FARMINGDALE STATE COLLEGE

# INSTITUTIONAL REVIEW BOARD

# IRB MANUAL

**FEDERALWIDE ASSURANCE ID#: 00011332**
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# Section 1: General Information

## 1.A. Overview

The Institutional Review Board (IRB) is the administrative body that supports, facilitates and promotes the ethical conduct of research involving human participants at Farmingdale State College-SUNY (FSC). Its mission is to protect the rights and welfare of human research participants. In the review and conduct of research, all applicable federal, state and local laws, regulations and/or requirements will be followed. The actions of the College will be guided by and uphold the principals set forth in *The Belmont Report Ethical Principals and Guidelines for the Protection of Human Subjects of Research* (1979, The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research):

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**Respect for Persons**: Ensured by obtaining Informed Consent, consideration of privacy, confidentiality, and additional protection for vulnerable populations.
**Beneficence**: Ensured by assuring that possible benefits are maximized and possible risks are minimized to all human subjects.
**Justice**: Ensured by the equitable selections of subjects.

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FSC's Federalwide Assurance (FWA) ID number is 00011332. An FWA is an institution's assurance to the federal government that human subject research conducted at a site is in compliance with federal regulations pertaining to the protection of human participants. FSC has chosen to extend the applicability of the FWA and federal regulations to all research at FSC, regardless of funding source. *The Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services; Part 46 Protection of Human Subjects* (i.e., *The Common Rule*) was revised on January 21, 2019. All studies approved or deemed Exempt before this date are subject to the prior regulations through the close of the study.

Regulatory compliance for research funded by federal agencies (e.g., Department of Defense, Department of the Energy, Department of Education, etc.) will also guide reviews (if applicable).

The IRB is comprised of college faculty, administrators, scientists, non-scientists, and community members; and membership is in accordance with the federal policy. The IRB must review and approve research involving human participants prior to its initiation. It is the responsibility of the IRB to determine whether proposed research exposes participants to unreasonable or unnecessary risk, to review informed consent forms and process, and to monitor the progress of research. The IRB may be assigned other review functions as required by the institution.

No involvement of human participants in research, including recruitment, is permitted until the IRB has reviewed and approved the research protocol. No participant in a research activity shall be exposed to unreasonable risk to health or well-being, and the participant has the right to withdrawn/refuse to participate at any time and for any reason without the loss of otherwise entitled benefits.

The policies outlined in this manual apply to and must be complied by all FSC faculty, staff, and students using the college facilities, the facilities of another institution as a representative of FSC, or any other off-campus site for the purpose of conducting research involving human participants on behalf of FSC, including collaborative projects. The IRB acknowledges that federal and institutional regulations and/or guidance may be revised periodically, and this manual will be updated accordingly.

## 1.B. Definitions

- **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
    - The following activities are deemed not to be research:
        - Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
        - Some specific activities involving public health surveillance, criminal justice agencies (authorized by law or court order), and authorized government operational activities (defense, intelligence, homeland security, etc.). See the federal regulations for additional details.
- **Systematic Investigation** is an activity that involves a prospective study plan that incorporates data collection and analysis, either quantitative or qualitative, to answer a research question.
- **Human Subject*** means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- **Generalizable Knowledge**: The information resulting from the research is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following: Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- **Research Protocol**: Documents describing the background, rationale, objectives, design, methodology, statistical considerations, and organization of a research project.
- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- **Intervention** includes both physical procedures by which information or biospecimens are gathered (*e.g.,* 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.

- **Agent**: An individual performing institutionally designated activities or exercising institutionally delegated authority or responsibility.
- **Secretary**: The Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

*The terms *Human Subjects* and *Human Participants* are used interchangeably within this document.

## 1.C. IRB Administration and Membership

The College President is the OHRP Signatory Official for the IRB. The IRB reports to the Institutional Official (IO) in the Office of Academic Affairs. The IO assumes the obligations of the institution's Assurance, and is the contact representative for all correspondences addressing human participant research with federal regulatory agencies. The IO appoints the IRB Chairperson and supervises the IRB Coordinator.

The IRB Chairperson is an individual from within the College who pledges to be fair and impartial concerning all IRB matters. The Chair should possess a holistic knowledge of research with human subjects, and is expected to investigate related topics as needed. The Chair is responsible for conducting all Full Board meetings of the IRB.

Additionally, the Chair is the signatory for all correspondences regarding routine IRB operations (e.g., approval letters, correspondences to investigators, etc.). When appropriate, the Chair will delegate this signatory responsibility to the IRB Coordinator or other members of the IRB.

The IRB Coordinator provides programmatic and office support to the IRB. Additionally, the Coordinator conducts administrative reviews of protocols and is the liaison between the IRB and investigators.

IRB members are selected based on appropriate diversity (e.g., gender, race, cultural background, etc.), and relevant professional experience. The IRB includes both scientific and non-scientific members and representation from each of the College's four schools. Additionally, the IRB includes at least one member who is not affiliated with the College and who does not have an immediate family member who is affiliated with the College.

The Chair and IRB members are appointed by the IO for renewable, three-year periods of service. All members have full voting rights (no proxy voting is permitted). Attendance records and members contributions to the committee are reviewed to determine if appointments will be renewed. There is no remuneration for individuals serving as IRB members. Annually, the Chair, IO and Coordinator review the membership and composition of the IRB to determine if regulatory and institutional requirements are satisfied. IRB members who are found not to be acting in accordance with the College's mission, polices and/or procedures, and/or federal regulations may be removed at any time.

Employees and volunteers are protected against suits under Public Officers Law Section 17 for actions or alleged actions that occur while they are acting within the scope of their employment.

IRB members and IRB administrative personnel must complete an approved human research participants training program and refresher courses as required. Continuing education training will be provided as needed to keep members current on regulations and other issues related to their IRB duties. Members are required to submit an updated version of their curriculum vitae or professional resume. These documents are kept on file in the Office of the IRB.

IRB members, external consultants and local context reviewers are expected to protect the confidentially of the investigator(s) and the research protocol. Research protocols should not be discussed with anyone other than members of the IRB or IRB staff except in general terms for the purpose of the review.

The Chair or designee has the authority to act on behalf of the IRB when immediate action is required prior to a convened IRB meeting to protect the rights and welfare of human subjects. The Chair or designee, in conjunction with the IO, has the authority to evaluate and provide a resolution for emergent issues related to human subjects protections that are not covered by these policies. Any such action will be brought to the attention of the convened IRB at the next meeting. The IRB has the authority to promulgate or amend policies and procedures as necessary for the proper protection of human subjects in research. In its deliberations, the IRB adheres to the ethical principles detailed in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Biomedical and Behavioral Research* (1979). FSC has a Federalwide Assurance (FWA #00011332) on file with the Office of Human Research Protections (OHRP – a subdivision of the Department of Health and Human Services – DHHS), and complies with the requirements of *Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46)*, FSC institutional policies, other applicable regulatory bodies, and all federal, state, or local laws, regulations and/or requirements as they relate to research (when appropriate and/or when research will be conducted outside of the geographic area surrounding FSC's campus, investigators should inform the IRB of any know to them that are applicable). This applies to all research involving human participants regardless of source of funding or support. When research involves products regulated by the FDA, both OHRP and FDA regulations apply, and the requirements of both sets of regulations must be met.

Investigators assume the primary responsibility for ensuring that research protocols meet the standards established by federal/state/local regulations and the Institutional Review Board, and every aspect of the research activity is

conducted as described in the protocol. Compliance with these regulations helps to ensure the protection of human subjects and the integrity of research at FSC.

## 1.D. IRB Functions and Operations

The College will provide access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

Additionally, FSC's IRB will establish and follow written procedures for:

- Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution.
- Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
- Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.
- Ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate federal department or agency of
    - Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB.
    - Any suspension or termination of IRB approval.

## 1.E. IRB Meeting Schedule

The IRB meets once during the Fall semester and once during the Spring semester and additionally as needed based on receipt of a protocol requiring Full Board review.

