G U I D E L I N E S©

for the

FGCU Institutional Review Board (IRB)

Office of Research & Sponsored Programs
Florida Gulf Coast University
10501 FGCU Boulevard South
Fort Myers, FL 33965-6565

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Table of Contents

Preface

These guidelines encompass the procedures and operational guidelines of the Florida Gulf Coast University Institutional Review Board. The guidelines are a “living document” that will be reviewed and revised at regular intervals.

The procedures and guidelines were developed to reflect the requirements of and best practices in meeting the federal, state and local regulations relating to human subject research, and the high ethical standards of Florida Gulf Coast University in carrying out these standards. Written guidelines and procedures for the proper functioning of our Institutional Review Board are essential to provide a framework for a uniform decision making process. The goal of these procedures and guidelines is to assure that human subjects in all Florida Gulf Coast University research studies receive ethical treatment according to the principals of the Belmont Report, the federal regulations and the ethical standards of the university and its community of scholars.

It is recognized that situations will occur that are not explicitly covered in this document. In this circumstance, reference shall be made to existing guidelines and procedures, and decisions of the IRB and the university will be guided by federal regulations and the university's ethical standards for the protection of human subjects.

The IRB works in collaboration with the Office of Research & Sponsored Programs. The Office of Research & Sponsored Programs provides administrative support to the IRB and is located in Howard Hall, Suite 202. The Chair of the IRB is Dr. Cliff Renk. Questions pertaining to meetings and/or application forms should be directed to Sandy Terranova at (239) 590-7522 or through e-mail at sterrranova@fgcu.edu.

Please address all IRB-related correspondence to:

Institutional Review Board
Florida Gulf Coast University
Office of Research & Sponsored Programs
10501 FGCU Blvd. South
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Statement of Ethical Principles Guiding the FGCU's Conduct of Human Subjects Research

Florida Gulf Coast University (FGCU) is committed to excellence in research, teaching, scholarly/creative activity, and public service. The university takes pride in conducting these activities with the highest possible ethical standards.

In its conduct of human subjects research, the university is bound by the ethical principles established by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the, Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report, the ethical principles set forth in the Declaration of Helsinki, and those found in the Nuremburg Code. The university will follow the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations for all applicable Department of Health and Human Services (DHHS) funded research and, except for the requirements for reporting information to DHHS, for all other research activity regardless of the source of funding.

For purposes of these guidelines, research involving human subjects includes all activities relating to the conduct of a study… advertising for, recruiting and/or screening of potential participants; consenting participants, accessing or obtaining identifiable, private information from or about living individuals; and/or data analysis of identifiable, private information.

The following broad principles are the basis for development of FGCU'S guidelines concerning the review of research involving human subjects:

1. All activities involving humans as subjects must ensure respect for all human subjects and provide for the safety, health, privacy and welfare of every individual. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information to the extent permitted by law. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.

2. Participation in studies must be voluntary. Informed consent must be obtained from all subjects, unless this requirement is waived by the IRB.

3. The direct or potential benefits to the subject, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.

4. An individual does not abdicate any rights by consenting to be a research subject. 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.

5. Research subjects must be selected with consideration of the purpose and expected outcome of the research. The subjects should be similar to those who may benefit from the results of the research.

6. All vulnerable groups and individuals must receive specifically considered protection, including the giving of informed consent.

7. The study must be conducted by qualified individuals with the appropriate ethical training, scientific education, and qualifications. All students who serve as the Primary Investigator of a study must be supervised by a FGCU faculty member.

8. No distinctions in the approval and monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other university employees, on-campus or off-campus.

All funded or unfunded, sponsored or unsponsored activities, that constitute "human subjects research" conducted by FGCU faculty, staff or students on or off campus, *must be reviewed* and approved by the FGCU IRB *prior to initiation*. This includes human subject research activities that are conducted outside the aegis of the university for which students receive credit for course assignments.

Example: a student receives credit for advertising for or recruiting potential participants; consenting participants, accessing or obtaining identifiable, private information from or about living individuals; data analysis, etc. for a research study his/her instructor is conducting as an outside consultant. This study requires IRB approval prior to a student's participation.

Investigators holding university appointments are encouraged to obtain approval from a duly constituted IRB when conducting human subjects research outside of their employment with the university, especially if the study will be included in one's promotion portfolio.

Faculty, staff and/or students who conduct human subjects research without receiving approval from the IRB *prior* to conducting the research risk, among other things, one's eligibility to participate in FGCU's Research Day, one's eligibility to access participant pools, submit grants; apply for promotion; having a journal, conference, etc. refuse to publish the research.

Definitions

Adverse Event: An unintended, but not necessarily unexpected, result of an intervention that is unpleasant or dangerous.

Anonymized Information or Data: The identifiers, codes that are linked to identifiers and other values that would enable individuals to be identified by inference are removed.

Anonymous Data: Data collected without identifiers of any kind.

Anonymous: Subjects' identities are unknown to the investigator, not requested, and not given. Data are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

Assent: Agreement by individuals unable to give legal informed consent (e.g., children or cognitively impaired people) to participate in a study.

Benefit: An outcome to the study that will be an advantage to the subjects participating.

Coded data/Confidential Data: Data for which identifying information (such as the participant's name) has been replaced with a number, letter, symbol, or combination of coding mechanisms; a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Co-Investigator: An individual involved with the PI in the development and/or execution of a study. Co-PIs also are obligated to ensure the project is designed and conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of human subjects research. The Co-I must be qualified by training and experience to conduct his or her responsibilities on the research project.

Compensation: Remuneration for participation in the research study.

Confidentiality: The manner of treating private information, which has been disclosed by the individual subject of the information to a particular person or persons for a specific purpose, such that further disclosure of the information will not be allowed to occur without authorization.

Continuing Review: Protocols approved as Full Board or Expedited must undergo a review at intervals appropriate to the degree of risk, but not less than once per year until the completion or termination of the research.

Data: Information that is collected for analysis or used to reason or make a decision.

De-Identified: Data which has been stripped of all identifying information and there is no way (a data key, coding system, or other means) to link the data with an individual.

Enrollment: The number of participants who participate in the study or the number of individuals of whom biospecimens or data and/or private health information was collected.

Exempt Review: This IRB category of study involves very little, if any, associated risk and falls within narrowly defined categories. These studies are exempt from further IRB review upon IRB assignment of this category to the protocol.

Existing Data: Data that exist at the time the research is proposed. The data may include data sets, specimens, interview notes, audio- or video tapes. The data may have been originally collected or created for research or non-research purposes.

Expedited Review: This IRB category of study represents minimal risk and falls within one of the "expedited review categories" defined by DHHS. Expedited reviews occur outside of a regularly convened IRB Committee meeting and are conducted by the IRB Chair or designee.

Faculty Sponsor: An FGCU faculty member who project assumes all of the roles and responsibilities of a Principal Investigator when the student is listed as the PI.

Full Board Review: This IRB category of study involves more than minimal risk and/or vulnerable populations. Risks to research subjects must be justified by the anticipated benefits to the subjects or society.

Generalizable knowledge: Knowledge gained from an activity designed to draw general conclusions, inform policy, contribute to professional knowledge in a discipline, or generalize outcomes beyond the specific group, entity, or institution studied. Findings can be disseminated via presentations at scientific meetings (university, state, national, or international settings), submission for publication in a scientific journal, Internet postings, etc.

Guardian: An individual who is authorized under applicable state or local law to consent on behalf of another person (e.g., minors).

Health Insurance Portability and Accountability Act (HIPAA): A United States law that includes privacy and security standards for health information created, received, stored or transmitted by health plans, healthcare providers, or healthcare clearinghouses.

Human Subjects: Living individuals about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Identifiers: Identifiers include names, Social Security numbers, medical record numbers, UIN numbers and any code that permit data to be linked to individuals. Audio and video tapes recordings include identifiers, even if they are not labeled with codes/identifiers, unless the person’s image and voice are blacked out or blurred such that they cannot be identified.

