



Policies and Procedures

Institutional Review Board Committee

Chair: Michael Magee, Ph.D.

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MISSION STATEMENT

The Institutional Review Board (IRB) exists to support the stated mission of the University, which affirms the dignity, freedom and inherent value of each person while seeking to provide a value-oriented education characterized by integrity and social responsibility. By providing institutional oversight for the ethical conduct of research with human participants, the IRB is designed to ensure such values are maintained, whether the research is for the edification of our students or for the advancement of general knowledge. The principles governing the structure and procedures of the IRB were drawn from several public sources, including the Code of Federal Regulations (Title 45, Part 46) adopted by the Office of Human Research Protections (OHRP) of the Department of Health and Human Services (HHS), the Belmont Report commissioned by the Department of Health Education and Welfare (HEW), the Protecting Human Beings report provided by the American Association of University Professors (AAUP), Ethical Principles of Psychologists endorsed by the American Psychological Association (APA), and the Codes of Ethics endorsed by the American Sociological Association (ASA) and the American Nurses Association (ANA).

The focus of the St. Joseph's University, New York IRB is limited solely to the ethics of research with human participants conducted: (1) by our faculty, administration, staff or students; (2) with students affiliated with St. Joseph's serving as participants; or (3) at St. Joseph's facilities. As we are committed to academic freedom, an IRB review will not consider the methodological soundness, educational value or political correctness of human participant research, unless these factors directly impact the ethical conduct of the research or violate any applicable laws.

Reviews conducted by the IRB will adhere to the following ethical principles reflected in the Belmont Report (1979) and embedded in most governmental and institutional review boards:

- **Respect for Persons:** In most cases, prospective research participants should be treated as autonomous agents who must be given adequate information so as to make informed decisions whether or not to voluntarily participate in the research. In cases where prospective participants have diminished autonomy due to cognitive, emotional or situational factors, additional measures should be employed to protect them from harm. The principles of informed consent and voluntary participation can be waived only under special circumstances which must be specified by the IRB.
- **Beneficence:** Research should strive to maximize benefits for research participants and/or the general public while minimizing potential physical or psychological harm to them. Research that puts participants at more than minimal risk for harm must be fully justified in terms of expected benefits as well as specific procedures to minimize their risk as much as possible and to treat any harm that may result.
- **Justice:** Classes of potential research participants should not be systematically selected for their easy availability, compromised position or expected manipulability, rather than for reasons directly related to the problems being studied. Once obtained, participants must be treated fairly and honestly, free of prejudice based on gender, age, race, religion, sexual orientation or any other protected class status. The research findings should be made available to interested participants except in cases when such findings are expected to be more harmful than beneficial.

The specific applications of these general principles are delineated in the IRB procedures for Exempt, Expedited and Full Review.

IRB BOARD STRUCTURE

The IRB has a two-tiered structure composed of (A) Department Representatives and (B) the Executive Committee.

A) DEPARTMENT REPRESENTATIVES

Department representatives are responsible for the initial review of all research proposals submitted to the IRB by St. Joseph's faculty, administration, staff or students. Each academic department in which research with human participants is deemed likely must provide at least two faculty members, with at least one from each campus, to serve as representatives to the IRB. Departments anticipating a high volume of reviewable research may elect to provide more than two representatives.

- 1) Each department can establish its own procedures for determining who will serve as its representatives.
- 2) **Departmental Registration** – By May 1 of each academic year, department chairs must provide the IRB chair with the names and academic credentials for any new or renewed representatives for their departments by submitting an Assigned Department Representative Form for each. Terms of service for new and renewed representatives will begin Sept. 1 of the next academic year.
- 3) **Term of Service** – Representatives serve three-year renewable terms ending on Aug. 31 of their final service year.
- 4) **Resignation and Replacement of Representatives** – Department representatives may resign without penalty before the end of a term two weeks after submitting letters of resignation to their respective chair and the IRB chair. If their resignation reduces department representation below the minimum of two members, the department chair must submit a replacement to the IRB chair as soon as possible. The replacement will complete the term of the resigning representative. Beyond this special circumstance, replacement with a new representative is at the discretion of the department chair.
- 5) **Representative Training** – Prior to reviewing any submitted research proposals, department representatives must satisfy each of the following requirements:
 - a) Read the policies and the procedures of the St. Joseph's IRB in the St. Joseph's IRB manual.
 - b) Read the Belmont Report [HEW] and Code of Federal Regulations (Title 45, Part 46) [HHS], provided through links at the Training Site for IRB Members and Faculty.
 - c) Complete the Protecting Human Research Participants (PHRP) online training program (<https://phrptraining.com/>). There are two (2) versions of the training: those engaged in social, behavioral, and educational research (most St. Joseph's researchers) should choose the PHRP SBE version; those who engage biomedical research should choose the PHRP course.
 - d) Submit to the IRB Chair the PHRP certificate of completion, a signed Ethics Assurance form (for faculty teaching research courses), and a signed Training Declaration indicating they have read and understood these materials.