## 1.F. IRB Activity Report

At each convened IRB meeting, the IRB membership will be informed via a written report of all Exempt and Expedited reviews conducted since the previous meeting. Members may request to review any protocol by contacting the IRB Coordinator.

## 1.G. Electronic Management System

Since September 2020, the IRB utilizes an electronic management system (Axiom Mentor) for administration and management featuring on-line submissions and web-based protocol sharing. All new protocol submissions and continuing review activities must be submitted electronically via this system.

## 1.H. IRB Records

FSC's IRB will prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings (which shall be in sufficient detail to show attendance at the meetings; quorum status; 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). Draft minutes will be reviewed by the IRB and voted on by a quorum of the membership for ratification.

- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.
- Copies of all correspondence between the IRB and the investigators.
- A list of current IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.
- Written procedures for the IRB (see above).
- Statements of significant new findings provided to subjects (46.116(c)(5).
- The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
- Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the federal requirements.

IRB records will be retained for at least 3 years or longer if required by a specific sponsor or funding agency, and records relating to research that is conducted shall likewise be retained for at least 3 years after completion of the research or longer if otherwise required.

## 1.I. Policy Manual Revisions

All recommended revisions to the IRB policy manual will be reviewed by the IRB and voted on by a quorum of the membership. The approved recommendation will be forwarded to the Office of the Provost for final approval. A revision may be temporarily implemented by the IRB Chairperson in conjunction with the Office of the Provost without the above process being completed; however, this process will be followed before the revision is permanently applied to the IRB manual.

# Section 2: Investigators

## 2.A. Definitions

- **Principal Investigator (PI)** is the lead researcher of a study. At FSC, only one PI is allowed per protocol.
- **Co-Investigator (Co-I)** is an individual recognized as someone who shares scientific and administrative leadership responsibilities for a project with the PI.
- **Key Personnel** is defined as individuals who contribute in a substantive way to the scientific development or execution of the project.
- **Research Assistants (RA)** are individuals who are interacting and/or intervening with human subjects or who handle the personally identifiable data of a human subject, and/or are involved in the informed consent process. This also includes additional personnel who are involved in this project in a limited role (i.e., Technicians, Institutional Research Personnel, etc.).

## 2.B. Responsibilities and Certification: Principal Investigator

The PI is the ultimate protector of human participants in research. When designing a research protocol, the PI is expected to incorporate the principals of the Belmont Report, as well as the highest ethical standards. All PIs must certify that the research described in the protocol and supporting materials will be conducted in full compliance with FSC's policies and federal regulations governing human subject research.

If the IRB deems the research project Exempt, the PI must provide the following confirmations:

1. I will conduct every aspect of the project as described to the IRB and consistent with all federal, state, and institutional regulations as set forth in the IRB Policy Manual, the institution's Federalwide Assurance, and all other pertinent regulatory and ethical documents.
2. I will assume full responsibility for assuring that all study personnel have complete understanding of the research protocol and the consent process and are qualified by education, training, and experience to perform their assigned protocol tasks.
3. I will ensure the protection of every research subject enrolled in this protocol and minimize risks and maximize benefits to the greatest extent possible.
4. I will promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocol.
5. I will promptly (within 24 hours via telephone, followed by written notification within 2 business days) report any unanticipated problems involving risks to subjects or others, or any instance of serious or continuing noncompliance with federal regulations or IRB requirements.
6. To the best of my knowledge, no study personnel (or any member of their families) have a conflict of interest related to this research (e.g., significant financial interest, relationship with sponsors, vendors, or sub-contractors). [If a conflict of interest exists, please contact the IRB Office].

If the IRB approves this research project through the Expedited or Full Board process, the PI must agree to the following:

1. I will ensure the protection of every research subject enrolled in this protocol.
2. I will minimize risks and maximize benefits to the greatest extent possible.
3. I will conduct every aspect of the project as approved by the IRB and consistent with all federal, state, and institutional regulations as set forth in the IRB Policy Manual, the institution's Federalwide Assurance, all other pertinent regulatory and ethical documents.
4. I will promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocol.

5. I will promptly (within 24 hours via telephone, followed by written notification within 2 business days) report any unanticipated problems involving risks to subjects or others, or any instance of serious or continuing noncompliance with federal regulations or IRB requirements.
6. I will assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the applications materials.
7. I will use the IRB-approved, stamped form in the consent process (if applicable) and retain all original, signed forms in the research file.
8. I will assume full responsibility for assuring that all personnel whom I have delegated to obtain informed consent from subjects has complete understanding of the research protocol and the consent process and are qualified by education, training, and experience to perform their assigned protocol tasks.
9. I will ensure that the consent process is ongoing throughout the subject's participation in the research.
10. I will submit progress reports, as requested, in a timely fashion.
11. I will ensure that no research project will be continued beyond the approved period set by the IRB.
12. I will cooperate with the IRB, comply with its decisions, and keep the committee informed of any changes in the research activity with accurate, up-to-date information, as appropriate.

## 2.C. Human Subjects Training

All investigators conducting research involving human participants, information or biological specimens, regardless of funding source or status, must be trained in the protection of human subjects in research activities. Valid proof of training must be provided to the IRB at the time of protocol submission for the Principal Investigator and Faculty Advisor/Mentor for all Exempt protocol reviews and for all research personnel for Expedited or Full Board protocol reviews. The maintenance of valid training records for all research personnel is the responsibility of the Principal Investigator. Updated proof of training for research personnel should be submitted to the IRB by the Principal Investigator (when applicable). The requirement is for all those included as "Key Personnel" on the study. Key Personnel is defined as individuals who contribute in a substantive way to the scientific development or execution of the project. This includes all investigators who meet this definition, including PI, Co-I, and most RAs. Protection of human subjects training for a consultant is only required when their level of involvement meets this definition of Key Personnel. Personnel with a limited role (i.e., Technicians, Institutional Research Personnel, etc.) may only be required to complete a modified protection of human subjects training course or the training may be waived. This determination will be made by the IRB based on the individual's access to identifiable data, the risk level of the study, and on the specific role of the individual.

Acceptable training includes courses offered by FSC through CITI. More information concerning FSC's CITI course options for research involving human participants is listed on FSC's IRB webpage. Similar programs offered by other institutions may qualify as equivalent to this training. Contact the Office of the IRB regarding equivalent training.

# Section 3: Conflict of Interest/Financial Disclosure Policies

## 3.A. Definitions

- **Conflict of Interest**: Any interest, financial or otherwise, direct or indirect; participation in any business, transaction or professional activity; or incurring of any obligation of any nature, which is or appears to be in substantial conflict with the proper discharge of an employee's duties in the 'public interest'. A conflict of interest is also any financial interest that will, or may be reasonably expected to, bias the design, conduct or reporting of research.
- **Investigator**: The Principal Investigator (PI), Co-Investigators (Co-I) and all other persons who are responsible for the design, conduct, or reporting of research as described to the IRB or in an application or prospective application made through FSC for support of research.
- **Significant Financial Interest**: Anything of monetary value to the Investigator that would reasonably appear to be directly and significantly affected by the research activity, including but not limited to: salary or other payments or services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, warrants or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Examples include ownership of stock, stock options, or any equity, debt, security, capital holding, salary or other remuneration, or financial consideration, or thing of value for services as an employee, consultant, officer, or board member in: the entity to which the funding application will be submitted; any entity that owns or has applied for the patent manufacturing or marketing rights to product or procedure involved in, or will predictably result from the research activity; any entity that is known by the Investigator to own or have applied for such rights in any product or procedure that will predictably result from the research activity; or any entity that will be a sub-recipient from FSC of funding resulting from the application; any entity where the value of financial interests exceeds $5,000 and represents more than a 5% ownership interest for any one enterprise or entity when aggregated for the Investigator and all related parties; any entity from which the Investigator consults or receives other remuneration where the value is greater than $5,000 annually. Excluded are: salary, royalties or other remuneration paid to an Investigator by FSC; income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities; income from service on advisory committees or review panels for public or nonprofit entities.
- **Related Parties**: Spouse, domestic partner, dependent children, siblings, parents, or equivalents by marriage, or other individuals residing in the household.