Individually Identifiable Data: Data attached to a participant identifier (such as name, address and other contact information, social security number, identifiable photographic images, medical record number, etc.) such that the identity of the subject is or may readily be ascertained by the investigator or associated with the information by others.

Informed Consent: An ongoing process to assure participants understand the nature of the research and can knowledgeably and voluntarily choose to participate in the study. Informed

consent forms provide a clear appreciation and understanding of the facts, implications, and consequences of the study. The consent forms must minimize the possibility of coercion or undue influence to participate in the study. To give informed consent, an individual or the individual's legally authorized representative must be age 18 or older, possess adequate reasoning faculties and understand all aspects of the study.

Interaction: Includes communication or interpersonal contact between investigator (or his/her research staff) and participant (or the participant's identifiable private information).

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

IRB Approval: The written determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

Key Personnel: All members of the study, including students, involved in the consent process, recruiting, obtaining data, manipulating data, or supervision of these activities.

Minimal Risk: 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. [45 CFR 46.102(i)]

Oral History: A method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life.

Personal Identifiers: Data elements that singly or in combination can uniquely identify an individual, such as a social security number, name, address, demographic information (e.g., combining gender, race, job, and location), UINs, or other identifiers.

Personally Identifiable Health Information: Health or medical data, or data elements that singly or in combination can uniquely identify an individual, such as one’s past, present or future physical or mental health or condition; past, present, or future payment for the provision of health care; or other identifiers (e.g., name, address, birth date, Social Security Number, medical record number, etc.).

Principal Investigator: The individual with primary responsibility for the design and conduct of a research project.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) regardless if the information is obtained by the PI or a third party.

Protocol: A detailed research plan that describes in detail how the research will be conducted. It includes purpose of the research, the research question, why the study is

important, anticipated results, and all materials that will be used in the study (questionnaires, consent documents, recruitment materials, surveys, etc.).

Publicly Available: Public sources of data, such as telephone books, newspapers, magazines, and databases such as the U.S. Bureau of the Census and National Center for Health Statistics. Data obtained from data banks, archives, or organizations that make data sets broadly accessible at a reasonable cost to the research community are also considered publicly available.

Readily Identifiable: The identity of a participant could be ascertained by the investigator or associated with the data by others without requiring time or special effort.

Scientific Research: Conduct of a methodical study in order to prove a hypothesis or answer a specific question that contributes to the body of generalizable knowledge.

Waiver of Informed Consent: An option of the IRB if it determines and documents that the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Chapter 1: Defining Research with Human Subjects

1.1 Definition of Human Subjects Research

The determination if an activity is human subjects research is based on the answer to two questions.

a. Does the activity meet the definition of research as defined by DHHS 45 CFR 46.102 (d)
"*a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*. "

Guidance
A systematic investigation involves a plan to study a specific topic, answer a specific question, test a specific hypothesis, or develop a theory. It incorporates the collection of quantitative or qualitative data, or specimens, and analysis. Activities that *are typically considered* systematic investigations include:

- interviews and focus groups
- surveys and questionnaires
- analysis of data
- observational studies
- cognitive studies
- medical chart reviews
- test and survey/questionnaire development
- pilot studies and feasibility studies

Activities *not typically considered* systematic investigations include:

- activities not designed to develop or contribute to generalizable knowledge
- case studies
- in-house quality improvement

Generalizable knowledge is knowledge gained from an activity designed to draw general conclusions, inform policy, contribute to professional knowledge in a discipline, or generalize outcomes beyond the specific group, entity, or institution studied. Findings can be disseminated via presentations at scientific meetings (university, state, national, or international settings), submission for publication in a scientific journal, Internet postings, etc.

It is important to note that the focus is on the *intent* of the investigator to contribute to generalizable knowledge, not its actual dissemination.

Both a systematic approach and the intent of the investigation to develop or contribute to generalizable knowledge must be met to meet the first half of the definition of research.

The second question is:

b. Does the activity involve human subjects as defined by DHHS CFR 46.102 (f)
"a living individual about whom a research investigator (whether a professional or a student) obtains (1) data through intervention or interaction with the individual or (2) from individually identifiable information."

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

Guidance
Examples of identifiable, private information include names, addresses, phone numbers, social security numbers, medical record numbers, student or employee identification numbers, *or the combination of data such that they can identify a single individual through deductive reasoning*.

Information is not considered private identifiable information if it cannot be linked to a living individual, is considered publically available (readily available to the broad public) or is given with the expectation that it will be made public and that it will be linked to the individual (e.g. news story).

To meet the definition of research with human subjects, you must be conducting research AND obtain data through an intervention or interaction with an individual; or identifiable private information.

1.2 History of Human Subject Protection

Prior to World War II, medical research was performed with minimal concern about the protection of the individuals participating in the research. The modern system of human subject research protections began following the discovery of the atrocities committed by Nazi doctors in their concentration camps prior to and during World War II.

The modern principles of conducting human subject research were developed during the Nuremburg trials of Nazi war criminals. Known as the Nuremburg Code the code's three basic elements, voluntary informed consent, adequate risk/benefit analysis, and one's right to withdraw from the study without ramifications, serve as the foundation of the conduct of human subjects research.
In 1964, the World Medical Association released the Declaration of Helsinki. Built on the principles of the Nuremberg Code, the Declaration adapted the existing guidelines to address the growing field of clinical research and expanded the informed consent process.

The expansion of the rights of individuals involved in human subjects research continued in 1974 with the National Research Act**.** Created partly as a response to the infamous Tuskegee syphilis study, the Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged to develop guidelines for human subject research and oversee and regulate the use of human subjects in medicinal research. In 1979, the Commission issued the Belmont Report, the foundation of the current human subjects protections. The Report established three ethical principles for conducting human subjects research: respect for persons, beneficence, and justice.

The Office of Human Research Protections in the U.S. Department of Health & Human Services oversees Title 45, Part 46 of the Code for Federal Regulations, Protection of Human Subjects. That office oversees human-subjects research through local institutional review boards (IRB).

1.3 Authorities and Responsibilities

a. Authority of the IRB

The IRB derives its authority from both federal regulations (45 CFR 46) and the university. Institutional authority is conveyed by the Interim Associate Vice President of Research Administration through approval of these guidelines. The Interim Associate Vice President of Research Administration, or designee, acts as liaison with the University Administration.

The IRB has full authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. The Board's decision to require modifications of a protocol or not approve a protocol cannot be overturned by any university official or committee. The Board also holds the authority to conduct audits of research records randomly, for cause, and based on the compliance records of the investigators.

IRB approval must be obtained *before* a research project involving human subjects may begin.

The responsibilities of the IRB extend to all human subject research performed under the auspices of the faculty, staff or students of Florida Gulf Coast University, regardless of whether a study is funded by a sponsor, funded by university sources, or not funded. The responsibilities of the IRB include but are not limited to the following:

- Protecting the rights and welfare of human subjects participating in research projects conducted under the jurisdiction or sponsored by the university;
- Protecting the rights and welfare of human subjects participating in research projects for which students receive credit for course assignments;
- Assuring that risks to subjects are minimized and the risks are reasonable in relation to anticipated benefits, through sound research design (**§**46.111);
- Reviewing, approving, monitoring, requiring modification, or disapproving research activities involving the use of human subjects to ensure the protection of human subjects (§46.109);
- Approving modifications of previously approved research (§46.109(a));

- Conducting continuing reviews of all human subject research activities, at least annually, and more often if deemed necessary to protect participants ((§46.109(e)); and
- Taking any measures necessary to assure the safety of each and all human subject participants including the suspension or termination of its approval to conduct the research.

The Board is independent of but coordinates with other committees, as needed. The Board's determination whether to approve or disapprove a protocol is based upon the protection of the human subjects involved with the study.