6) **Conflicts of Interest** - Department representatives must recuse themselves from the review process of any research proposals in which they have interest as investigators, consultants or faculty supervisors; or of any research proposals for which they cannot provide unbiased and impersonal reviews. In such cases, review applications must be transferred to non-conflicted representatives.

B) THE EXECUTIVE COMMITTEE

The Executive Committee is responsible for -

- (1) reviewing research proposals from St. Joseph's faculty, administrators, staff or students that have been submitted for full review by the principal investigator or forwarded for full review by a department representative (all members of the IRB executive committee, including the community representatives, participate in all full reviews, regardless of campus of origin);
- (2) keeping abreast of changes in ethical standards for human participant research;
- (3) informing and educating the University community about ethical standards;
- (4) reporting serious violations of IRB regulations to the University administration for possible disciplinary action;
- (5) supervising the effectiveness of the department representatives; and
- (6) maintaining written and/or electronic records of all IRB activities, including membership documents, meeting minutes, submitted proposals, review decisions, investigator appeals and adverse incident reports.

The Executive Committee includes the following seven members:

- (1) University provost (ex officio).
- (2) Two community-based representatives unaffiliated with the University (one in Brooklyn and one on Long Island) who are solicited by the administration for three-year renewable terms. Both representatives participate in all full reviews of proposals (see Notes 1 and 2 below).
- (3) Four faculty: one from Brooklyn Liberal Arts, one from Long Island Liberal Arts, one from Professional and Graduate Studies and one at-large. Each faculty member is appointed by the Provost for a 3-year renewable term (see Note 2 below). The terms of two members are staggered to maintain consistency.

The IRB Chair is appointed by the Provost and will assume the position no later than Sept. 10 of each academic year. The Chair is responsible for calling all meetings of the Executive Committee, setting the agenda, and ensuring compliance with all IRB regulations and procedures.

Note 1 - The community representatives must complete the same training program as the faculty representatives (see section A, part 5) and submit appropriate documentation (Training Declarations and Certificates of Completion) prior to reviewing any submitted research proposals.

Note 2 – All members of the Executive Committee are subject to the same regulations for managing conflicts of interest specified for department representatives (see section A, part 6).

LEVELS AND PROCEDURES OF REVIEW

The Code of Federal Regulations (Title 45, Part 46.102, Section L) defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” As is common practice among college-and university-based IRBs, however, the St. Joseph’s IRB also extends some level of ethical oversight to class-based student research projects not designed to contribute to generalizable knowledge (see section A, point 2 below). In compliance with Title 45, Part 46.102, Section E of the Federal Regulations, a human participant is defined as:

Human subject means a living individual about whom an investigator (whether a professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable private information involves behavior displayed or information provided in a context the participant could reasonably expect would not be made public, but which the investigator can readily link to the individual.

LEVELS OF REVIEW

A) EXEMPT FROM REVIEW AND IRB APPROVED EXEMPTIONS

The following are exempt from IRB review. For cases (1) through (3) below, exempt status is automatic and investigators do not need to seek IRB approval. However, for cases (4) through (7), the investigator must submit an Application for Exempt Status to the IRB Chair for determination.

The research is eligible for automatic exemption if –

- (1) it does not involve human participants;
- (2) it is a faculty-supervised, class-based project designed solely to enhance the educational experience of the students (see Note 1 below) and all of the following criteria are met:
 - a) Project findings will not be shared with the research participants unless they also are members of the class in which the project originated.
 - b) Project findings will not be presented in any public forum outside the class in which the project originated.
 - c) The procedures and materials in the project put research participants at no more than minimal risk for physical or psychological harm ordinarily encountered in daily life.
 - d) The project does not involve the collection of sensitive aspects of participants’ behavior, such as substance use, illegal conduct or sexual behavior that can be linked through identifiers to any specific participants.

e) Prior to the collection of data, the class instructor has submitted to the IRB Chair their PHRP certificate of completion, and a Training Declaration attesting to their completion of the SJNY IRB training requirements for department representatives (see Note 1 below).

f) Prior to the collection of data, the class instructor also has submitted to the IRB an Ethics Assurance Form indicating he/she will instruct the students in the principles of ethical research and insure their projects conform to these principles (see Note 2 below).