## 3.B. Overview

According to SUNY Policy 6001 (Conflict of Interest): Faculty and staff of the State University of New York (University) are encouraged to foster an atmosphere of academic freedom by promoting the open and timely exchange of scholarly knowledge independent of personal interests and are required to avoid conflicts of interest. Where potential or actual conflicts exist, faculty and staff are expected to consult with appropriate University officers and abide by University policy. This policy represents a restatement of existing University policy and pertinent state and federal law and regulations.

The purpose of the conflict of interest disclosure process is to ensure that the design, conduct, or reporting of research will not be biased by any conflicting commitment or financial interest of the investigators who are responsible for the research. Conflicts of interest arise with increasing frequency from the diversity of roles research college faculty are expected to play. Rather than ignoring or seeking to prohibit them, FSC will endeavor to develop and implement conflict management strategies in order to facilitate the fulfillment of these diverse faculty roles in support of the College's multiple missions. All FSC investigators seeking approval to conduct research are required to complete and file a signed conflict of interest disclosure statement with the submission of each proposal. An affirmative answer to any of the questions below will initiate the process of developing a management strategy; there may be rare cases where no strategy can be developed that will satisfy all relevant constraints. Disclosures shall be

reviewed by the Chair of the IRB or a designee, and if it is determined that a conflict exists, the IRB will determine whether the conflict can be eliminated or managed.

If a new reportable significant conflict of interest arises at any time during the period after submission of the proposal through the period of approval, the filing of a new or updated COI disclosure is required.

Investigators have a Conflict of Interest if they answer "Yes" to any of the following questions:

1. Do you or any related party hold a position of management, such as board member, director, officer, partner trustee, employee or consultant with a sponsor, a vendor or (sub)contractor related to the proposed activity?
2. Do you or any related party have a Significant Financial Interest in a sponsor, vendor, or (sub)contractor related to the proposed activity?
3. Do you or any related party assigned to a sponsor, a vendor, or (sub)contractor, related to the proposed activity, have rights to a disclosed intellectual property, pending patent application or an issued patent to an invention(s) or copyright for software?
4. Do you or any related party have a Significant Financial Interest in a for-profit entity that will manufacture or commercialize any drug, vaccine, device, product, procedure, or process that is associated with or that will predictably result from the proposed activity?
5. Do you or any related party have a Significant Financial Interest in a for-profit entity that can reasonably be expected to benefit directly and significantly from the design, conduct, or reporting of the proposed activity?
6. If you answered yes to any of questions 1-5, is it reasonable to anticipate that your financial interest could be directly and significantly affected by the design, conduct, or reporting of the proposed activity?

The following questions will be considered by the IRB when reviewing financial interests of parties involved in human subject research:

1) Who is the sponsor, who designed the study, and who is analyzing the data?
2) What are the financial relationships between the investigator and the study sponsor?
3) Is there any compensation that is affected by study outcome?
4) Does the Investigator have any proprietary interests in the product including patents, trademarks, copyrights, and licensing arrangements?
5) Does the Investigator have an equity interest in the company?
6) Does the Investigator receive payments of other sorts from the sponsor (e.g., grants, research equipment, consultant fees, honoraria)?
7) Are there any incentive payments?
8) How should financial interests be managed?

If any of the investigators on a particular protocol are determined to have a significant financial interest or other conflict of interest, the IRB requires, as a condition of approval, that:

a) The IRB determines that the COI can be managed [If the COI cannot be managed, the research will be prohibited];
b) The investigator cannot be involved in the recruitment or consenting of subjects;
c) The investigator cannot place undue pressure on, or offer incentives to, other investigators to enroll subjects; and
d) The IRB may require additional measures or prescribe additional appropriate action to manage the conflict. These actions may include, among other things, limitations on a particular investigator's participation in: study, design, or data collection; monitoring of study conduct by the IRB or independent observers
e) A section of the consent form be added that states:

> *One or more of the investigators conducting this study has a significant financial (or other) interest in the company supporting the study, which means that they may receive personal financial benefit from the results obtained. No one with such interest is involved in recruiting or consenting of subjects.*

There may be circumstances that warrant a more detailed disclosure to the subjects. The IRB may draft additional disclosure language. In addition, as with any study, the consent processes for any or all subjects may be witnessed by a member of the IRB or a representative.

## 3.C. Violation of the Policy

In the event a violation of the conflict of interest policy is reported or suspected, such violation shall be immediately reported to the IRB Chair and IO. In the event of investigator violation of the policy, the IRB Chair shall determine if any action is necessary to protect human subjects and may take such action, including suspension of IRB approval. The violation shall be reported to the IRB at its next convened meeting for further investigation and determination.

## 3.D. Studies Sponsored by Pharmaceutical or Biotech Companies

An institution conducting research that is sponsored by a pharmaceutical or biotech company is usually paid in accordance with the reasonable costs of conducting the study. This may include being paid on a 'per enrolled subject' basis. These funds may be used to support research work in the investigator's laboratory. This, in and of itself, does not constitute a conflict of interest, but the subject has the right to disclosure of this relationship. A section should be added to the consent form as follows:

*Investigator Compensation*
*The principal investigator is being paid by the study sponsor, [Name of Company] to conduct this study.*

Rarely, there are provisions in some contracts that allow for 'enrollment incentives', also referred to in other terms such as 'competitive enrollment'. This refers to the situation where the institution will be paid more by the sponsor if a certain quota is met (based on the number of participants, or time it takes to enroll the subjects). FSC does not always prohibit enrollment incentives, but acknowledges that such incentives may also serve to keep the investigator aware of the need for eligible subjects. Furthermore, it is clearly advantageous for research on the causes, prevention and treatment of diseases to be conducted as quickly as possible so that results can be assessed, and future research planned. As such, protocols involving enrollment incentives will be assessed by the IRB on a case-by-case basis. Allowance of such incentives will be based on several criteria, including the amount and scheduling of the incentive and the aims of the research. The IRB retains the right to refuse to allow enrollment incentives for a particular protocol. Further, enrollment incentives (monetary and otherwise) meant to provide personal benefit to any investigator (PI, Co-I, etc.) are prohibited.

## 3.E. Externally Funded Research

All study team members (including non-FSC collaborators and volunteers) of externally funded research projects are also required to submit a *Disclosure Statement of Significant Obligations, Significant Financial Interests (SFI) and Sponsored Travel* (prior to the submission of a proposal for external funding to a sponsor; annually for the duration of the project; and within 30 days of an event that would change the disclosure on file) via the Pre-Award and Compliance System (PACS). Additionally, all study team members must complete the *Conflict of Interest* training course through the CITI program. Please contact the Office of Sponsored Program Administration for guidance.

## 3.F. IRB Member Conflict of Interest Procedures

*No Institutional Review Board (IRB) may have a member 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. [45 CFR 46.107(d)]*

Category I:
An IRB member is deemed to have a conflict of interest if one or more of the following situations exist: An IRB member:

- Is included on the research as an investigator or member of the research team.

- Has a financial conflict of interest in the research.
- Is an immediate family member of the investigator.

Category II:
The following situations may be deemed a conflict of interest if expected to preclude an objective assessment of the research. The IRB Chair and/or Coordinator in consultation with two randomly selected members of the IRB Committee will review each situation to determine whether it constitutes a conflict of interest. An IRB member has/had:

- Significant involvement in preparation of materials submitted to the IRB for review or approval.
- A supervisory relationship (either past or present) with the investigator.
- A close personal relationship with the investigator.
- A competitive relationship with the investigator (e.g., direct competition for funding, scholarship, research subjects) or the IRB member is considered a personal or professional adversary of the investigator for reasons not related to the IRB.
- Other interests that would conflict with the member's ability to objectively review the research.