In conducting its reviews, the IRB is guided by the principles of the Belmont Report, the ethical principles set forth in the Declaration of Helsinki, and those found in the Nuremburg Code, and all applicable federal and state regulations and laws, and the ethical standards of the university. If the IRB chair or an IRB member reviewing an initial or continuing study determines that additional expertise is required for the review, the chair or member has the authority to contact one or more experts within or outside of the university to request additional expertise. Review of the specific study requiring this consultative input shall be deferred until the expert advice is received and considered by the IRB.

b. FGCU's Office of Research & Sponsored Programs Responsibility to the IRB

The mission of the Office of Research & Sponsored Programs (ORSP) is to facilitate research among the faculty, staff, and students of FGCU. The office is committed to ensuring that the university's research is conducted according to the university's high ethical standards and in compliance with federal, state and local regulations.

The Associate Vice President for Research, or designee, acts as liaison with the university Administration. Specific responsibilities of ORSP to the IRB and the university include:

- Maintain up-to-date knowledge of guidelines, procedures and regulations regarding human subjects research and IRB operations.
- Perform administrative duties to assure systematic flow of work through the IRB.
- Maintain files on all active human subject research studies.
- Maintain the institution's Federalwide Assurance and the IRB membership rosters.
- Screen IRB applications for completeness prior to initiating the IRB review process.
- Compose written correspondence (technical review, approval, continuing review, study suspension or termination, etc.) from the IRB to the Principal Investigator.
- Prepare and maintaining permanent files of minutes of convened IRB meetings.
- Maintain the meeting schedule and creating agendas for each IRB meeting.

c. Responsibilities of the Principal Investigator

Principal investigators (PI) are responsible for protecting the rights and welfare of human subjects and conducting sound, ethical research consistent with research plans approved by the IRB. Along with meeting the specific requirements of a particular research study, their responsibilities include:

- Submitting one original copy of the IRB application with the appropriate attachments to ORSP;
- Ensuring the study is conducted following the ethical principles that protect the rights and welfare of human research subjects, complying with applicable FGCU guidelines relating to the conduct of human subject research, and complying with the determinations of the IRB;
- Providing oversight of the study team members;
- Obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB (§46.116; §46.117);
- Obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects (§46.103(b)(4));
- Ensuring that progress reports and requests for continuing review and approval are submitted timely to the IRB (§46.109(e));
- Reporting any unanticipated problems involving risks to subjects or others (§46.103(b)(5)) to the IRB *within 24 hours of its occurrence*;
- Providing prompt reports of serious or noncompliance with the regulations or the requirements of the IRB, to the IRB (§46.103(b)(5));
- Submitting a Final Report within 30 days following the completion of all human subject research activities, including recruitment and data collection/analysis to the IRB;
- Keeping all records, including copies of all signed informed consent forms, related to the study for at least three years after completion of the study in an on-campus location (§46.115(b)). Access to these documents should be limited to those authorized persons who have a need to know their contents, the investigator and co-investigators, a representative of the IRB, and the Associate Vice President for Research.

d. Responsibilities of Department Chairs and College Deans

Departmental Chairs and College Deans or their designees are required by the IRB to:

- Review all IRB applications and protocols submitted by faculty, staff, and students in their department;
- Assure the soundness of the research design and its scientific and scholarly merit;
- Assure the department has adequate staff and resources to conduct the study;
- Sign-off on the IRB application indicating departmental/college approval and forward the application to the IRB for review; and
- Inform the IRB of situations that may preclude a PI from continuing in his/her role as PI.

e. Responsibilities of Faculty Sponsors and Student Investigators

Student investigators and faculty sponsors must hold a current certificate of completion of the Collaborative Institutional Training Initiative (CITI) course for Social & Behavioral Research

Investigators, or the Biomedical and Social and Behavioral Investigators course, and, if appropriate, the certificate for Health Information Privacy & Security.

A faculty sponsor to a student project assumes all of the roles and responsibilities of a Principal Investigator when the student is listed as the PI. Responsibilities of a faculty sponsor may only be carried out by a member of the FGCU faculty.

A faculty sponsor must:

- Act as a co-investigator;
- Ensure the student investigator possesses the knowledge necessary to conduct the research in according to applicable federal, state and local laws, and FGCU guidelines;
- Review and approve the scientific integrity of the proposed research project and assess its scientific rigor and merit of the study;
- Assure the student investigator obtains IRB approval for the research study prior to its initiation and obtains IRB approval prior to the implementation of subsequent revisions;
- Oversee the reporting of any unanticipated problems to the IRB within 24 hours of its occurrence;
- Ensure a Request to Close Protocol form is submitted to the IRB upon completion of the research. In the event that the student investigator fails to do so, the faculty sponsor is responsible for submitting the form to the Board;
- Retain, on campus, the data, informed consent forms, surveys etc. For a minimum of three years following the completion of the study (§46.115(b)); and
- Ensure the student investigator complies with the additional responsibilities listed above as responsibilities of the principal investigator.

Under the guidance of the faculty sponsor, the student investigator is responsible for the following:

- Being familiar with and adhering to the relevant guidelines governing the ethical conduct of research with human subjects;
- The design of the study (with supervision of the faculty sponsor);
- Obtaining IRB approval prior to the initiation of research (including subject recruitment);
- Protecting the rights and welfare of study participants;
- Obtaining informed consent;
- Maintaining privacy and confidentiality of data of study participants;
- Conducting the study according to the IRB-approved protocol;
- The conduct of collaborators;
- Submitting the required continuing review (annual report) to the IRB;
- Consulting with the faculty sponsor when problems are encountered;

- Reporting unanticipated problems or adverse events involving risk to human subjects to the faculty sponsor and IRB *no later than 24 hours of its occurrence*;
- Maintaining, in the manner specified in the protocol, all signed consent documents and research data in the office of his/her faculty sponsor;
- Obtaining IRB approval prior to initiating changes in the protocol; and
- Completing the necessary paperwork to close the study when complete.

1.4 Conflict of Interest

Forthcoming

1.5 Institutional Review Board (IRB)

a. Membership and Structure

The University President appoints the individuals to the IRB on a staggered basis for a minimum of two years (including the Chair). Nominations may be submitted by Deans, Vice Presidents and the Associate Vice President for Research. The IRB is comprised of at least five members from varying backgrounds for the complete and adequate review of research activities commonly conducted at FGCU. A minimum of one member will be from a scientific area, one from a healthcare area, one whose primary concern is in a nonscientific area, and one who is not affiliated with the university or is a member of the immediate family of a person affiliated with the university. Members shall have the experiences and skills necessary to evaluate human research and its institutional, legal, scientific and social implications. The Associate Vice President for Research, or designee, is a non-voting member of the IRB.

No member of the IRB may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. When it is deemed necessary by the chair, or at the request of a member of the Board, the Board may invite an individual with competence in a special area to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB and are not considered part of quorum.

Absence from twenty percent (20%) of meetings within an academic year without due cause will result in a request by the IRB chair to the Associate Vice President for Research to replace that member. The Associate Vice President for Research will take the matter up with the University President through the Vice President of Academic Affairs and offer suggestions for replacement.

b. IRB Chair Responsibilities

- Maintain a thorough understanding of federal regulations pertaining to human subject protections, the FGCU IRB Guidelines and other applicable state and local regulations.