(3) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

The research is eligible for **IRB approved exemption** if –

(4) The data are de-identified human subjects data.

(5) The principal investigator is a member of the St. Joseph's faculty, administration or staff; no St. Joseph's students, faculty, administration or staff are employed as research participants; no St. Joseph's facilities are utilized for the research protocol; and it has been approved by an external IRB acceptable to the Executive Committee of the St. Joseph's IRB. The investigator must submit appropriate documentation of the external approval to the Executive Committee prior to data collection.

(6) The research is conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Code of Federal Regulations, § 46.104, Section d-1)

(7) the research only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. (Code of Federal Regulations, § 46.104, Section d-2)

Note 1 – Faculty-supervised, class-based projects that fail to meet all the above criteria must be submitted for IRB review. Applications for Exempt Status or Full IRB Review must be submitted to the IRB chair. Applications for Expedited IRB Review may be submitted to any IRB department representative.

Note 2 – Training Declarations and Ethics Assurance Forms for class instructors are held to be in effect for a period of three years from their dates of submission. Both can be renewed for additional three-year terms through resubmission.

Application Dispositions

Within 7 - 10 days of receiving an Application for Exempt Status, the IRB Chair must notify the principal investigator by email of its disposition. The following three dispositions are possible:

- 1) **Disposed as Exempt** – The project meets the criteria for exempt status and can proceed as described.
- 2) **Approved Pending Revision** – The project fails to meet the criteria for exempt status but with revision can be approved. The IRB Chair must specify the changes required. If the investigator makes the required changes and submits an amended Application for Exempt Status, the amended project can proceed as described.
- 3) **Denied** – The project fails to meet the criteria for exempt status, and cannot be readily revised. The IRB Chair must specify the reasons for denial and recommend either an expedited or a full review. The investigator then can seek an expedited or full review of the project by submitting an appropriate application.

B) EXPEDITED REVIEW

Research that does not meet the criteria for exempt status may be eligible for expedited review and approval by a department representative if it meets all the following criteria. The investigator must submit an Application for Expedited IRB Review to their department representative. In cases for which the appropriate department representative is unclear, the investigator should contact the IRB Chair for guidance.

The research is eligible for expedited review if –

- (1) it does not intentionally include members of at-risk populations, such as children under 18 years of age (except as described for exempt educational research in section A, part 6), cognitively or emotionally compromised adults, pregnant women, fetuses or prisoners as participants (see Special Regulations for At-Risk Populations);
- (2) it does not involve the collection of sensitive data on substance use, illegal conduct or sexual behavior that can be linked through identifiers to specific participants and which, if known by others, could reasonably place participants at risk for criminal or civil liability, or damage their financial standing, employability or reputation;
- (3) it employs procedures and materials that put participants at no more than minimal risk for physical or psychological harm ordinarily encountered in daily life;
- (4) it does not involve deception by commission in which participants are deliberately misled by the investigator as to the purposes or procedures of the study;

(5) any use of deception by omission, in which the investigator fails to disclose all relevant details of the study's purposes or procedures, is scientifically justified and debriefing procedures are detailed and appropriate; and

(6) it does not involve audiotaping, videotaping or photographing of participants.

Application Dispositions

Normally, within seven days of receiving an Application for Expedited Review, the department representative must notify the principal investigator by email of its disposition. The following three dispositions are possible:

1) **Approved** – The research protocol meets all criteria for expedited review and meets the ethical standards for research with human participants. Expedited applications approved by a department representative are deemed approved by the IRB. The investigator may proceed with data collection. Unless the St. Joseph's IRB determines otherwise, continuing review of expedited research is not required.

2) **Approved Pending Revision** – The research protocol fails to meet the criteria for expedited review and/or fails to meet the ethical standards of research with human participants. However, with revisions, the protocol can be approved. The representative must specify the changes required for approval. If the investigator makes the required changes and submits an amended Application for IRB Review, they can proceed with the amended protocol upon approval from the representative. If the investigator rejects the required changes, they can request the representative to forward the application to the Executive Committee for a full review and attach a written justification for its approval as submitted. The investigator also must complete section 4 of the Application for Full IRB Review.

3) **Deemed in Need of Full Review** – The research protocol fails to meet the criteria for expedited review and the department representative determines a full IRB review is warranted. The investigator must complete and submit an Application for Full IRB Review.

C) FULL REVIEW

There are three avenues by which an IRB Application must proceed to the Executive Committee for a full review:

(1) The principal investigator is unaffiliated with St. Joseph's.

(2) A St. Joseph's-affiliated principal investigator deems their research does not meet the criteria for exempt status or for expedited review.