Procedures for Disclosing a Conflict of Interest

- IRB Member Voluntary Disclosure: It is the responsibility of the IRB member to disclose all certain or potential conflicts of interest prior to engaging in any IRB review or determination activities.
- Query at Convened IRB Meetings: At the beginning of each IRB meeting, the IRB Chair asks members to disclose any conflict of interest concerning any items on the agenda.
- Principal Investigator Disclosure: The investigator submitting a protocol may submit a written explanation of an IRB member's certain or potential conflict of interest prior to the IRB engaging in any review or determination activities.

Determination and Resolution of a Conflict of Interest

- Conflict of interest disclosures will be reviewed by the IRB Chair and/or Coordinator in consultation with two randomly selected members of the IRB Committee.
- If a conflict of interest is identified, the IRB Member will be notified in writing that a disclosure statement has been submitted to the IRB and by whom. The applicable category description(s) listed in the IRB Members-COI Procedures will also be included in the letter. The conflicted IRB member will not participate in the pre-review, exempt determination, or expedited review of the project. For Full Board reviews, the IRB member will be recused. This means that the IRB member will not vote and will be asked to leave the IRB meeting before discussion on the item with which they have a conflict unless the IRB requests that they provide information. When recused, the member does not count towards the quorum for the vote.

# Section 4: Review Procedures and Categories

## 4.A. Data Collection/Reporting/Storage

The protocol must state the manner in which the information (data) will be collected (recorded*), reported (disseminated), and stored.

*Classification of data is determined at the point of collection and recording (i.e., even if the investigator is aware of a participant's identity at the time of collection, the data is still considered anonymous as long as the data is recorded with no links to the participants' identification). If there is a possibility that this or a similar situation may occur during data collection, the protocol should state as such.

Anonymous Information is collected information that does not contain any links to participants' identifiable information.

Confidential Information is collected identifiable private information that the investigator will not divulge improperly (i.e., participants' identities will not be revealed during dissemination or be released to other investigators).

The term *confidential* should not be referenced concerning anonymous information.

Coded Information is collected information that is linked to participants' identifiable information through a confidential code. If the data is coded, this protocol should describe the extent, if any, to which confidentiality of records that identify the subject will be maintained. For example: coded by a random number, the linking information will be kept separate in a locked file or compute, and if identifiers will be destroyed when the study is complete. If participants will be identified in any resulting dissemination (i.e., presentations, publications, etc.) this should be stated in the protocol.

Fully Identifiable Information is collected information that is stored with participants' identifiable information (i.e., name, Social Security Number, etc.). Additional consideration should be given to the confidentiality of records. The protocol should state if confidentiality of records will be maintained and include details on how the participants' identity will be kept confidential in connection with the research study. Exceptions to this confidentiality should be explained (i.e., 'absolute confidentiality cannot be guaranteed, but will be maintained to the extend allowed by law'). If participants will be identified in any resulting dissemination (i.e., presentations, publications, etc.) this should be stated in the protocol.

*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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

*Identifiable Private Information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Identifiable Biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

De-Identified Information is collected Information that was originally fully identifiable or coded but has now had all personally identifiable information and/or links removed.

This label refers to the research data set that is being created. If the data that is recorded by an investigator does not contain any identifiers, the data set is considered de-identified research data even if the investigator otherwise has

access to the data in its identifiable form as long as procedures have been followed to randomize or aggregate the data.

## 4.B. Department Chairperson Review

All research protocols at FSC must be reviewed by the PI's Department Chairperson or Supervisor, who will confirm that the investigator(s) has the appropriate expertise and credentials to perform the research procedures, and, if applicable, the Faculty Advisor/Mentor or Program Coordinator [for student-lead protocols] has the training and expertise to mentor the student researcher(s).

## 4.C. IRB Review

The IRB will use three review categories when considering research protocols. The IRB Chair or designee will determine the appropriate category of review based of the type of research proposed.

A. **Exempt**: Research reviewed by an IRB member. Not subject to continuing review.
B. **Expedited:** Research reviewed by an IRB team comprised of two IRB members. Not subject to continuing review unless FDA regulated or deemed necessary by the reviewers.
C. **Full Board:** Research reviewed by the convened IRB, with a quorum of members present, and subject to continuing review at regular intervals not to exceed 365 days.

There is no distinction made by the IRB in the review of grant funded and non-funded research activities.

## 4.D. Categories Not Considered Research

The following categories are not considered research and do not require review by the IRB. It is recommended that investigators who believe that their project falls into one of the below categories submit a completed *Research Questionnaire* to the IRB for confirmation.

- Scholarly or journalistic activities that focus directly on the specific individuals about whom the information is being collected and will not be used to draw conclusions about the larger population, cultures, norms, and practices, or to generalize findings (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship).
- Secondary analysis of publicly available data / specimens obtained from a producer or supplier of public use data or for which information about the data / specimens is available in the public domain.
- Secondary analysis of de-identified or non-identifiable data. (Additional Information is required. Contact the IRB Office.)
- Institutional assessment / program evaluation for which results are not intended to be generalized or disseminated outside the State University of New York (SUNY).
- Quality assurance / quality improvement / organizational efficiency or other consulting projects for which outcomes will remain specific to the organization, programs, or services, and will not be generalized.
- Class projects for which the sole intent is to meet course requirements with no intention to generalize or disseminate results outside of the course.
- Public health surveillance activities limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate issues of public health importance.
- Collection and analysis of information by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. [Note: Not intended to include social or behavioral studies of the causes of criminal behavior.]
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

## 4.E. Data Use Agreements (DUA)

### Transferring Data to FSC:

New FSC faculty members intending to transfer their previously collected data from a previous institution (either identifiable or de-identified/anonymous): If a DUA is required by the previous institution, the agreement would be between the PI and their previous institution, but it is the responsibility of the PI to inform FSC's IRB of the DUA and/or any restrictions that the previous institution has on the future use of the collected data.

### Secondary Data Provided by Third-Parties:

If a PI plans to obtain data that is not publicly available from a third-party source, a DUA may be required by that third-party prior to releasing the data. FSC's IRB requires the PI to submit a copy of the DUA or written confirmation from the third-party (stating that a DUA is not required). The DUA or written confirmation must state if the data will be provided to the PI as identifiable, de-identified, or anonymous. If the original dataset contains identifiable data, the third-party must stipulate whether or not all identifiable links will be stripped from the data before being provided to the PI. All applicable IRB requirements for the use of secondary data must be followed. Secondary data provided to the PI by a third-party without any identifiable links may not require IRB review. The PI should compete and submit an IRB Questionnaire to the Office of the IRB for an official determination.

## 4.F. Engagement

In general, FSC is considered engaged in a research project when the involvement of FSC employees or agents in the research include any of the following:

- A grant or contract for the research has been awarded to FSC as a lead institution or secondary institution.
- Using FSC property or non-public information to identify and/or recruit human participants.
- Interactions with human subjects (including collecting informed consent).
- Interventions with human subjects.
- Involvement with the data collection activities (including observations).
- Using, studying, or analyzing identifiable private information. Depending on the specific project, using, studying, or analyzing non-identifiable information may also constitute engagement and/or require IRB review or local IRB review. Contact the Office of the IRB for more information.

In general, FSC is not considered engaged if:

- FSC employees/agents perform commercial or other services for investigators provided that all the following conditions are met:
    - The services preformed do not merit professional recognition or publication privileges;
    - The services preformed are typically performed by the institution for non-research purposes; and
    - The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
- FSC employees/agents:
    - Inform prospective subjects about the availability of the research;
    - Provide prospective subjects with information about the availability of the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representative of the investigators;
    - Provide prospective subjects with information about contacting investigators for information or enrollment; and/or
    - Seek or obtain the prospective subjects' permission for investigators to contact them.
- FSC permits the use of campus facilities for intervention or interaction with subjects by investigators from another institution (i.e., an investigator from another institution conducts or distributes a research survey in an FSC classroom). Please see *External Researchers* for more information.
- FSC employees release to investigators at another institution human subjects information.