- Determine whether a project is considered “human subject research” in accordance with the regulatory requirements under § 45 CFR 46 and § 21 CFR 56.
- Review and approve, when appropriate, exempt submissions according to 45 CFR 46.101 and expedited submissions according to 45 CFR 46.110 and 21 CFR 56.111; designate an experienced reviewer to conduct expedited or exempt reviews.
- Review (or assign the review to other IRB members as appropriate) adverse event reports and unanticipated problems/protocol deviations to determine if the event affected the safety of subjects and conduct the official review. As warranted, the IRB Chair may determine the course of immediate action to address the safety of subjects; and if necessary and in consultation with the Associate Vice President for Research, convene an emergency meeting of the IRB.
- Review continuing reviews and amendments; determine if review by the full Board is required.
- Review and approve guidelines, procedures and forms on an ongoing basis.
- Serve as a sponsor and educator in the institution's research community.
- Complete the required training in conducting human subjects research.

c. IRB Member Responsibilities

- Maintain up-to-date knowledge of guidelines, procedures and regulations regarding human subjects research and IRB operations.
- Review applications and other appropriate materials prior to meetings.
- Attend meetings and contribute to the Board’s discussion.
- Disclose any potential conflict of interest to the IRB chair as soon as it is recognized.
- Maintain confidentiality regarding any information contained in any review.
- Review and approve IRB guidelines, procedures and forms.
- Complete the required training in conducting human subjects research.

d. IRB Meetings

Meetings shall be scheduled on a monthly basis, but convened as necessary. Special meetings may be called by the Chair as deemed necessary for the performance of the IRB’s responsibilities. Meetings require a quorum of members in attendance; at least one member from a non-scientific area and a community member must attend. Members may attend IRB meetings via teleconferencing. No meeting shall proceed without a quorum of its members being present.

Each board member is responsible for informing the IRB chair and/or IRB staff of any existing or potential conflict of interests**.** If an IRB member or members believe, they may be involved in, or may be perceived as being involved in a conflict of interest relative to the review of a particular application, they must recuse themselves from IRB deliberations and voting. A simple majority of the voting membership shall constitute a quorum, with at least one member whose primary

concern is in non-scientific areas. For reasons other than conflict of interest, abstentions do not alter the quorum, or change the number of votes required.

At the direction of the IRB Chair, ORSP will prepare the meeting agenda. ORSP will distribute copies of the research proposals to be reviewed, including surveys, recruitment scripts, consent documents, etc., to Board members one week prior to the meeting. Investigators will be invited to attend the meeting to answer any questions the Board may have concerning their protocol. On the day of the meeting, ORSP will distribute a summary of the Board's activity relating to, among other actions, applications received, exempt and expedited protocol approvals, amendments received and approved, continuing review requests sent and received and reported unanticipated problems or serious or continuing non-compliance issues.

The representative from ORSP will take the meeting minutes. Minutes of the meetings shall be in accordance with §46.114(2) and include sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. A tally of the actions the Board has taken on submitted and approved protocols, including continuing reviews and amendments, will be distributed to the Board members at every meeting.

Board meetings are scheduled monthly August through June. The meetings are cancelled if there is no business for the Board; additional meetings are added throughout the year as needed.

e. Record Retention

ORSP shall maintain records of IRB activities including the following, for a minimum of six years either electronically or as hard copy.

- Copies of all research proposals reviewed, approved consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings.
- Records of continuing review activities.
- Modifications to previously approved research.
- Copies of all correspondence between the IRB and the investigators.
- Statements of significant new findings provided to subjects.
- Reports of injuries to participants
- Unanticipated problems involving risks to subjects or others
- Written procedures for the IRB.
- A list of IRB members.

All principal investigators and faculty sponsors are required by 45 CFR §46.115(b) to retain records relating to the research for a minimum of three years following the completion of a study or longer, if required by another agency. This applies to all research studies, whether or not

participants were enrolled. Additionally, the research data must be available for audit and inspection by authorized representatives of the federal government and university. It is the responsibility of the PI to retain the data, including consent forms, for the required period.

The annual review and study closure processes require the submittal of copies of the two most recently signed consent/assent forms with the names blackened out with the review/closure form. Principal investigators and faculty sponsors will receive one reminder to submit copies of the consent/assent forms.

Failure to provide the Board with the requested information and forms by the date in the reminder email will result in the Board notifying the principal investigator's or faculty sponsor's chair and dean of the failure. In its notification, the Board will request the chair or dean provide the Board with the requested information within 10 business days.

Failure to provide the requested information twice during one's tenure at FGCU will result in the removal of the offender from all IRB protocols for which they are the principal investigator or faculty sponsor for a period of one year. The Board will close the studies if a new PI is not recruited within 30 days of the failure to produce the requested documents.

Chapter 2: General Principles for IRB Submissions

2.1 Application Review Process

All applications to conduct human subject research must be prospectively reviewed and approved by the IRB. All requests must be submitted on the current FGCU IRB Application Form.

PIs should submit their completed application, with required attachments, to ORSP. Upon receipt of a complete application, ORSP will assign a unique identification number to the application, and notify the PI of the receipt of the application and its identification number. The Board's review begins with a technical review, typically conducted weekly by the IRB chair or designee. This review ascertains the presence of all the required application components and compliance with the federal requirements. If the protocol falls under the exempt or expedited category, is complete, and adequately explains the research, it may be approved at this time. Complete protocols requiring full Board approval will be placed on the agenda of the Board's next meeting.

If the application is incomplete or does not adequately comply with the federal review requirements, it is returned to the PI with a memo stating its deficiencies and a request to appropriately revise the application and resubmit it. Additional reviews will be conducted as needed. The department chair and dean of the PI are copied on all review memos, notifying them of the findings of the IRB review.

The IRB utilizes the Department of Health and Human Services criteria for reviewing and approving all projects involving human subjects research. The IRB chair or designee may take the following actions on an application:

- Approve the application as submitted,
- Require additional information or modifications in order to approve the application, or
- Disapprove the application.

Applications will be assigned one of three categories during the technical review: exempt (from further IRB review upon IRB approval of the protocol), expedited review, or full board review. The category is determined by the amount of risk a study participant is exposed to. A copy of the IRB Application Checklist is used during the technical review.

The IRB determines the review category based on the level of risk to participants. An application must be filed for all research involving human subjects, even if the investigator believes the application will fall into the exempt review category.

a. IRB Review Categories

Exempt (from further IRB review upon IRB assignment of this category to the protocol) §46.101(b)

Protocols meeting the following criteria fall under the Exempt category. Continuing (annual) reviews are not required in this category. Any change to the protocol requires submission of an Amendment IRB Form.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   i.) research on regular and special education instructional strategies, or
   ii.) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement) if 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 the use of survey procedures or interview procedures **unless**
   i.) information obtained is recorded in such a manner that individuals can be identified, directly or through identifiers linked to the individuals;
   ii.) any disclosure of the individuals ' responses outside the research could reasonably place the individuals at risk of criminal or civil liability or be damaging to the individuals' financial standing, employability, or reputation;
   iii.) the research deals with sensitive aspects of the individual's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4) Research involving the observation (including observation by participants) of public behavior **unless** the:
   i.) observations are recorded in such a manner that the individuals can be identified, directly or through identifiers linked to the individuals;
   ii.) observations recorded about the individuals could reasonably place the individuals at risk of criminal or civil liability or be damaging to the individual's financial standing or employability; if they became known outside the research;
   iii.) research deals with sensitive aspects of the individual'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, directly or through identifiers linked to the subjects.*
6) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs; 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.
7) Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental

contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

8) All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office, or federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Expedited

Research activities involving no more than minimal risk and the only involvement of human subjects will be in one or more of the following categories may be reviewed using the expedited review procedure (review by the IRB Chair or designee).

Research Categories

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in amounts not exceeding 450 milliliters in an eight-week period, and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.
2. Prospective collection of biological specimens taken in a nondisfiguring manner of hair and nail clippings; deciduous teeth at time of exfoliation or if routine patient care; permanent teeth if routine patient care indicates a need for extraction;
3. Collection for analysis of excreta and external secretions (including sweat), uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
4. Collection of supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, mucosal and skin cells collected by scraping or swab, skin swab, or mouth washings, or sputum collected after saline mist nebulization.
5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice such as physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

   It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays and microwaves).
6. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

7. Collection of data from voice, video, digital, or image recordings made for research purposes.
8. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
9. Moderate exercise by healthy individuals.

Full Board

Research studies involving more than minimal risk to human subjects or protected populations such as children, prisoners, or disabled individuals are required to be reviewed by the full board. A full board review is required for research that is not eligible for exempt or expedited review. The IRB Chair or designee makes this determination during the technical review.