(3) A St. Joseph's-affiliated principal investigator submits their application for expedited review, but the department representative determines it fails to meet the relevant criteria and must be forwarded for full review. In such cases, it is incumbent on the investigator to then complete section 4 of the application and attach a detailed description of the research protocol as specified in the application material before it is forwarded. The department representative, at their discretion, may also forward their recommendation with justifications to approve, approve pending revision or deny the investigator's application.

In all the above cases, the investigator must submit an Application for Full IRB Review and all supporting documents to the IRB Chair. Applications for full review are reviewed as soon as possible on a rolling basis. To render a decision, a quorum of four Committee members, including the community representative(s), must be present at the full review meeting and be sufficiently informed about the application. In addition, the Committee reserves the right to solicit input from individuals having specialized knowledge when reviewing proposed research for which its members lack sufficient expertise. If the committee cannot achieve a consensus decision, the majority opinion determined by ballot prevails. If no majority emerges, the more ethically conservative opinion prevails.

Application Dispositions

After the IRB committee has made their decision regarding a full review proposal, the IRB Chair will notify the principal investigator by email of the application's disposition, including, when applicable, the committee's reasons for requiring revision of, or denying, the application. The following three dispositions are possible:

- 1) **Approved** – The research protocol meets all ethical standards for research with human participants. The investigator may proceed with data collection. Please note that an IRB Full Review approval is *limited to a term of one year*. Any project extending beyond that term must submit to the IRB Chair an Application for Continuation, indicating there have been no material changes in the research protocol.

- 2) **Approved Pending Revision** – The research protocol fails to meet all ethical standards for research with human participants. However, with revisions, the protocol can be approved. The committee must specify the changes required for approval. If the investigator makes the required changes and submits an amended Application for IRB Review, they can proceed with the amended protocol upon approval from the Executive Committee. If the investigator rejects the required changes, they can appeal the IRB decision (see link for Appealing Adverse IRB Dispositions).

- 3) **Denied** – The research protocol fails to meet all ethical standards for research with human participants and cannot be easily revised to attain those standards. The committee must specify the reasons for denial and stress the proposed research cannot proceed. A principal investigator may appeal the decision by writing a letter to the IRB requesting reconsideration. At the discretion of the IRB Chair, the investigator may make such an appeal in person and/or in writing to the IRB.

INFORMED CONSENT PROVISIONS

- (1) Informed consent is required for all human participants.

- (2) Informed consent forms must be sufficiently detailed to enable a prospective participant to make well-reasoned judgments about the nature of the research and the potential risks and benefits of participation (sample informed consent forms are available on the St. Joseph's IRB website). To this end, all informed consent forms must include the following elements:
 - a) a statement indicating the purposes of the research, its expected duration and the procedures to which the participant will be exposed;

 - b) contact information pertaining to the principal investigator and faculty supervisor;

 - c) a description of reasonably foreseeable risks or discomforts to the participant;

- d) a description of any expected benefits to the participant or to others;
- e) a statement indicating the degree of confidentiality afforded the participant's data;
- f) a statement noting participation is voluntary and that the participant may refuse or withdraw from participation, for any reason or no reason, at any time without penalty;
- g) for research involving more than minimal risk, an explanation of the medical and/or psychological services that will be provided, or are available; and
- h) an indication that the research has been approved by the St. Joseph's IRB, as well as contact information pertaining to the IRB Chair — should the participant have ethical questions or wish to submit a claim to the IRB Executive Committee for a perceived violation of their rights and/or a research-related injury.

(3) When informed consent is in written format (in-person research), participants (or their legal representatives when appropriate) must sign and date two copies of the consent form, retaining one copy for themselves and returning one copy to the investigator. As with any identifying data that is collected, the principal investigator must store the collected consent forms in a secure location for a period of at least three years after the conclusion of the research. For research in which the principal investigator is a student, their faculty supervisor must retain and store the collected forms under the same conditions. At any time during the three-year storage period, in response to a request from the IRB Chair, the investigator or faculty supervisor must produce the collected forms for examination by the St. Joseph's IRB Executive Committee. At the conclusion of the storage period, all consent forms must be destroyed in a manner that protects the identities of the research participants.

(4) When informed consent is obtained online, participants who indicate consent (e.g., via choices, radio buttons, or text responses) and click to continue will be considered to have given their consent to participate. However, online researchers must observe the following conventions:

- (a) The informed consent form must be isolated from the rest of the survey so that none of the survey is revealed to the participant until after they provide consent.
- (b) The participant must be given a choice to participate (gives consent) or not participate (does not give consent) and, if they do not give consent, the survey must be designed to terminate immediately. The participant must not be allowed to continue if they do not provide consent.
- (c) None of the items in the survey can be "forced-choice," as the participant has the right to refuse to respond to any item.
- (d) A working link to the completed survey must be included in the IRB application so that above points may be reviewed before approval can be given.