- If the information was collected for another research study covered by federal regulations, then FSC's IRB must be contacted by the investigators to:
  - Ensure that the release would not violate the informed consent provided by the subjects to whom the information pertain, or
  - If informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determination that permitted a waiver of informed consent under the federal regulations.
- FSC institutional approval may be required by the Office of the Academic Affairs before the human subjects information may be released. Contact the Office of the IRB to discuss.
- In general, the institution whose employees/agents obtain the human subjects information from FSC would be considered engaged in human subjects research.

The IRB will consider the HHS/OHRP guidance available on the HHS website when determining other engagement classifications.

## 4.G. Institutional Authorization Agreement (IAA)

A formal, written agreement that indicates that one institution's IRB is relying on another institution's IRB for the review of research project(s) rather than conducting their own independent review(s). IAAs are utilized when multiple institutions are engaged in a research activity. Contact the Office of the IRB for additional instructions and information.

## 4.H. Consultants and Local Context Reviewers

The IRB may, at its discretion, invite individuals with expertise in a special topic (Consultants) or the local norms, language and culture of the geographical area where the research will be conducted (Local Context Reviewer or LCR) to assist in the review of complex issues that require expertise beyond, or in addition to that available on the committee. The need for a Consultant/LCR may be determined in advance of or during the review of the study. If the need for a Consultant/LCR is determined at a Full Board meeting, the study will be tabled and reviewed at the next convened IRB meeting. The Consultant or LCR does not take part in committee deliberations or voting. The consultant or local context reviewer must not have a conflict of interest of any kind concerning the research protocol being reviewed (this process is equivalent to the *IRB Member Conflict of Interest Procedure*), and must be documented in the protocol record. A copy of the Consultant or Local Context Reviewer's curriculum vitae or professional resume is required and will be included in the protocol file.

## 4.I. International Research

The IRB will review all international research using human participants to assure adequate provisions are in place for the protection of human subjects (equivalent or greater than the Common Rule). The IRB will refer to the knowledge of the LCR or by requesting approval documentation from local IRBs or ethics committees (which may or may not be OHRP registered). If local oversight has been conducted (by an IRB or ethics committee), an LCR is not required. Additionally, site permission and local letters of support may be requested. All instruments and documents should be provided to the IRB in the primary language of the study site and in English.

Approval of research at foreign institutions or sites "not engaged" in research is only permitted if one or more of the following exist:

- The investigator receives approval from the local IRB or ethics committee to conduct research at the site or the local IRB or ethics committee determines that approval is not necessary.
- If there is not an established local IRB or ethics committee, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the site.

For federally funded research, approval of research at foreign institutions or sites “engaged” in the research is only permitted if the foreign site holds an Assurance with OHRP and local review and approval is obtained.

Investigators may have reporting responsibilities regarding foreign affiliations related to their academic work and international research. Investigators should contact the Office of Academic Affairs for more information. If the international research is grant funding, investigators should also contact the Office of Sponsored Programs Operations for more information.

## 4.J. Internet Research Recruitment

Internet research includes both the Internet as a research tool (i.e., participant recruitment through a social media platform message post, direct messaging, email, etc.; administering a survey through an online platform), and as a research site (i.e., collecting data from an Internet space such as a social media platform or user review).

Investigators should be cognizant that the authentication of identification of respondents and data provided through Internet-based research could be challenging and may threaten the integrity of research samples and the validity of research results. The need for identity confirmation depends on the following:

- Importance to the research
- Level of risk to subjects
- Third-party policy or terms of agreement
- Norms and expectations of users and venues

In general, if individuals intentionally post or otherwise provide information on the Internet, such information should be considered public unless existing law and/or the privacy policies and/or terms of service of the entity receiving or hosting the information indicate that the information should be considered private. Any venue where membership or participation must be authorized should be considered private. However, the IRB will use a holistic approach when making a determination and may consider:

- Is a password required?
- Is the venue moderated?
- Is the venue intended for use by individuals who share a particular condition or interest? Are the norms dictated or determined by the users "shared priorities"?

Moreover, if an Internet activity is being observed by the investigator, includes identifiable information, and is available without restriction to any authorized user of the site, it is considered research with human subjects (observation of public behavior). Examples include comments postings on news sites; posting on publicly available hosting sites (i.e., *YouTube*, etc.); postings on classified sites (i.e., *Craigslist*, etc.); postings on unrestricted blog or wiki sites; and information posted without restrictions to social networking sites (i.e., *Facebook*, *Instagram*, *LinkedIn*, etc.).

However, if the identity of the subject cannot be readily ascertained by the investigator or associated with the information then the activity is not research involving human subjects. Please note that forms of identity, including avatars, can be considered as virtual representations of a human subject (if personally identifiable information about living individuals can be obtained by observation or interaction).

## 4.K. FSC Faculty/Staff Doctoral Dissertations

FSC's IRB requires review of FSC faculty/staff member research projects involving human subjects conducted in conjunction with their doctoral dissertation if any of the following conditions are met:

1. Researcher (i.e., FSC faculty/staff) affiliates with FSC on any dissemination of results (i.e., publications/presentations), and/or FSC institution affiliation is referenced in any part of the research activity or citation.
2. Study team members such as Co-Is or RAs are FSC faculty members (excluding adjunct professors), staff, or students.
3. Project funding is provided by FSC.
4. Research participants (i.e., subjects) will be recruited at FSC (i.e., FSC students, faculty, or staff), and/or data will be collected at FSC.

If none of the above criteria are met, no action is required by the researcher at FSC. If the researcher has not already done so, FSC's IRB strongly recommends that the researcher contact the IRB at their "home" institution for guidance on submitting a research protocol for review before initiating any research activities, including participant recruitment and data collection.

If a research project meets any of the criteria above, the following steps must be completed prior to the initiation of any research activities including participant recruitment and data collection:

1. The research protocol must be submitted to the doctoral institution's IRB for review.
2. Once an Exempt determination or an approval has been issued, the investigator should then submit the complete protocol and official decision letter to FSC's IRB.
3. Depending on the category of research, FSC's IRB will either conduct an independent review or enter into an Institutional Review Board Authorization Agreement (IAA) with the home institution.

Please note: FSC's IRB is not able to provide retroactive approvals. If there is any possibility that the project meets any of the criteria indicated above, the project must receive FSC's IRB approval/ Exempt determination or an IAA must be fully executed before initiating any research activities including participant recruitment and data collection.

## 4.L. Adjunct Professor Research Activities

**Adjunct Professor** is a college professor whose employment is temporary or part-time.

FSC's IRB requires review of adjunct professor research projects involving human subjects if any of the following conditions are met:

1. Researcher (i.e., adjunct professor) affiliates with FSC on any dissemination of results (i.e., publications/presentations), and/or FSC institution affiliation is referenced in any part of the research activity or citation.
2. Study team members such as Co-Is or RAs are FSC faculty members (excluding adjunct professors), staff, or students.
3. Project funding is provided by FSC.
4. Research participants (i.e., subjects) will be recruited at FSC (i.e., FSC students, faculty, or staff), and/or data will be collected at FSC.

- If none of the above criteria are met, no action is required by the adjunct professor researcher at FSC.
- Research projects that meet any of the criteria above will require FSC's IRB review/approval before initiating any research activities including participant recruitment and data collection.
    - If the protocol has been reviewed by an external IRB, please contact the Office of the IRB for guidance.
    - If the protocol has not been reviewed by an IRB, please submit the protocol to FSC's IRB for review. Please see the IRB webpage for more information. If you have any questions, please contact the Office of the IRB.

- If the researcher has not already done so, FSC's IRB strongly recommends that the researcher contact the IRB at their "home" institution for guidance on submitting a research protocol for review before initiating any research activities, including participant recruitment and data collection. Please note: FSC's IRB is not able to provide retroactive approvals. If there is any possibility that the project meets any of the criteria indicated above, the project must receive FSC's IRB approval before initiating any research activities including participant recruitment and data collection.

## 4.M. External Researchers

These policies also apply to and must be complied with by external investigators (not affiliated with FSC) who plan to conduct research accessing FSC facilities and/or resources; and recruiting faculty, staff, and students as research participants.