The following are examples of protocols that require full IRB approval.

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
4. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).
5. Minor subjects (children 17 years of age or younger).
6. Special populations (prisoners, pregnant women, individuals with disabilities).
7. The use of video- or audiotape to record subjects if deemed necessary by the IRB Chair.

b. Criteria for IRB Approval of Research

The following criteria are the principal criteria used for the approval of an application follow.

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. The informed consent will be sought from each prospective subject or the subject's legally authorized representative unless waived by the IRB in accordance with, and to the extent required by 45 CFR 46.116
5. The informed consent process is documented representative unless waived by the IRB in accordance with, and to the extent required by 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Additional safeguards are in place to protect the rights and welfare of populations vulnerable to coercion or undue influence.

It is important to note that the primary responsibility for the review of scientific merit of study proposal rests with the college. However, during its examination of the risks versus the benefits to the potential participants, the IRB will consider the scientific merit of the study design. It is unethical to put subjects at risk or inconvenience them through participation a study that is methodologically flawed and will result in little or no reliable information.

c. Application Review Process

Within one week of the receipt of an application by ORSP, the PI, co-investigators, department chair, dean and IRB Chair, receive written acknowledgement of the receipt of the application and the assigned IRB number. Following the notification, the IRB Chair will conduct a Technical Review to determine if the application is complete and which classification - exempt, expedited, or full board review – is appropriate. The Technical Review should occur within two weeks of the receipt of the application.

Applications assigned to the exempt or expedited status are reviewed and approved by the IRB Chair; applications requiring review by the Full Board will initially be reviewed by the chair and placed on the agenda of the Board's next meeting once it is complete and complies with the federal requirements.

If an application in any review category is incomplete, a memo, requesting specific revisions, will be sent to the PI, co-investigators, department chair and dean with instructions to revise the protocol and resubmit it. Subsequent reviews will be conducted until the requested modifications are complete. The PI is notified of the findings from subsequent reviews within two weeks of the receipt of the revisions.

Once an exempt or expedited application is approved by the IRB Chair, ORSP will send a memo to the PI, co-investigators, department chair, and dean informing them that the application has been approved. PIs will be instructed to request of the Board any modifications to the protocol and notified that modifications require approval by the Board before they are implemented. PIs of approved expedited protocols will also be informed of the date of their continuing review.

Applications going before the full Board must be completed and approved for inclusion on the Board's agenda by the IRB Chair a minimum of two weeks prior to the Board's meeting. Investigators are encouraged to attend the meeting to address any questions or concerns the Board may have concerning the application. Activities on all applications are recorded in the IRB meeting minutes as an attachment to the meeting agenda.

The IRB may take one of the following actions concerning applications.

Approve: The application is approved; approval commences on that day. The IRB informs the PI, co-investigators, department chair, and dean of the application's approval in writing and attaches a copy of the approved informed consent document, recruitment scripts and flyers, with the IRB date noted on the last page, within one week of the approval. The PI may begin the research project upon receipt of IRB written approval.

Approve Subject to Modification: The Board requires minor modifications of, or additions to a protocol or accompanying document(s). A memo is sent to the PI, co-investigators, department chair and dean, informing them of the requested clarifications and/or items within one week following the Board's meeting.

The IRB Chair has the authority to review the submitted revisions or information via the expedited review process unless the Board specifies that the material or information must be reviewed by the convened Board. The IRB Chair will review the revised protocol and/or consent document within one week of receipt of the revised documents.

Once approved, the IRB informs the PI, co-investigators, department chair and dean of the application's approval in writing and attaches a copy of the approved informed consent document, recruitment scripts and flyers, with the IRB approval stamp, within one week of approval. The PI may begin the research project upon receipt of IRB written approval.

Communication from the PI that the Chair determines is relevant to the Board's deliberation will be shared with the Board at its next meeting.

Defer: The Full Board requires significant clarifications or modifications to the protocol, the informed consent form, recruitment materials, etc. A memo is sent to the PI, co-investigators, department chair, dean, within one week following the meeting, informing them of the requested clarifications and/or items. The IRB Chair will screen the revised materials and request additional clarifications, if needed, before placing the application on the Board's agenda.

Disapprove: The Full Board finds that the application fails to meet one or more of the criteria the Board uses to approve research. Applications cannot be disapproved through the expedited review process and may only be disapproved by majority vote at a convened meeting of the IRB.

If the IRB disapproves a research protocol, the Board will send a memo to the PI, co-investigators, department chair, and dean within one week of the determination, providing the reasons for the Board's decision and an opportunity for the Principal Investigator to appeal the decision. The appeal process consists of resubmission of the project to the IRB, with or without modification, accompanied by a letter from the Principal Investigator indicating why he or she believes the project should be again considered by the IRB.

d. Determination of the Length of the Application's Approval Period

The length of the time of approval of an application is dependent upon the:

- category of the application – exempt, expedited, full board
- level of risk to participants
- confirmed instances of serious or noncompliance by the PI and/or research team,

- belief by an IRB member that more frequent review is required, or
- other reasons identified by the Board for closer monitoring of the study.

Applications in the expedited and full board categories are approved for one year following the date of approval unless they meet one of the above criteria. The expiration date is one year from the date of approval stated in the approval memo. Protocols that have not successfully completed its continuing review expire at midnight on the expiration date. Research activities may not continue after midnight of the expiration date.

Protocols in the exempt category do not require review. However, PIs will be contacted every three years to verify that the research is ongoing and remains exempt. If the research is completed prior to the 3-year period, investigators are requested to notify the IRB of the study's closure.

2.2 Informed Consent/Assent

a. Informed Consent - Adults

Every potential research participant who is a competent adult (at least 18 years of age), or his/her legally authorized representative, must provide informed consent to participate in research prior to the engaging in the study. The consent must provide information to enable persons to voluntarily decide to participate in the study and include the risks and benefits of participation. The consent process is ongoing. It begins with the drafting and approval of the consent form and it continues through the completion of the participant's involvement in the study. The consent document is only a confirmation of the consent process.

The investigator must ensure the following.

- The participants (or their representatives) are provided with sufficient opportunity to consider whether to participate.
- The possibility of coercion or undue influence that might be experienced by the participants is minimized.
- In instances where full *a priori* disclosure of the purpose of the research is not possible because full disclosure could affect research outcome, the PI has the responsibility to attempt to fully debrief the research participant concerning the purpose of the study.

The informed consent document communicates the following to the prospective participant:

- The study involves research;
- The purpose, procedures, risks and benefits of the study;
- Participation is voluntary;
- The subject's rights in participating in research;
- The name and telephone number of person to contact for questions about the participant's rights;
- The freedom to decline to participate without any jeopardy;

- The expected duration/frequency of participation;
- An explanation of any available applicable alternative treatments, if appropriate;
- The identification of any experimental medical treatments or procedures, if appropriate;
- The right to obtain further information and answers to questions related to the study;
- The name and telephone number of person to contact for questions about the research, and name and telephone number of responsible project investigator, if different;
- An explanation of any compensation and, if appropriate, procedures to pro-rate compensation for subjects who withdraw prior to completion of the study;
- The name of person to contact in the event of research-related injury;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- A statement that participants will receive a copy of the consent form;
- The participant is not waiving any legal rights, including any release of the university or its agents from liability or negligence;

A model of a consent form is available on the IRB webpage along with a document to assist in drafting a consent form at the 8th grade reading level. In some circumstances, investigators can seek alternatives to standard signed informed consent procedures. Please see section f. Waiver of Consent for additional information.

b. Assent – Minors

"Assent" means a child has agreed to participate in the research study. Assent forms are required for minors along with a parental consent form. A child's failure to object, absent affirmative agreement, *should not* be construed as assent. When assenting children:

- Different assent documents may be required when a study involves several age groups.
- *A Parent Consent Form must be signed by a parent or guardian prior to obtaining their child's assent.* Parent Consent Forms contain all of the required elements of a standard informed consent form with a modified signature section. The Board may find that the permission of one parent is sufficient for the study if it does not involve greater than minimal risk. Refer to the Parent Consent Form model available on the IRB webpage.
- All assents must be documented and include the signature of the witness to the assent process.

