tests or procedures already being used for learning, diagnostic, or treatment purposes.

- Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in the research).

- Selection of the subjects is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.

- Voluntary informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Title 45 Code of Federal Regulations Part 46.116 (see pages 14-16).

- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

- Where appropriate, the research plan makes adequate provision for monitoring the data collected to attempt to insure the safety of subjects. If any serious breech in the procedure or harmful event occurs with a subject it should be reported to the IRB as soon as possible.

- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects.

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at Xavier University and/or by Xavier University faculty, staff, or students within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Types of IRB Review and Approval

The IRB will utilize the guidelines in Title 45 Part 46 of the Code of Federal Regulations to determine the level of review to be used in evaluating research proposals involving human subjects. The following section elaborates upon the types and levels of IRB review.

Research Considered Under the "Exempt from Federal Policy" Category

In order to establish an individual research project as exempt from the policies of 45CFR46, the principal investigator must submit the IRB Submission Form. Exemption from this policy (which pertains to IRB oversight) does not exempt the researcher from following ethical practices such as obtaining informed consent from research subjects as appropriate. Final determination as to whether a research project is exempt rests with the IRB. If the project is certified exempt by the IRB, the researcher need not resubmit the project for continuing IRB review as long as there are no modifications in the exempted procedures.

The following categories of research are considered as exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational strategies, or research on the effectiveness of, or the comparison among, instruction techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement) if the information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, **except** where the following conditions exist:
    a. responses are recorded in such a manner that the human subject can be identified either directly or through identifiers linked to the subject;
    b. the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
    c. the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4. Research involving observation (including observation by the subjects) of public behavior **except** where the following conditions exist:
    a. responses are recorded in such a manner that the human subject can be identified either directly or through identifiers linked to the subject;

   b. the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
   c. the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects.
6. All research involving survey or interview techniques is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

If the applicant is confident that the protocol fits the exempt category, one copy of the necessary materials should be submitted. The chair or vice-chair of the IRB will verify that the protocol is indeed exempt. A decision is usually made within three working days of receipt of complete documentation. Acceptance (or recommendations leading to acceptance) will be mailed in a timely manner.

Research Considered Under the "Expedited Review" Category

The principal investigator must submit the IRB Submission Form (IRB Forms). Research activities involving no more than "minimal risk"* to subjects and in which the only involvement of human subjects will be one or more of the listed categories may be reviewed by an Expedited Review Subcommittee.

*"Minimal risk" means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigation does not manipulate subject's behavior and the research will not involve stress to subjects.
2. The study of existing data, documents, records, and pathological/diagnostic specimens.
3. Moderate exercise by healthy volunteers.
4. Voice recordings made for research purposes such as the investigation of speech defects.
5. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. (See 45CFR46 for a complete list of clinical procedures that may be reviewed by expedited procedures.)
6. Collection of blood samples . . . from subjects 18 years of age or older who are in good health and not pregnant. Collection of samples of such items as hair, nail clippings, etc., that present no more than minimal risks to subjects. (See 45CFR46 for a complete list of sample collection that may be reviewed by expedited procedures.)

Expedited review does not involve the whole IRB and, thus can be completed in a shorter period of time than full board review. The IRB will be informed of all expedited review activity at its regular meetings. The IRB may be restricted from using Expedited Review by federal oversight or by its own decision.

If the applicant is confident that the protocol fits the expedited category, three copies of the necessary materials should be submitted. The chair or vice-chair and one or two members will verify that the protocol fits the expedited category. A letter granting approval or recommendations leading to approval usually will be sent within seven working days of receipt.

Research Considered Under the "Full Board Review" Category

Any research involving the use of human subjects which does not fall into the "Exempt" or the "Expedited Review" categories must be submitted to the IRB for full board evaluation. The principal investigator must complete and submit the IRB Submission Form (IRB Forms).

If the protocol is submitted for full review, ten (10) copies of the full application should be submitted. If the materials are received ten (10) days before the next IRB meeting, the protocol will be discussed at the meeting and acceptance or recommendations leading to acceptance will be mailed to the applicant within two working days of the full meeting of the IRB.