While the previously cited elements are sufficient for most written consent forms, the IRB reserves the right to require additional elements when it deems they are needed to protect the rights of prospective participants in a specific research protocol.

PROCESS FOR APPEALING ADVERSE IRB DISPOSITIONS

The intent of the appeal process is to provide an avenue for a principal investigator to seek reconsideration of an adverse IRB disposition. If the investigator believes a disposition by the IRB Executive Committee to approve pending revision or to deny approval of the application has resulted from a misapplication of IRB regulations, a misunderstanding of the proposed research protocol or other reasons, the investigator may appeal the disposition by writing an email to the IRB Chair requesting reconsideration. The investigator must provide detailed justification for approval of the research protocol as submitted and attach any documents deemed supportive of the presented justification.

The Executive Committee will review all submitted appeals. At the IRB Chair's discretion, the principal investigator may be invited to a meeting to provide additional clarification. Furthermore, when issues raised in an appeal are deemed by the committee members to be beyond their areas of expertise, the IRB Chair may solicit external input from individuals with specialized knowledge relevant to such issues. In either case, however, neither the investigator nor the external expert may be present for the committee's final deliberations on the appeal.

The IRB Chair will notify the principal investigator by email of the appeal's disposition, including, when applicable, the committee's reasons for denying the appeal. Denial of an appeal by the Executive Committee is final.

RESOLVING NON-COMPLIANCE ISSUES

The Executive Committee of the IRB maintains the right to monitor regulatory compliance by investigators, department representatives and faculty supervisors. When evidence or allegations of non-compliance are presented, the committee must investigate their veracity and may solicit relevant documents, written statements and/or personal interviews in support of the investigation.

If the committee determines non-compliance has occurred or is ongoing, it first will seek to resolve the issue in a manner that will restore compliance with IRB regulations. A report detailing the nature of the non-compliance, the individual involved and the nature of the resolution must be filed in the IRB records. If restoration attempts do not produce an ethical outcome acceptable to the committee, it may proceed to one of the following actions if approved by majority vote of the committee members.

- 1) **For an Investigator** – Approval is rescinded immediately for any of their research projects currently operating under IRB approval, and consideration of any new applications for IRB review is suspended for a term to be determined by the Executive Committee (normally six months). After the suspension, any new applications for review of research from this investigator must be participant to full review and will be evaluated in light of the investigator's previous non-compliance. In addition, reports detailing the nature of the non-compliance, the individual involved and the failed restoration attempts must be filed in the IRB records and forwarded to the Office of the Provost for appropriate action.

- 2) **For a Department Representative** – A department representative to the IRB who intentionally or repeatedly misapplies IRB regulations in their review of research applications is suspended from the IRB immediately and for a period of one year. Reports detailing the nature of the non-compliance, the individual involved and the failed restoration attempts must be filed in the IRB

records and forwarded to the Office of the Provost for appropriate action. After the suspension and with the approval of their department chair, the individual may apply to the committee for consideration of reinstatement.

3) **For a Faculty Supervisor** – A faculty supervisor who intentionally or repeatedly misapplies IRB regulations in their supervision of class-based research projects is suspended from such supervision immediately and for a period of one year. Reports detailing the nature of the non-compliance, the individual involved and the failed restoration attempts must be filed in the IRB records and forwarded to the Office of the Provost for appropriate action. After the ban and with the approval of their department chair, the individual may apply to the committee for consideration of reinstatement.

STORAGE AND DISPOSAL OF RESEARCH DATA

The following regulations apply to any research approved by the IRB through expedited or full review. Furthermore, research automatically exempt from review or that received an IRB approved exemption, while not constrained by the following storage and disposal regulations, are encouraged to adhere to relevant regulations that protect the confidentiality of research participants.

Each investigator should be cognizant of the fact that any guarantees made to research participants during the consent process (e.g., limited access to the data, anonymity, confidentiality, etc.) remain in force after the study concludes and throughout the data storage process. It is the investigator's responsibility to ensure secure storage of the data that maintains these guarantees and to demonstrate to the satisfaction of the IRB that these guarantees are being met throughout the conduct of the study and the data storage period.

A) STORAGE OF NON-SENSITIVE DATA

Data is non-sensitive when it has been obtained anonymously from participants such that no identifiers can link any data to individual participants (see Note 1 below). In this case, data storage need only be secure to the extent it can be retrieved easily by the principal investigator in response to a request for ethical review by the IRB Executive Committee. If stored electronically, the data file must be backed up on an independent storage device.