The following guides should be used for children of different ages. Refer to the models available on the IRB webpage.

Ages 2-6: Children under 7 years of age are assumed unable to give assent. A Parent Consent Form is required. Document the reason for waiver of the assent in the IRB application.

Ages 7-12: Children between the ages of 7 and 12 must have a parent sign a Parent Consent Form and the child must sign the assent form.

Ages 13- 17: Children between the ages of 13 and 17 must have a parent sign a Parent Consent Form and the child must also sign the assent form in order to participate in the study. A modified Informed Consent for Adults template can be used incorporating language appropriate to the child's level of comprehension.

c. Non-English Speaking Participants; Translating the Consent Document

Non-English speaking participants must receive a consent document written in a language understandable to them. Written consent documents should embody, in language understandable to the participant, all the elements of consent. It is important that consent forms be translated accurately. It is the responsibility of the PI to translate the English version of the consent form into the language of choice. The IRB will have the translation verified by a third party.

Additionally, the researcher or a member (or members) of the research team who speaks the language must consent the participants and be available during the study to answer questions and conduct the study.

d. Consenting Vulnerable Populations

Forthcoming

e. Waiver of Consent

Upon the request of the PI, the IRB may approve a waiver of the informed consent process that would allow the PI to alter some or all of the required elements of the consent or waive the requirement to obtain informed consent. One of the following two circumstances must exist:

1. The research involves no more than minimal risk **AND**:
   a. the waiver or alteration will not adversely affect the rights and welfare of the participants; **AND**
   b. the research could not practicably be carried out without the waiver or alteration; **AND**
   c. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
2. The research is designed to study certain aspects of public benefit or service programs such as the procedures for obtaining benefits or services under those programs or possible changes in methods or levels of payment for benefits or services under those programs.

Note: all of the points must be documented in the IRB application for a waiver. The IRB will consider the risks and potential harms involved in the research when determining if a waiver is appropriate. The Board may decide to not grant a waiver if it believes it is not in the best interest of the subjects.

f. Waiver of the Documentation of Consent (Waiver of Signed Consent Form)

A waiver of documentation of informed consent is a request to omit *a* signed consent document from the study. *Consent must still be obtained from participants*. However, participants will not be required to sign a consent form. This is also known as implied consent. Examples of studies that may qualify for this waiver include the completion of an online survey or telephone survey.

A waiver of documentation of informed consent may be approved by the IRB when it is impossible or undesirable to obtain written consent. The IRB has the authority to approve a waiver of documentation of informed consent when:

1. 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. An example is an interview with a gang member. **OR**
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (i.e., study does not include questions that could result in potential embarrassment, personally or professionally). **AND**
3. The research is *not a clinical investigation* subject to FDA regulations.

In cases in which the documentation requirement is waived, PI's must provide all participants with an IRB-approved verbal or written statement regarding the research. The request to waive or alter the informed consent process is included in the FGCU application. Models for online and oral consents are available on the IRB webpage.

Note: The IRB will consider the risks and potential harms involved in the research when determining if a waiver of the documentation of consent is appropriate. The Board may decide to not grant a waiver if it feels it is not in the best interest of the participants.

2.3 Training

a. Research with Human Subjects – Basic Training

All investigators, faculty sponsors, research team members, key study personnel, IRB members and pertinent ORSP staff must hold a current certificate of completion of the appropriate CITI Human Subjects in Research training program before conducting human subjects research. This includes investigators conducting research in the exempt category. Key study personnel include all individuals, including students, who contribute in a substantive way to the development, conduct and monitoring of studies. This includes persons who enroll research subjects, obtain informed consent or screen potential subjects, and who analyze or report research data.

Investigators should enroll in the appropriate course that is the best match for the research they are conducting – Social & Behavioral Research Investigators, or Biomedical and Social and Behavioral Investigators, and, if appropriate, the certificate for Health Information Privacy & Security.

The IRB will not approve an application to conduct research involving human subjects if the PI has not completed the appropriate CITI training. Additionally, co-investigators and research team members will not be added to the study until they complete the appropriate CITI training.
Note: If you have *not* previously completed the Basic Human Research Course, taking a Refresher Course or a Responsible Conduct of Research course *will not satisfy* the training requirement.

The initial renewal of training in Human Subjects in Research is required every five years. Investigators and key study personnel* must renew their training by taking a shorter refresher course offered by CITI. Subsequent renewals are required every three years. CITI will notify investigators of the expiration of their certification 90 days prior to its occurrence.

b. Research with Human Subjects – Health Information Privacy and Security Course (HIPS)

All investigators, faculty sponsors, research team members, and key study personnel conducting studies, which involve the use of Protected Health Information (PHI) are required to complete the CITI Health Information Privacy and Security (HIPS) course. This training is required in addition to the Social & Behavioral Investigators or the Biomedical AND Social and Behavioral Research course.

c. Responsible Conduct of Research (RCR) Courses

Research with human subjects funded by the National Science Foundation (NSF) requires that trainees, fellows, participants, and scholars receiving support through a grant must complete training in the responsible conduct of research course. Additionally, the National Institutes of Health (NIH) requires that individuals receiving funds for a training, career development award, research education grant, or dissertation research grant must complete training in the responsible conduct of research.

FGCU offers the online courses through the Collaborative Institutional Training Initiative (CITI). CITI registration and logon instructions can be found by clicking on the link.

2.4 Participants' Rights and Responsibilities in Human Subjects Research

It is important that researchers recognize the rights individuals have when participating in a study. These rights include:

- Learning about the nature and the purpose of the study;
- Asking questions about the study and/or their rights as a participant at any time during the study;
- Receiving an explanation of the procedures that might be used in the study;
- Learning about any benefits that might be expected from the study;
- Receiving a description of any reasonably foreseeable discomforts and/or risks they may experience from participating in the study;

- Learning how their will privacy be protected;
- Learning what treatment will be made available should they be injured as a result of the study;
- Learning about any compensation offered for their time and effort;
- Deciding to consent or not to consent to participate in the study without being unduly influenced and/or feeling forced, obligated, pressured, or coerced to participate;
- Receiving an Informed consent/assent form in a language that is understandable to them, unless the use of the form is waived by the IRB;
- Learning if there are alternatives to participating in the study; and
- The right to stop participating in the study at any time without penalty or loss of benefits to which they would otherwise be entitled.

The responsibilities of study participants include:

- Carefully weigh the potential benefit(s) of participation (if any) against actual risk(s) of participating;
- Understanding the time commitment and frequency of study visit(s);
- Making an informed decision about participation;
- Making reasonable effort to comply with protocol requirements and inform the investigators/study team of any unanticipated problems;
- Contributing to the integrity of the research through honest and ethical participation;

2.5 Research Participant Privacy, Confidentiality, and Data Security

The protection and respect of study participants' privacy and the preservation of the confidentiality of person-identifiable data is a basic principle of human subjects research. Studies must collect only the minimum information necessary to accomplish its intended purpose. The PI must demonstrate to the IRB that the study provides for the privacy and confidentiality of participants and the security of the collected data.

The review of the protection of a participant's privacy and confidentiality begins with the recruitment plan, extends to the consent process, through one's participation in the study and concludes with the appropriateness of the plan to protect the confidentiality of research data. Protecting the confidentiality of the research data includes its coding, the removal of identifying information, limitation of access to data, storage of the data, etc. Investigators must specify in their protocol how hard copies of data (informed consents, paper surveys, etc.) and electronic data will be securely stored to prevent unauthorized access, disclosure, or loss.

Investigators must inform the IRB immediately in the event of an unauthorized release or loss of participants' private or confidential information.

a. Privacy vs. Confidentially

It is important that researchers understand the difference between privacy and confidentiality when developing their IRB applications.