Researchers not affiliated with FSC must obtain approval from the appropriate Department Chairperson and Dean (if applicable) and FSC's Provost/Vice President of Academic Affairs (facilitated by the IRB) prior to conducting research accessing FSC facilities and/or resources; and recruiting students, faculty, and/or staff as research participants.

Procedures (*4-6 weeks)*:

- External Researchers must submit *FSC-IRB Form M: External Research Request* along with a copy of the approval letter from the IRB of Record and the complete research protocol including all supporting documents (i.e., Informed Consent forms, recruitment materials, study measures, human research participants training program certificate(s), etc.) to IRB@farmingdale.edu.
- FSC's IRB will evaluate the application and supporting documents and provide a recommendation to the appropriate FSC Department Chairperson (if applicable), Dean (if applicable), and Provost/Vice President of Academic Affairs. The Provost/Vice President of Academic Affairs may also seek input from additional stakeholders on campus.
- Institutional Approvals are granted on a case-by-case basis.
- If Institutional Approval is granted, the researcher will receive official notification from FSC. Researchers may not access FSC facilities and/or resources; or recruit or contact any potential participants from FSC until this notification is received.

## 4.N. Collaborative/Cooperative Research

Collaborative/cooperative research includes projects for which multiple institutions are engaged in human participants research and/or investigators from multiple institutions are engaged in human participants research.

*Principal Investigator is affiliated with FSC*:
For multi-site research, it is expedient to have the research reviewed at the institution of the PI. This, however, does not preclude the need for IRB approval from the other institutions. Rather than having each institution conduct a separate review, FSC's IRB will review and approve the protocol and Institutional Authorization Agreements (IAAs) will be requested from each institution.

*Principal Investigator is not affiliated with FSC:*
If the protocol has already been approved by another IRB, the PI may submit those protocol forms and the approval letter to the FSC's IRB. FSC's IRB may complete an independent review (if deemed necessary) or request an Institutional Authorization Agreement (IAA) with the PI's institution.

## 4.O. Research Conducted at Other Institutions

Investigators who plan to recruit participants and/or conduct study procedures at institutions other than FSC (e.g., schools, hospitals, organizations), must obtain and submit written permission from each site to conduct the research

in addition to receiving approval through FSC's IRB. A *Site Permission Letter* template is available on the IRB webpage. While investigators are not required to use this template, the permission letter must include all essential elements found in the template. In certain circumstances, the site permission requirement may be waived for Exempt reviewed research on a case-by-case basis. Please contact the Office of the IRB for additional information.

## 4.P. Student Coursework Research Activities

If the goal of the student coursework activity is to fulfill a course/major requirement and not to add to generalizable knowledge, the project may not meet the definition of "research" and therefore may not require IRB review.

These projects are conducted by students to fulfill a class assignment, and may involve interactions with members of the class and/or external research participants (e.g., Research Methods courses where students design and conduct a research protocol involving data being collected/analyzed for the purposes of learning how to do research under the supervision of the course instructor.) Typically, these assignments are initiated and completed within the timeframe of the course. These projects are not intended to create generalizable knowledge or to lead to publication or presentation outside of FSC, but findings may be presented in class to peers, and/or at a student research conference/showcase on FSC's campus.

Please note: The IRB is not able to provide retroactive approvals. If there is any possibility that the project may be presented/published outside of FSC or the project does not meet all of the criteria indicated below, the project must receive IRB approval before initiating data collection.

Faculty must be fully aware of all aspects of the project and take responsibility for overseeing the project and assuring that all research activities adhere to ethical principles. Faculty also should ensure, to the best of their ability, that students realize any potential for harm and take all possible steps to eliminate the risks to students or individuals outside the classroom involved in the assignment. These risks may include potential physical, psychological, social, economic, or legal harm.

A project that is solely a student coursework activity as described above does not require IRB review if it meets all of the following criteria:

- The project involves no more than minimal risk to subjects.
- The project topic and protocol activities are benign in nature; are course appropriate as determined by the instructor; and do not cover sensitive topics (such as sexual activity, substance abuse, spousal abuse, and/or other similar subjects). If you are unsure about a specific project, please contact the Office of the IRB.
- The project does not involve deception.
- The project does not involve vulnerable populations such as prisoners, people with diminished capacity for giving consent, and/or minors under the age of 18.
- The project involves the voluntary participation of individuals without any coercion or pressure being placed upon them.
- The research participants/information is anonymous (no identifiable data will be collected).
- The results will not be presented, published or distributed beyond the FSC campus.
- The student, not the course instructor, is the principal investigator of the project.
- A Research Information Sheet (following FSC's template) will be provided to all participants.
- Both the course instructor and the student researcher(s) must complete the appropriate FSC CITI training course option for research involving human participants. See the IRB web page for more information.
- Projects involving human subjects that do not meet all of these criteria, even if they are conducted as student coursework activity projects, will require IRB review/approval before initiating data collection. If you have any questions, please contact the Office of the IRB.

## 4.Q. FSC Student Researchers

Research protocols with a PI, Co-I or RA who is a FSC student are governed by the same federal policies mandating the protection of human subjects known as the "Common Rule" as other researchers on campus. The Faculty Advisor/Mentor or Program Coordinator associated with the project is ultimately responsible for assurance that the research conducted by FSC students is in full compliance with FSC's policies and federal regulations governing human subject research and the protocol is conducted as described to the IRB.

*FSC Lead Research*:
*Research projects with an FSC Student PI*:

- An FSC faculty member must be listed as a Faculty Advisor on the protocol. The Faculty Advisor shall become the PI if/when the student leaves FSC.
- A student may be listed as a PI for Exempt research; however, a student's role in research reviewed via the Expedited review process will be reviewed on a case-by-case basis. A student is not permitted to be listed as a PI for research referred to the Full Board for review.
- Refer to the procedures for submitting a research protocol for IRB review on the FSC IRB webpage and the Axiom IRB portal (Go to MYFSC, click Axiom Mentor on the left side navigation list and click IRB at the top).

*Research projects with an FSC Faculty PI*:

- FSC students involved in any aspect of a research project are subject to the same regulations and requirements as other Co-Is or RAs (e.g. Human Participants Research Training, Conflict of Interest Certification, etc.).
- Refer to the procedures for submitting a research protocol for IRB review on the FSC IRB webpage and the Axiom IRB portal (Go to MYFSC, click Axiom Mentor on the left side navigation list and click IRB at the top).

*Non-FSC Lead Research*:
*Research projects with an FSC student Co-I or RA lead by an outside Institution with an OHRP registered IRB**:

FSC's IRB will review the protocol documentation from the outside institution to determine if it qualifies as Exempt, Expedited Review or Full Board Review at FSC. The following documentation is required to be submitted via Axiom Mentor for review (see Axiom Mentor for additional instructions):

- The original IRB protocol and approval letter from the home institution.
- The modification documents adding the FSC student to the project and approval letter (if applicable).
- Proof of Human Participants Research Training for student and FSC Faculty Advisor/Mentor or Program Coordinator.
- Institutional Review Board Authorization Agreement (if applicable). The IRB of the home institution (the outside institution) in most cases will serve as the IRB of Record for Expedited and Full Board protocols. An Institutional Review Board Authorization Agreement (IAA) between FSC's IRB and the IRB of Record should be utilized for Expedited and Full Board protocols. Please contact the Office of the IRB at the start of the IAA process.

*This includes NSF Research Experiences for Undergraduates (REU) Research Sites (i.e., FSC student visiting another institution to work on an NSF funded research project to satisfy a program requirement at FSC).