IRB Review Process

Each fall and spring semester, the IRB's biweekly meeting schedule is posted on the IRB web site (www.xu.edu/IRB). In special circumstances, the Chair of the IRB may call a meeting in the summer months. Proposals requiring full board review must be received in the IRB office **at least ten working days prior** to a meeting to be considered at that meeting. Early submission will expedite the review of projects. Research qualifying for exemption and research qualifying for expedited review may be reviewed at any time since these studies may be reviewed without a meeting.

1. The Principal investigator prepares and submits the application packet to the office of the IRB, following IRB guidelines and instructions included in the IRB Submission Form.
2. A **Technical Review** is conducted to determine that the IRB application is complete and contains the following:
   (a) Completed IRB submission form with required signatures
   (b) Informed consent documentation or rationale if written informed consent is not planned (see Informed Consent section)
   (c) A copy of all additional required materials outlined in the submission form (i.e. the actual survey instrument or interview questions , recruitment materials, and letters of permission from study sites)

If the submission is incomplete, the researcher will be advised of the additional materials that are needed for the review to proceed.

3. The IRB Chair or designee determines the appropriate category for review of the project and assigns reviewers based upon the review category:
   (a) Exempt – The IRB Chair or designee verifies exemption.
   (b) Expedited Review – the Expedited Review Subcommittee is appointed, reviews the project and makes recommendations. A summary of all projects accepted for expedited review is recorded in minutes of the next IRB meeting.
   (c) Full Board Review – The application is forwarded to the full committee and two IRB Reviewers are chosen to review the application in depth and present it to the full IRB. These projects will be reviewed at the next meeting of the IRB. The principal investigator and/or consultant(s) may be asked to be present to respond to IRB inquiries.

Guidelines for Certification of Courses Involving Human Subjects

The instructor for each course in which instruction-related research is performed must submit a Certification of Course Form (IRB Forms) every two years. The form must be submitted prior to the initiation of any student projects involving human subjects research. If more than one instructor teaches the course, each instructor must submit a Certification of Course Form unless the sections/instructors use the identical experimental procedures. If this is the case, each instructors simply needs to sign a Certification of Course Form and attach them to the description of the description of the research methods. The submission of this form will certify to the IRB that the instructor(s) is (are) fully cognizant of the policies of Xavier University with respect to the protection of human research subjects. By submitting this certification, the instructor(s) is (are) certifying to the IRB that she/he will exercise reasonable and customary instruction supervision in an attempt to ensure that all student research projects will be conduced in compliance with these guidelines.

Faculty and academic staff who use the course certification process are responsible for informing their students of IRB policies. The instructor will have students seek IRB approval for the special categories of survey research outlined below.

Student-conducted studies which fall under the category of full board review must be submitted to the IRB, even if the course is certified. All human subject research studies conducted to satisfy master's thesis or doctoral dissertation requirements must be submitted to the IRB.

Guidelines for Course-Related Projects involving Survey Research

The IRB recognizes that many projects conducted to fulfill course requirements involve research with human subjects. Such research may entail certain risks to the subjects involved. As students vary in expertise regarding research procedures designed to protect the rights of human subjects, the IRB has developed the following guidelines regarding classroom-based survey research projects. These guidelines are intended to provide clarification and simplify the process for obtaining IRB approval.

Conditions under which IRB Approval IS Required for Course-Related Survey Research

Any project that proposes to investigate behaviors and/or experiences regarding sensitive topic areas such as those listed below requires IRB approval. In addition, any survey research projects that use subjects under the age of 18 years must be reviewed by the IRB.

<u>Sensitive Topic Areas</u>

a. Sexual Behavior
b. Sexual Orientation
c. AIDS or HIV
d. Incest
e. Rape or Date Rape
f. Sexual Molestation
g. Substance Use and/or Abuse
h. Eating Disorders or Behaviors
i. Contraception, Pregnancy, or Abortion
j. Questions dealing with any aspects of the subject's mental health, e.g., suicide, depression, compulsive behaviors
k. Religious Orientation and/or views
l. Veteran and/or Wartime Experiences
m. Vulnerable population (See page 12)
n. Subjects under 18 years of age

Conditions under which Professorial or IRB Approval IS NOT Required for Course-Related Survey Research

Students collecting data from human subjects as part of the requirements **for a specific course** may conduct opinion research that is not specific to the above behaviors and/or experiences of the interviewees, as long as the research subjects are not identifiable by name or description. For example, IRB approval is **not required** for a student to survey people's opinion about such topics as:

a. Opinions of political candidates or issues
b. Opinions regarding American made vs. foreign made products
c. Opinions concerning environmental issues or policies
d. Opinions regarding the subject's favorite television show, preferred vacation spot, musical preference, etc.