B) STORAGE OF SENSITIVE DATA

Data is sensitive when it contains identifiers that can link any data to individual participants (see Note 1 below). In this case, the investigator has a special obligation to maintain more secure data storage that protects the confidentiality of research participants. When the principal investigator is not a student, sensitive data may be stored on campus or off campus as regulated below. When the principal investigator is a student, however, sensitive data must be stored on campus by their faculty supervisor as regulated below.

- On campus – Hard copies of the data must be stored in a locked cabinet in a locked room. Data must be “de-identified” and the identifiers stored in a separate location. If stored electronically as well, data must be stored on a password-protected hard drive.
- Off campus – Hard copies of the data must be stored in a locked location, under the personal control and supervision of the investigator or to which only the investigator has access. Data must be “de-identified” and the identifiers stored in a separate location. If stored electronically as well, the data must be stored on a password-protected and encrypted device.

C) STORAGE DURATION

Both non-sensitive and sensitive data must be stored for a minimum of three years after the conclusion of the study. Principal investigators and faculty supervisors of student research may extend the storage duration beyond the minimum for reasonable cause. However, research data in either hard copy or electronic form should not be maintained in perpetuity. The sensitivity of the data and the reasons for maintaining the data should be the primary factors determining the length of retention beyond the minimum.

D) DISPOSAL OF DATA

Following the storage period, both non-sensitive and sensitive data must be destroyed in a manner that protects the confidentiality of the research participants. Hard copies of the data should be shredded and electronic data files should be deleted from all storage devices, including any recycling bins.

Note 1 - Obtained data is deemed sensitive if any of the following identifiers is linked to the responses of individual participants. Beyond the information noted below, it is the responsibility of the principal investigator to determine if other solicited information (such as sex or ethnicity) may function as participant identifiers in special circumstances, warranting classification of his/her data as sensitive:

1. Names.
2. Postal address information, other than town or city, state and ZIP.
3. Telephone numbers.
4. Fax numbers.
5. Email addresses.
6. Social Security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers.
11. Vehicle identifiers, serial numbers and license plate numbers.
12. Device identifiers and serial numbers.
13. Web universal resource locators (URLs).
14. Internet protocol (IP) address numbers.
15. Biometric identifiers, including fingerprints and voiceprints.
16. Full-face, oblique or full-profile photos and any comparable images.
17. Any other unique identifying numbers, characteristics or codes.
18. University ID numbers or login information.

SPECIAL REGULATIONS FOR AT-RISK POPULATIONS

Populations are categorized as at-risk if their members typically have diminished autonomy due to cognitive, emotional, health or situational constraints that may impair their ability to provide informed consent. At-risk populations include, but may not be limited to:

- Children under 18 years of age.
- Cognitively or emotionally compromised adults.
- Pregnant women and fetuses.
- Prisoners.

Any research intentionally including members of these populations as participants must be submitted to the IRB Executive Committee for full review and must comply with the special regulations applicable to the relevant intended population. In addition to these identified populations, the IRB retains the right to extend the at-risk designation to other populations as it deems necessary. The special regulations enumerated below are derived from the Code of Federal Regulations (OHRP), Title 45, Part 46, Subparts B, C and D.

A) CHILDREN UNDER 18 YEARS OF AGE

These special regulations apply to all research involving children as participants, except in the case of educational research that satisfies the criteria for Exempt Status as specified in Section A, Part 6 of Levels and Procedures of Review. The following definitions apply in this section –

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Permission means the agreement of a parent(s) or guardian(s) to the participation of his/her child or ward in research. **Parent** means a child's biological or adoptive parent. **Guardian** means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

(1) Children may be involved in research if any of the following conditions are met:

a) The research involves no more than minimal risk to children, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in Parts 2 and 3 below.

b) The research involves greater than minimal risk to children but presents the prospect of direct benefit to the individual participants and the following conditions are met:

(i) the risk is justified by the anticipated benefit to the participants;

(ii) the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and

(iii) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in Parts 2 and 3 below.

c) The research involves greater than minimal risk and no prospect of direct benefit to individual participants, but it is likely to yield generalizable knowledge about the participants' disorder or condition and –

(i) the risk represents a minor increase over minimal risk;

(ii) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

(iii) the intervention or procedure is likely to yield generalizable knowledge about the participants'

disorder or condition, which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and

(iv) adequate provisions are made for soliciting assent of the children and the permission of their parents or guardians, as set forth in Parts 2 and 3 below.