*Research projects with an FSC student Co-I or RA lead at an outside institution without an OHRP registered IRB*:
The FSC student must submit a protocol for FSC's IRB review if the project's outcome is considered or has the possibility to become generalizable knowledge. The key defining factor is whether the purpose of collecting the data is to answer a universal question that would apply outside the walls of the home institution. In other words, if the human participant information (i.e., data) are collected solely for internal "evaluation" it is not considered "generalizable knowledge" and such evaluation does not require IRB review. However, if the data have any relevance to answer research questions outside of the home institution, it is considered research with human

subjects and would require IRB review. In practical terms, if the data could lead to publication/presentation in any venue outside of home institution (conference presentation, professional journal, etc.) then the data are answering some aspect of generalizable knowledge and the project would, therefore, require IRB review. The IRB is not able to provide retroactive approvals, so if there is any possibility that the project may lead to information that would be presentable/publishable in the future, the project must receive IRB approval before initiating data collection. The student and/or Faculty Advisor/Mentor or Program Coordinator should explain generalizable knowledge to the home institution prior to the start of the student's involvement in the project.

The following documentation is required to be submitted for review:

- Exempt Application (completed by the student through Axiom Mentor- Go to MYFSC, click Axiom Mentor on the left side navigation list and click IRB at the top). An overall description of the project and details on the student's specific role should be included. If the project does not fall into an Exempt category, please contact the Office of the IRB for further instructions
- Proof of Human Participants Research Training for student and FSC Faculty Advisor/Mentor or Program Coordinator.

## 4.R. Research Involving Deception

If a research protocol involves deceiving study participants or omitting pertinent information from the Informed Consent form or Research Information Sheet, the protocol must include a detailed description, justification, and include a request for alterations to the Informed Consent or Research Information Sheet elements. Participants must be at least 18 years of age or older. The study procedure must include a debriefing process whereby the participants are informed of the deception, its purpose, and given the opportunity to withdrawn from the research. The written debriefing form that will be provided to participants must be submitted with the protocol for review. The deception must be necessary to execute the research (i.e., there are no other alternatives), and participation will not place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing. Specific protocols may require research team members conducting the debriefing to be trained to elicit and respond to subject concerns. At FSC, research that involves deception does not qualify for Exempt review unless the deception proposed is minor in scope and the impact to the risk to participants is deemed minimal (except where noted in the Section 4.T.(3) of this manual). The IRB will make this determination on a case-by-case basis.

## 4.S. Preliminary Review

The IRB Coordinator will conduct a preliminary review of all submitted protocols to verify the submission of valid human subjects' training certificates, conflict of interest disclosures and required signatures (Department Chairperson, PI, Co-I, etc.) Completion and accuracy of the protocol will also be checked. If needed, the Coordinator will communicate any required actions to the PI. The protocol will only be assigned to an IRB reviewer(s) after any issues identified by the Coordinator have been satisfied. The Coordinator may post additional comments for the IRB reviewer(s) to consider during their review.

## 4.T. Exempt Research Categories

Research activities qualify for exemption status as long as the activity fits into one of the categories below and the activity involves no more than minimal risk to human participants. FSC does not permit research that includes participants who are minors or prisoners to be determined as Exempt (exceptions for minors will be considered on a case-by-case basis). If the research includes participants who are minors or prisoners, FSC requires the protocol to be referred to Expedited review. Exempt status is determined based on the answers provided in the Exempt application by the PI. The only involvement of human subjects in the research activities must be in one or more of the exempt categories listed in the federal regulations below:

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

**(2)** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

**(3)**(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).
(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

**(4)** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and

E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

**(5)** Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
(ii) [Reserved]

**(6)** Taste and food quality evaluation and consumer acceptance studies:
(i) If wholesome foods without additives are consumed, or
(ii) 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.

**(7)** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).

**(8)** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 46.116(a)(1) through (4), (a)(6), and (d);
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;
(iii) An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The provision for obtaining broad consent as outlined in 45 CFR 46 is only allowed at FSC under limited circumstances; however, FSC Investigators are permitted to access previously collected data where broad consent was obtained from participants.

## 4.U. Exempt Review Procedure

FSC's IRB conducts local reviews of all Exempt protocols. This additional oversight allows the IRB to obtain holistic information about protocols with the goal of protecting the rights and welfare of participants in human research. A local review is conducted by a member of the IRB. Its purpose is to confirm that, when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Additionally, FSC's IRB utilizes this process to ensure that additional local requirements are satisfied, to confirm that there are adequate provisions to protect the rights and welfare of human participants, and to assure the risk level is not greater than what a participant would experience is everyday life. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. Exempt research must fall into one of the categories listed above. FSC requires each prospective subject or the subject's legally authorized representative be presented with a Research Information Sheet prior to their voluntarily participation in an Exempt research study (in rare cases a waiver may be granted). Documentation of this process (i.e., participant's signature) may be required.

Protocols determined to be Exempt are reviewed by an IRB Member and each protocol meets the criteria in 45 CFR 46.111(7) (When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data).

An IRB member will review this application to determine whether or not the research activity qualifies for Exempt determination. The Coordinator will then notify the investigator in writing regarding the status of the application and provide any reviewer feedback. Once the review is complete, the determination letter will site the specific category under which the research qualifies as Exempt, and will be signed by the IRB Chair/designee. The designation is valid as long as the project continues as stated in the original proposal. No modifications to the protocol may be implemented until first reviewed and approved by the IRB.

If the administrator determines that the protocol does not qualify as Exempt, the investigator will be advised in writing to submit the protocol to the IRB for either Expedited or Full Board review. Exempt studies are held to the same ethical standard as any other study. The exemption status does not absolve the investigator from following regulatory and ethical guidelines for research at FSC.

## 4.V. Expedited Research Categories

The IRB may use the Expedited review procedure to review research activities that fall under the following categories:

1. Clinical studies of drug and medical devices when an IND or IDE is not required.
2. Collection of blood samples by finger/heel/ear stick or venipuncture from:
    - Healthy, non-pregnant adult (weighing at least 110 lbs.) up to 550 ml in an 8-week period, nor more than 2x per week.
    - Others, no more than the lesser of 50 ml or 3 ml/kg in an 8-week period, nor more than 2x per week.
3. Biological specimens by non-invasive means (hair/nail clippings, deciduous or extracted teeth, excreta and external secretions (e.g., sweat), saliva, placenta, amniotic fluid (at time of rupture), dental plaque, mucosal/skin cells obtained via swabbing, sputum.
4. Data from non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice excluding procedures involving x-rays or microwaves.
5. Research involving materials collected for non-research purposes (data, documents, records, specimens). [Note: Research in this category may qualify as exempt.]

6. Data from voice, video, digital or image recordings made for research purposes.
7. Research on individual/group characteristics or behavior, or research involving survey, interviews, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [Note: Research in this category may qualify as exempt.]

- If the review team determines that the study involves more than minimal risk, it must be referred to the Full Board for review.
- The standard requirements for informed consent (or it's waiver, alteration, or exception) apply to studies approved via Expedited review.

## 4.W. Expedited Review Procedure

Expedited protocols are reviewed by a 2-person review team with the appropriate expertise chosen from the membership of the IRB. Reviewers are selected according to the specific expertise needed to review the protocol. Additional consideration will be given to special issues and populations when reviewers are assigned (whenever possible).

The full protocol, including consent form(s) and all pertinent supporting documents, will be considered. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research (disapproval may only be decided at a meeting of the full committee). Once the review has been completed, the investigator will be notified regarding the status of the application and provide any reviewer feedback. This written notification will indicate that the application was fully approved, required modifications/ clarifications in order to secure approval, or referred for full committee review. Expedited protocols are not subject to continuing review unless deemed necessary by the reviewers.

## 4.X. Full Board Review Procedure

All non-Exempt research that does not qualify for Expedited review as determined by the primary two-member IRB review team will be reviewed by the IRB at one of its convened meetings. Alternatively, the Expediting reviewer(s) may refer a submission to the Full Board for guidance (e.g., clarification, expertise) concerning various topics including risk level determination. At the Full Board meeting, the review team members will lead the discussion of the research including the positive and negative aspects, risk and benefits, suggestions for changes to the proposed research (if applicable), determining if the IRB approval criteria are met, etc.