The key element shared by these examples is that they do not require subjects to reveal anything about their personal experiences, behaviors, and/or identity. Therefore, the subjects are not considered to be placed **at risk** by their participation. In such cases, IRB approval is not required for student projects.

If you have questions regarding a project, please contact the IRB office at 745-2870 or irb@xavier.edu.

All research projects involving human subjects completed to satisfy *Master's* thesis or *Doctoral* dissertation requirements are subject to the IRB review guidelines.

Procedure for Continuing Review/Monitoring of Projects

The IRB informs the principal investigators and advisors of ongoing reporting requirements at the time of approval and annually thereafter. These requirements apply to research reviewed in all categories unless specified. **The principal investigator is required to:**

(1) submit proposed protocol modifications to the IRB for approval prior to implementing the modification (Modification Request Form). This requirement also applies to exempt studies in order to verify continued exempt status.

(2) notify the IRB and submit an Adverse Event Report if adverse events occur (examples include injury to subjects, breaches of confidentiality and unapproved deviations from the protocol) and

(3) submit to the IRB a progress report annually and/or upon completion of the project (Progress Report Form). The IRB may require more frequent reporting in certain situations such as greater than minimal risk to subjects. The annual /final reporting requirement applies only to research reviewed in the expedited and full board review categories. Exempt studies require no annual reporting.

All research approved by the IRB is open to site review on a random basis by the Chair or his/her appointee. Research with highly vulnerable populations and/or research exposing volunteers to high risk will be site-visited at the recommendation of the IRB. Adverse event reports, reports of noncompliance, and complaints by subjects to the IRB will be investigated within five (5) working days and the research halted when necessary and, when appropriate, the funding agency and OHRP notified. Investigation of adverse events can include on-site review of study materials and procedures, interview of study personnel, and/or interview of subjects, as deemed appropriate by the IRB. Any other body charged with oversight will report any serious deviation to the IRB who will act with appropriate speed to correct the situation including withdrawal of approval. Any actions taken by the IRB will be communicated to the researcher and through the minutes available to the Institution.

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.

Informed Consent and Assent Form Templates

Writing a consent document that includes all of the necessary elements for true informed consent and stating the information in a way that is understandable to potential research subjects is an extremely important piece of the research proposal. Therefore, it is strongly recommended that researchers utilize the informed consent and assent form templates on the following two pages and cut and paste appropriate sections into the informed consent form to be submitted as part of the research protocol.

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 the 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.

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.
In other words, this assent form uses age appropriate language for a young child but this language would not be appropriate for adolescents. The language must be adapted to meet the age range of the subjects.

_____ _____
Signature Date

_____ _____
Witness (someone other than parent/guardian) Date
[Witness signature is 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.

Other Protections for Human Subjects in Research

Certificates of Confidentiality

Researchers may protect the privacy of subjects against compulsory legal demands (e.g. court orders and subpoenas) that seek the names or other identifying characteristics of a research subject. Confidentiality Certificates are issued by the Department of Health and Human Services pursuant to Section 301(d) of the Public Health Services Act (42 U.S.C. Section §241(d)). Researchers may contact the IRB Chair for more information about Certificates of Confidentiality.

HIPAA Privacy Rule

The HIPAA Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI). The Privacy Rule does not apply to de-identified data. Researchers should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for many purposes, including research. Researchers must be prepared to provide the covered entity the supporting documentation and information required by the Privacy Rule as a condition for the covered entity's providing the requested PHI to the researcher.

It is important to understand that many research organizations that handle individually identifiable health information will not have to comply with the Privacy Rule because they will not be covered entities. The Privacy Rule will not directly regulate researchers who are engaged in research within organizations that are not covered entities even though they may gather, generate, access, and share personal health information. For instance, entities that sponsor health research or create and/or maintain health information databases may not themselves be covered entities; however, the Privacy Rule may affect their relationships with covered entities.

Covered entities are permitted to use or disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances.