(2) Requirements for permission by parents or guardians and for assent by children:

a) The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

b) The IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardians. Normally, when permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

c) If the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the consent requirements of this section, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol; the risk and anticipated benefit to the research participants; and their age, maturity, status and condition.

d) Permission by parents or guardians shall be documented by the use of a written consent form approved by the IRB and signed by the participants' legally authorized representative(s). A copy shall be given to the person signing the form.

e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

(3) Requirements for wards:

a) Children who are wards of the state or any other agency, institution or entity can be included in research only if such research is –

(i) related to their status as wards; or

(ii) conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as participants are not wards.

b) If the research satisfies the criteria in Part A, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research, and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s) or the guardian organization.

B) COGNITIVELY OR EMOTIONALLY COMPROMISED ADULTS

Compromising conditions affect cognitive and/or emotional functions to the extent that capacity for judgment and reasoning are significantly diminished. A person may be cognitively or emotionally compromised due to any of the following:

- Psychiatric disorder (e.g., psychosis, neurosis, personality or behavioral disorder).
- Organic impairment (e.g., dementia or Alzheimer's disease).
- Developmental disorder (e.g., intellectual disability or autism).
- Severe acute or chronic physical illness (e.g., coma or AIDS).
- Drug intoxication.

(1) Compromised adults may be involved in research if any of the following conditions are met:

a) The research involves no more than minimal risk and adequate provisions are made for soliciting their assent when possible and the permission of their legal guardians, as set forth in Part 2 below.

b) The research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants and –

(i) the risk is justified by the anticipated benefit to the participants;

(ii) the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and

(iii) adequate provisions are made for soliciting their assent when possible and the permission of their legal guardians, as set forth in Part 2 below.

c) The research involves greater than minimal risk and no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participants' disorder or condition and –

(i) the risk represents a minor increase over minimal risk;

(ii) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

(iii) the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition, which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and

(iv) adequate provisions are made for soliciting their assent when possible and the permission of their legal guardians, as set forth in Part 2 below.

(2) Requirements for permission by legal guardians and for assent by participants:

a) The IRB shall determine that adequate provisions are made for soliciting assent when, in the judgment of the IRB, the participants are incapable of providing assent. In determining whether participants are capable of assenting, the IRB shall take into account their physical and psychological states. This judgment may be made for all participants to be involved in research under a particular protocol, or for each individual, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research, the assent of the participants is not a necessary condition for proceeding with the research.

b) The IRB shall determine that adequate provisions are made for soliciting the permission of each participant's legal guardian.

c) If the IRB determines that a research protocol is designed for conditions or for a participant population for which guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused individuals), it may waive the consent requirements of this section, provided an appropriate mechanism for protecting the participants is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their physical and psychological condition.

d) Permission by legal guardians shall be documented by the use of a written consent form approved by the IRB and signed by the participants' legally authorized representative(s). A copy shall be given to the person signing the form.

e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

C) PREGNANT WOMEN AND FETUSES

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women) have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

(2) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

(3) Any risk is the least possible for achieving the objectives of the research.

(4) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with informed consent provisions.

(5) If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with informed consent provisions. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity, or if the pregnancy resulted from rape or incest.

(6) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

(7) For children who are pregnant, assent and permission are obtained in accord with the special regulations of Section A – Children Under 18 Years of Age.

(8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(9) Individuals engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy.

(10) Individuals engaged in the research will have no part in determining the viability of a neonate.

D) PRISONERS

Inasmuch as prisoners may be under constraints because of their incarceration, which could affect their ability to make truly voluntary and non-coerced decisions whether or not to participate as participants in research, it is the purpose of this section to provide additional safeguards for the protection of prisoners involved in research. Prisoner is defined as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution; and individuals detained pending arraignment, trial or sentencing.

(1) An IRB reviewing prisoner-based research must meet the following specific requirements:

a) A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved.

b) At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one need satisfy this requirement.

(2) A duly composed IRB may approve prisoner-based research only if it finds that:

a) It represents one of the following categories of permissible research –

- (i) study of the possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- (ii) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- (iii) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults), provided that the study may proceed only after the IRB has consulted with appropriate experts including experts in penology, medicine and ethics, and published notice in the FEDERAL REGISTER of his intent to approve such research; or
- (iv) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may proceed only after the IRB has consulted with appropriate experts, including experts in penology, medicine and ethics, and published notice in the FEDERAL REGISTER of the intent to approve such research.