Privacy concerns people and their **choice** to share personal information. In the context of an IRB application, privacy refers to an individual's desire to control the access of others to him or herself. Privacy is an individual's right to be free from unauthorized or unreasonable intrusion and their control over the extent, timing and circumstances of obtaining personal information (physically, behaviorally, or intellectually) from or about them. For example, individuals may not want to be seen entering a place that might stigmatize them, such as a clearly identified methadone clinic. It is important for researchers to remember that persons of different ethnic or cultural groups or different ages may have differing concepts of privacy.

Confidentiality is an extension of privacy. It is the treatment of the data an individual disclosed during the study. It includes the researcher's agreement with the participant about how the participant's identifiable information will be handled, managed, and disseminated. It is the investigator's obligation to protect subjects' information.

Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

2.6 Recruitment of Participants

Forthcoming

2.7 Compensating Study Participants

Forthcoming

Chapter 3: Applications with a Unique Focus

3.1. Case Studies

A case study is qualitative descriptive research, focused on an individual or group (≤3), that draws conclusions only about that individual or small group and only in the specific context reviewed. Case studies generally involve the collection and presentation of detailed information to highlight an interesting condition, treatment, presentation or outcome.

Case studies that will be published must be prepared in accord with the requirements of the HIPAA privacy regulations.

Case studies do not meet the federal definition of research **unless** the study:

- involves a protocol/study plan,
- has the primary purpose of answering a research question, not providing care,
- involves a sensitive topic, confidential information, or identifiers that could place a participant at risk if disclosed,
- is intended to be published as a report that is analytical, not descriptive,
- involves at-risk or special populations (i.e., children, pregnant women, human fetuses, neonates, prisoners, etc.),
- uses an experimental intervention/treatment , or
- uses statistics to allow possible extrapolation of the results to a larger population

3.2. Oral Histories

Oral history is defined by the National Oral History Association as ""a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life". The following guidelines should be to be used to determine if an activity is human subjects research. The guidelines are based on guidance received in a letter from Dr. Michael Carome, Associate Director for Regulatory Affairs, OHRP, dated September 22, 2003.

IRB review *is required* for oral history projects that meet the following conditions:

1. research as defined by 45 CFR 46.102(d)
   "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." , and

2. research with human subjects as defined by 45 CFR 46.102(f),
   "a living individual about whom a research investigator (whether a professional or a student) obtains (1) data through intervention or interaction with the individual or (2) from individually identifiable information."

An example of an oral history activity that *does not require IRB approval* is the documentation of a specific historical event or experiences of individuals without the intent to draw conclusions or generalize findings… a researcher will be conducting interviews of former gang members to

document the impact belonging to a gang had in their lives. IRB approval is not needed as there is no hypothesis and therefore is not a systematic investigation, nor will the work contribute to generalizable knowledge.

Examples of oral history activities that *do require IRB approval* include activities that

- are designed to develop or contribute to generalizable knowledge, or
- create an archive to provide a resource for others to conduct research. This activity meets the definition of "research" because the intent of the archive is to create a repository of information for other investigators to conduct research.

A researcher plans to conduct oral histories of former gang members to gain an understanding of the challenges one faces when leaving a gang to assess what resources are needed to support one during the separation process.

Investigators are advised to consult with the IRB Office regarding whether their oral history project requires IRB review.

Note: When a specific oral history project does not require review by the IRB, the research must be conducted according to the ethical and legal standards appropriate to oral history, including consenting the participant and collecting legal releases as appropriate. Investigators are expected to apply the principles and standards of the Oral History Association set forth in the Association's Oral History Evaluation Guidelines when conducting these types of activities.

3.3. Ethnographic Research

Ethnography research is a qualitative science that collects data through observations and interviews to draw conclusions about how groups and individuals function. Ethnographic researchers spend time observing and/or interacting with participants in areas of their everyday lives. This is different from interview-based research, which is limited to a traditional interview or survey, typically occurring outside the participant's environment. Historically employed by anthropologists and social scientists, the research methodology has expanded into business where researchers visit consumers in their homes or offices to observe and listen in a non-directed way to learn patterns of behavior with their product and future business trends.

Ethnographic researchers produce a detailed description of how a particular social group operates, based on observation of, and may participate in the group being studied. Although ethnographic research takes place in natural settings, IRB review *is required* as it is:

1. *"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."* (45 CFR 46.102(d)), and involves

2. *"a living individual about whom a research investigator (whether a professional or a student) obtains (1) data through intervention or interaction with the individual or (2) from individually identifiable information."* (45 CFR 46.102(f))

An application to conduct ethnographic research must be approved by the IRB before the study begins.

3.4. Clinical Trials (Studies with health related interventions)

The IRB has adopted the definition of a clinical trial as ***any research study that prospectively assigns four or more human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes***.

> Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, quality improvement interventions, and process-of-care changes.
>
> Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. This definition incorporates the requirements imposed by the September, 2007 FDA Amendments Act and the International Committee of Medical Journal Editors' policy relating to clinical trials.

All studies meeting the above definition of a clinical trial must be registered at Clinical Trials unless exempted by the IRB. Confirmation of the clinical trial registration must be submitted to the IRB. IRB applications will not be approved until this confirmation is received. The IRB will activate the clinical research account.

Both the FDA and the NIH encourage the registration of ALL trials, whether or not required under the FDA Amendments Act of 2007. Additionally many, if not most, medical journals require prospective registration of certain clinical trials as a prerequisite for publication. For a complete listing of journals that follow the International Committee of Medical Journal Editors requirements, see ICMJE International Committee of Medical Journal Editors.

The PI should refer to the document Guidance in Registering your Study on the clinical trial on Clinical Trials. FGCU is registered as an institution with ClinicalTrials.gov for all FGCU investigators to register under. DO NOT request an Individual Account or another Organizational Account on the clinicaltrial.gov website.

The PI is also responsible for the following:

1. ensuring the registration information is complete, accurate and updated as needed;
2. reviewing the listing and making necessary changes/updates every six months or more frequently if significant changes occur;
3. updating the site when enrollment ceases;
4. closing-out studies on ClinicalTrials.gov before departing from FGCU. This includes ensuring that studies are properly closed or transferred to another investigator;
5. submitting summary results to ClinicalTrials.gov no later than 1 year after the Primary Completion Date (applicable clinical trial under FDAAA only*).

Faculty sponsors for student PI's are responsible for ensuring studies on ClinicalTrials.gov are closed on or transferred to another PI for graduating students.

* *Trials of drugs and biologics; controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation and trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.*

3.5. Pilot/Feasibility Study

A pilot/feasibility study is a preliminary investigation of the feasibility of a study. It is usually done a small scale (< 10 participants) and is exploratory in nature. These studies are designed to help the investigator refine data collection procedures and instruments or fine-tune the research design. Pilot studies recruit participants from the population upon which the study will be based. Pilot studies may also be conducted to collect initial data in support of or preparation for a grant submission.

Pilot studies involving human subjects require the same scrutiny as full-scale research projects and must be submitted for IRB review and approval.

If you pilot your study or calibrate your measures with anyone other than yourself or a member of your research team, you are conducting research and an IRB application is required.

3.6. Scholarship of Teaching and Learning (SoTL)

The scholarship of teaching and learning is the systematic investigation and development of best teaching practices, designed to draw generalizable conclusions **for dissemination of the practices beyond one's classroom**. It typically involves:

- interviewing, questioning, surveying, or observing students in one's classroom setting
- comparing instructional techniques, learning tools, curriculum materials, or teaching strategies, and
- analysis of papers or assignments.

Although SoTL research occurs in the classroom, IRB review *is required* as it is:

1. *"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."* (45 CFR 46.102(d)), and involves
2. *"a living individual about whom a research investigator (whether a professional or a student) obtains (1) data through intervention or interaction with the individual or (2) from individually identifiable information."* (45 CFR 46.102(f))

SoTL activities present ethical issues for the IRB, in particular when PI's utilize their own students as participants. There is a strong potential for coercion due to the power differential in the teacher-student relationship.