Use/Disclosure with Authorization by Research Subject

The Privacy Rule specifies that a covered entity may neither use nor disclose PHI for research purposes unless the patient has provided, in advance, his or her written authorization for such use or disclosure. The Authorization must provide notice of a patient's right to revoke the Authorization. It may be combined with the informed consent document. Six essential elements apply to any Authorization:

- A description of the information to be used
- Who will use or disclose it
- To whom it will be disclosed
- The purpose for which it will be disclosed
- An expiration date which may be indicated as "end of study" or "none" for Authorization to place PHI in a research database
- A patient's dated signature

Use/Disclosure without Authorization by Research Subject

Short of a HIPAA Authorization, there are several ways PHI may be obtained for research: Covered entities may release PHI to a researcher with documentation that an IRB has granted a waiver or alteration of Authorization or covered entities may release a limited data set with a data use agreement. Covered

entities may release PHI to researchers without any of the above-listed documents for activities preparatory to research or for research on PHI of decedents if researchers agree to certain stipulations.

Alteration or Waiver of Authorization

For research uses and disclosures of PHI, an IRB or Privacy Board may approve an alteration or waiver of the Authorization requirement in whole (Waiver) or in part (Alteration). Partial waivers are likely to be sought to enable investigators to contact and recruit individuals as potential research subjects. To grant alteration or waiver, an IRB or Privacy Board must find that the research satisfies the following criteria:

- **Minimal risk to privacy.** There must be an adequate plan to protect patient identifiers, to destroy identifiers at the earliest opportunity (unless there is a health or research justification or it is required by law), and there is adequate written assurances against re-disclosure.
- **Practicality.** The research could not be practically conducted without the Waiver/Alteration.
- **Access.** The research could not be practically conducted without access to PHI.

Covered entities must receive documentation of the Waiver form before use or disclosure is permitted. This documentation must include the identity of the IRB or Privacy Board, the Wavier of approval date, and a brief description of the PHI involved, the review and approval procedures used (i.e. full or expedited review), and the signature of the Chair or other designated member of the reviewing board.

Data Use Agreement for Limited Data Set

The Privacy Rule permits the use and disclosure of a "limited data set" for research purposes as long as a data use agreement is in place that provides assurance that the recipient will not misuse the data. A limited data set is described at health information that excludes certain direct identifiers (16 listed) but that may include city, state, zip code, and other numbers and characteristics or codes not listed as direct identifiers. The recipient of a limited data set must agree to limit the use and disclosure of the data, agree not to re-disclose information, and not use the PHI to contact subjects. Neither an Authorization nor a Waiver is required to disclose information in a limited data set. Limited data sets would be used for situations where it would be unreasonable to try to obtain Authorization, such as registries for public health or epidemiological research.

Activities Preparatory to Research

Covered entities may use or disclose PHI to a researcher without an individual's Authorization, a Waiver, or a data use agreement for activities preparatory to research. However, the researcher must represent to the covered entity in written or oral form that (1) the PHI is requested solely to review PHI as necessary to prepare a research protocol, (2) the PHI will not be removed from the covered entity during the course of review and (3) the PHI sought is necessary for the research.

Research on Protected Health Information of Decedents

Likewise, covered entities may use or disclose PHI to a researcher without an Authorization, a Waiver, or a data use agreement for research on the PHI of decedents. However, the researcher must represent to the covered entity in written or oral form that (1) the use/disclosure is requested solely for research on the PHI of decedents, (2) the PHI sought is necessary for the research, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought.

Other Uses and Disclosures of Protected Health Information

PHI may be disclosed without Authorization, Waiver, or Data Use Agreement to the extent required by law, to public health authorities authorized by law to collect and receive information, in situations involving FDA-regulated products or activities, and to health oversight agencies.

IRB Forms List

IRB Submission Form (SF) with Instructions

Submit this form and accompanying documents to initiate IRB review

Course Certification Form

Instructor submits this form for each course incorporating course required student-conducted research that involves neither sensitive topic areas nor minor subjects. Any other studies conducted as part of courses requires IRB review.

HIPAA Privacy Rule Waiver Form

Submit this form if obtaining protected health information (PHI) from a covered entity as defined in HIPAA (Health Insurance Portability and Accountability Act)

Progress Report Form

Submit this form if research was previously approved in the expedited or full review category to request an extension of approval or to report that research has been completed

Protocol Modification Request Form

Submit this form to request a modification to a previously approved protocol

Adverse Event Report Form

Submit this form immediately upon occurrence of an adverse event or subject injury