- b) Any possible advantages accruing to the prisoner through their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
- c) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- d) Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- e) The information is presented in language that is understandable to the participant population.
- f) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole.
- g) Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

REPORTING ADVERSE INCIDENTS

Adverse incidents broadly encompass both physical and psychological harms to a participant observed by an investigator or reported by the participant. They include any abnormal signs, symptoms or reactions temporally associated with the participant's participation in the research, whether or not they are considered related to that participation. The principal investigator must submit an Adverse Incident Report to the IRB Chair within 24 hours of becoming aware of the adverse incident. Concurrently, data collection must be suspended until the IRB Executive Committee has reviewed the incident and determined an appropriate response.

Upon receipt of the report, the IRB chair will inform the Executive Committee of the adverse incident. After collecting any additional information deemed necessary to render an informed decision, the Committee will notify the investigator as quickly as possible what protocol revisions, if any, are necessary in order to resume data collection.

RESOURCES

OFFICE FOR HUMAN RESEARCH PROTECTIONS

[hhs.gov/ohrp/](https://www.hhs.gov/ohrp/)

AMERICAN ANTHROPOLOGICAL ASSOCIATION

[aaanet.org/issues/policy-advocacy/code-of-ethics.cfm](https://www.aaanet.org/issues/policy-advocacy/code-of-ethics.cfm)

AMERICAN ASSOCIATION FOR PUBLIC OPINION RESEARCH

[aapor.org/Standards-Ethics/AAPOR-Code-of-Ethics.aspx](https://www.aapor.org/Standards-Ethics/AAPOR-Code-of-Ethics.aspx)

ACADEMY OF CRIMINAL JUSTICE SCIENCES

[acjs.org](https://www.acjs.org)

AMERICAN EDUCATIONAL RESEARCH ASSOCIATION CODE OF ETHICS

[aera.net/AboutAERA/AERARulesPolicies/CodeofEthics/tabid/10200/Default.aspx](https://www.aera.net/AboutAERA/AERARulesPolicies/CodeofEthics/tabid/10200/Default.aspx)

[aera.net/Portals/38/docs/About_AERA/CodeOfEthics\(1\).pdf](https://www.aera.net/Portals/38/docs/About_AERA/CodeOfEthics(1).pdf)

ASSOCIATION OF INTERNET RESEARCHERS

[aoir.org/ethics/](https://www.aoir.org/ethics/)

ASSOCIATION FOR INSTITUTIONAL RESEARCH

[airweb.org/Membership/Pages/CodeOfEthics.aspx](https://www.airweb.org/Membership/Pages/CodeOfEthics.aspx)

AMERICAN NURSES ASSOCIATION CODE OF ETHICS

[nursingworld.org/codeofethics](https://www.nursingworld.org/codeofethics)

AMERICAN POLITICAL SCIENCE ASSOCIATION

[apsanet.org/TEACHING/Ethics](https://www.apsanet.org/TEACHING/Ethics)

AMERICAN PSYCHOLOGICAL ASSOCIATION CODE OF ETHICS

[apa.org/ethics/code/principles.pdf](https://www.apa.org/ethics/code/principles.pdf)

[apa.org/ethics/](https://www.apa.org/ethics/)

AMERICAN SOCIOLOGICAL CODE OF ETHICS

[asanet.org/about/ethics.cfm](https://www.asanet.org/about/ethics.cfm)

BELMONT REPORT

[WWW.HHS.GOV/OHRP/REGULATIONS-AND-POLICY/BELMONT-REPORT/INDEX.HTML](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)

COMMON RULE (2018)

WWW.HHS.GOV/OHRP/REGULATIONS-AND-POLICY/REGULATIONS/45-CFR-46/REVISED-COMMON-RULE-REGULATORY-TEXT/INDEX.HTML

HHS ETHICAL CODES AND RESEARCH STANDARDS

WWW.HHS.GOV/OHRP/INTERNATIONAL/ETHICAL-CODES-AND-RESEARCH-STANDARDS/INDEX.HTML

MARKETING RESEARCH ASSOCIATION

marketingresearch.org/code

ORAL HISTORY ASSOCIATION

oralhistory.org/about/principles-and-practices/oral-history-evaluation-guidelines-revised-in-2000/

SOCIETY FOR RESEARCH IN CHILD DEVELOPMENT CODE OF ETHICS

srcd.org/about-us/ethical-standards-research

RESOURCES FOR ETHICS EDUCATION

THE NATIONAL CENTER FOR PROFESSIONAL AND RESEARCH ETHICS

nationalethicscenter.org/

CENTER FOR ETHICS EDUCATION

fordham.edu/info/24014/center_for_ethics_education

Includes case studies, measurement, IRB resources.

THE POYNTER CENTER FOR THE STUDY OF ETHICS AND AMERICAN INSTITUTIONS

provost.indiana.edu/poynter-center/index.html

Includes case studies, syllabi.