Participants in SoTL research are awarded the same protections as participants in biomedical, social sciences, behavioral and humanities research.

- Students must be **free not to participate**. Students have the right to participate and withdraw from the study at any time without penalty.
- Participation in the study CANNOT be a condition of completing a course. Instructors may offer an alternative assignment of equal time, effort and credit to students who choose not to participate in the study.

- Students must give informed consent; an assent form and parental consent form must be received from students who are under 18 years of age
- Risks to participants must be minimized. This includes physical, psychological and social risks.
- Privacy and the confidentiality of participants must be maintained.

The majority of SoTL projects will qualify for "exempt" or "expedited" review. The IRB review is to ensure that the research protects the rights given to individuals issued by the Federal Government and the handling of student education records mandated in the Family Educational Rights and Privacy Act – FERPA. Note: Exempt category explanation

Common SoTL Myths and the IRB

1. I'm working with old test papers and assignments so my research does not involve human subjects.

   FALSE: Research involving previously collected data, unless this data *has <u>never</u> had any identifying information associated* with it, requires IRB review. The Board will address consent issues and confidentiality concerns.

2. I'm still developing my survey instrument and am just 'trying it out' in my classroom. It is not a 'polished' study and does not require IRB review.

   FALSE: Testing the feasibility of a questionnaire, instrument, etc., with individuals outside of the investigator and research team is a pilot study and requires IRB review and approval prior to distributing the instrument.

3. I'm really conducting program evaluation and it is exempt from IRB review.

   TRUE: *If* the program evaluation is conducted for the sole purpose internal assessment or improvement and the results are *not shared outside of the university*.

   Note: If subsequent analysis is undertaken to develop or contribute to generalizable knowledge, the analysis constitutes human research that now requires IRB review and approval.

4. I just want to test a new study aid with one class and compare it to another, I do not need IRB review.

   FALSE: Testing a new study aid with students is a pilot study and requires IRB review and approval prior to conducting the analysis.

   When in doubt, consult with the IRB.

3.7. Secondary Analysis of Data

Secondary data is data that was collected by someone other than the user and was collected prior to the time the study is proposed. This data may include medical records, audio/video recordings, student records, data collected from previous studies, etc., that were collected for a purpose other than that of the newly proposed study.

The analysis of secondary data requires IRB review if its use meets the definition of "human subjects" as defined by 45 CFR 46.102(f) **"*living* individuals about whom an *investigator obtains identifiable private information for research purposes.*"**
Private information includes information:

1. about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or
2. data through intervention or interaction with an individual that the individual can reasonably expect will not be made public (i.e., grades, survey responses, medical record, etc.).

Additionally, private information must be **individually identifiable** (i.e., the identity of an individual is or may readily be ascertained by the PI, or associated with the information).

Information is individually identifiable if:

1. the identity of an individual is known or may be readily ascertained by the PI or associated with the information through direct identifiers (name, address, telephone number, email address, Social Security Number, medical record number, employment/student number, date of birth, image, etc.),
2. the information can be linked to an individual directly, indirectly through a coding system, or
3. characteristics of the information would allow a reasonably knowledgeable person to identify the individual.

Although the definition of a human subject includes only living individuals and excludes decedents, there are cases in which the health information of the deceased and death data files may require IRB review.

The use of secondary data does not require IRB review when it is collected from

1. **public use data sets** available in a library, some sources of data on the internet (example, non-public chat rooms or listservs, etc., *are not* publically available), U.S. Census data, data from the National Center for Educational Statistics, National Center for Health Statistics, public libraries, newspapers, Inter-University Consortium for Political and Social Research (ICPSR), National Election Studies, etc.

2. **de-identified data sets** which have been stripped of all identifying information and there is no way (a data key, coding system, or other means) to link the data with an individual.

3.8. International Research

Forthcoming

3.9 Research with Vulnerable Populations

Forthcoming

Chapter 4: Monitoring of Human Subject Research

4.1 Amendments to Pending or Approved Applications

The PI is responsible for submitting the Request for Amendment/Modification for Submitted or Approved IRB Protocol when *any* change (change in investigators, risk level, number of participants, survey instrument, consenting process, etc.) is necessary. All modifications must receive IRB approval *prior* to implementation.

The one exception is when the change is necessary to eliminate apparent immediate hazards to the subjects. In such cases, the investigator must submit a report to the IRB explaining the protocol deviation within 48 hours of the occurrence.

4.2 Continuing Review

Approved IRB protocols are required to submit a continuing review at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109, 21 CFR 56.109). Studies determined to be exempt from IRB oversight do not need to submit a continuing review. During the review, the reviewer has access to the original application, all documents submitted since the original approval and new documents submitted with the continuing review form.
If a study was originally approved by the Full Board and the Board determined that the study meets the expedited status criteria set forth under expedited category 8 (45 CFR 46.110 (a) list), the review will be conducted by the IRB Chair or designee. Protocols remaining in the category of Full Board review must have their continuing review conducted by the Full Board at a scheduled meeting, prior to the protocol's expiration.

IRB staff members will send PIs a courtesy reminder and Continuing Review Form two months prior to the protocol's expiration date. A reminder will be sent to the PI and his/her Chairperson if the completed review is not received within the requested period. Failure to return the completed review by the protocol's expiration date will result in the Board closing the protocol. However, **it is ultimately the PI's responsibility to monitor the project's expiration date, and apply for continuing review/renewal in a timely fashion to continue the study.**

The PI is required to submit the Continuing Review Form and copies of the two most recently signed informed consent forms, with the names blackened out, if required by the study. Reviews are typically conducted within two weeks following their receipt.

Failure to provide the Board with the requested information and forms by the date in the reminder email will result in the Board notifying the principal investigator's or faculty sponsor's chair and dean of the failure. In its notification, the Board will request the chair or dean provide the Board with the requested information within 10 business days.

Failure to provide the requested information twice during one's tenure at FGCU will result in the removal of the offender from all IRB protocols for which they are the principal investigator or faculty sponsor for a period of one year. The Board will close the studies if a new PI is not recruited within 30 days of the failure to produce the requested documents.

Investigators will be notified in writing of the decision of the IRB and if any changes/modifications are required. Changes/additions requested by the Board must be received in order for the continuation to be approved. Once the review is completed and approved, a memo approving the continuation of the study will be sent to the PI, co-investigators, chair and dean indicating the next date of the study's expiration.

The FGCU Continuing Review Form allows PIs to request an amendment to an approved protocol. It is important to note that amendments can be submitted throughout the year and must be approved by the Board before implemented. A PI does not need to wait for the continuing review to file an amendment.

If the approval expires prior to the approval of the continuing review, the investigator is required to stop all contact with participants, and data collection and analysis of identifiable private information until the request to continue the study is approved by the IRB. No new subjects may be contacted, recruited, or enrolled in the study until IRB approval is received.
The exception is if the PI determines and documents the need to continue the study in a memo to the Board justifying that continuation is in the best interest of the participants. The Board must receive this memo within 48 hours of the protocol's expiration. If the Board determines that continuation in the study at this time is not in the best interests of the participants, the study is halted.

Studies that do not receive approval to continue within 30 days after its expiration will be closed by the IRB and a new IRB application will have to be submitted and approved to continue the research.

4.3 Study Closure

A study may be closed when research-related interventions or interactions with human subjects have been completed. This includes data analysis with individually identifiable or coded private information) have been discontinued.

A PI can inform the IRB that the study is closed at the time of continuing review or by submitting the Request to Close Protocol form.

Following review by the Board, the IRB may request additional information to ensure that the study is in good standing and ready to be closed. Once approved, the Board will send a memo to the PI, co-investigators, chair and dean notifying them that the Board has closed its file and the study is closed. A new application will need to be submitted if a PI wishes to resume the research.

Once the Board has closed a study, the PI is responsible for maintaining the data for a minimum of three years following its closure. The data retention must be consistent with the IRB-approved research plan