Full Board Review refers to review at a convened IRB committee meeting where a quorum is present. A quorum is the presence of greater than half of the voting membership including at least one member whose primary concerns are in non-scientific areas. All IRB members are expected to review all protocols referred to the Full Board. Approval of research is by a majority vote of the quorum. The IRB Chair will confirm that an appropriate quorum is present before calling the meeting to order. IRB members are considered present if participating through teleconference or videoconference. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, or absence of a non-scientific member) the IRB may not take further actions or votes unless a quorum is restored. The Chairperson shall be counted as a voting member and will count towards quorum. The Chair can vote on all protocols, or choose to abstain.

Copies of all protocols to be reviewed at the meeting are made available to the members through Axiom Mentor approximately 10 days before the meeting. All committee members have access to the full protocol including all supporting documentation.

The IRB may, at its discretion, invite the following individuals to attend a meeting. Such guests do not take part in committee deliberations or voting:

- The PI and other members of the study team (if applicable) to answer questions from the committee.

- Individuals with competence in special areas (consultants, local context reviewers, etc.) to assist in the review of complex issues that require expertise beyond, or in addition to that available on the committee.

Ex-officio guests are individuals who are not members of the IRB, but by virtue of their position, regularly attend IRB meetings (e.g., the IRB Coordinator). Ex-officio guest may participate in discussions and deliberations, but do not vote.

After the meeting, the investigator is notified in writing regarding the status of the application. The application may be approved, require clarifications/modifications in order to secure approval (revisions are clearly delineated by the IRB), deferred/tabled (i.e., responses from the investigator must be brought back to the full committee), or disapproved. The approval period will be indicated in the letter, and the approved consent form will be officially stamped (copies of which must be utilized for consenting subjects).

Approval periods of projects requiring full committee review (initial or continuing) are dependent on the degree of risk associated with a study and cannot extend beyond the 1-year anniversary (minus 1 day) of the convened committee approval date. Certain projects may require review more often than annually based on other factors, aside from degree or risk (e.g., past history of investigator non-compliance, emerging technologies, new investigators).

The IRB can review minor changes to research approved by the full committee via the expedited review procedure. A minor change is defined as one that has no substantive effect upon or reduces the protocol risk already approved by the full committee.

Continuing review, protocol amendments, consent form modifications, adverse event reports, protocol violations, and other related research activities will be reviewed by Expedited or Full Board review procedures as appropriate.

## 4.Y. Required IRB Protocol Documents

All research activities that involve human participants must be reviewed prior to commencement of any research activity. All protocols should be electronically submitted for review through Axiom Mentor, unless otherwise directed by the IRB.

**Exempt Protocols**: PI must complete the Exempt application, file the Conflict of Interest disclosure and submit proof of valid human subjects' research training. Additional supporting documents such as the Research Information Sheet should not be submitted unless requested by the IRB.

**Expedited/Full Board Protocols**: PI must complete the Expedited/Full Board application and submit all supporting documentation including Informed Consent Form, recruitment materials (i.e., letters, emails, social media post, posters, flyers, etc.), study measures (i.e., surveys, questionnaires, interview/focus group questions, tests, puzzles, etc.). Conflict of Interest disclosures and proof of valid human subjects' research training must be submitted for all study team members. Additional documents may be required based on the specific protocol reviews.

## 4.Z. Criteria for IRB Approval of Expedited/Full Board Research

- If the review team determines that the study involves more than minimal risk, it must be referred to the Full Board for review.
- Please refer to the federal guidelines for additional guidance, if the protocol involves:
    - Subpart B—Additional Protections for **Pregnant Women, Human Fetuses and Neonates** Involved in Research
    - Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving **Prisoners** as Subjects
    - Subpart D—Additional Protections for **Children** Involved as Subjects in Research

- Continuing reviews of Expedited protocols are not required unless the review team determines that it is warranted appropriate based on the degree of risk, or if the research is subject to FDA regulation. The IRB review team may determine that length of the approval (one year or less). A justification for this determination will be documented in the Axiom protocol record.

In order to approve a research activity, the IRB must determine that all of the following criteria are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.,* the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with 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.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(8) For purposes of conducting the limited IRB review required by 46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- The provision for obtaining broad consent as outlined in 45 CFR 46 is only permitted at FSC under limited circumstances; however, FSC Investigators are permitted to access previously collected data where broad consent was obtained from participants.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

## 4.AA. Research Conducted Without IRB Approval

FSC's IRB does not provide retroactive approvals. If the information that will be collected has any relevance to answer research questions outside of FSC (e.g., generalizable knowledge), and/or if there is a possibility that the project may lead to information that would be presentable/publishable (e.g., conference presentation, scientific journal, educational journal, etc.) in the future, the project must receive IRB approval before initiating data collection. There may be circumstances where the research activity involves the secondary use of data collected for another purpose, but the original data collection must be outside the purpose of the research (e.g., quality improvement, normal educational practices, etc.)

Research initiated or completed without IRB review/approval will be considered by the IRB on a case-by-case basis. Although IRB approval will not be permitted, a review of the project will be conducted by the IRB Chairperson. If the protocol raises to the level of Expedited review, an additional IRB member will also review; if to Full Board review, the protocol will be reviewed by a quorum of the IRB membership. Consideration will be given to whether the PI and/or Faculty Advisor/ Mentor was unaware of the IRB review requirement, the original intent of the data collection, and if the study procedures were otherwise in accordance with Federal and the College's standards for ethical conduct in research. The IRB will make determinations concerning the following:

- Permission to use the already collected data
- Permission to continue the data collection (if collection is not complete)
- Modifications required to the protocol

A letter from the IRB Chairperson will be sent to the PI and/or Faculty Advisor/Mentor detailing the IRB's decision; however, formal IRB approval cannot be retroactively provided.

## 4.AB. Appealing an IRB Determination:

Investigators who believe an IRB determination to be unfair, unsubstantiated, and/or unduly restrictive on the research should follow the following appeal procedure:

- Contact the IRB Coordinator to discuss the determination and the reason(s) for the informal appeal. The IRB Coordinator will present the appeal to the IRB Chairperson for review and determination.
- If the informal appeal cannot be resolved by both parties, a formal appeal may be submitted in writing to the IRB within 90 days of the date of the decision letter from the IRB. The appeal must be made in writing and sent to the Office of the IRB along with any supporting documents. The Chair and the IRB Coordinator will review the appeal and decide whether additional information is necessary to present to the full committee at the next convened meeting. The Chair may invite the investigator to attend the meeting to give a presentation of the protocol and to address problematic issues. Written notification of the IRB's decision of the appeal will be sent to the PI following the meeting. A decision for disapproval after appeal is final. If significant modifications are made to a previously disapproved protocol it may be submitted as a new protocol. The IRB Chair has the authority to determine whether a previously disapproved protocol has been amended sufficiently to warrant review as a new protocol.

# Section 5: Recruitment of Study Participants

*The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude the consideration of inherent risks to the individual.*

## 5.A. Recruitment Plan

Investigators must include their plan for recruiting human research participants in their IRB application. If a protocol is already approved and an investigator wishes to utilize a new method for recruiting participants, the recruitment plan must first be approved by the IRB. Potential research participants may be recruited for research studies using a number of different methods. Potential recruitment methods include the FSC Participant Pool, direct contact, advertising, record review, database review, or other written/verbal correspondence. Recruitment methods must comply with federal regulations regarding the protection of human subjects.

## 5.B. Written Correspondences

Any written Correspondences that are sent to a potential research participant is considered under the guidelines for advertising (see below) and must not contain coercive language. It should briefly explain the study, its purpose, and the reason why the person is being asked to participate. There should be a mechanism by which the person can express an interest (i.e., e-mailing the investigator, clicking a link, etc.). Failure to respond should not be construed as a willingness to participate. It must also be clearly stated that participation is voluntary, and the subject has the right to refuse to participate without any loss of benefit to which they would otherwise be entitled. If possible, a copy of the consent form for the study should be sent with the letter/email, along with contact information where the person can direct questions.

In some cases, contacting potential research subjects in writing will occur only when that potential subject is familiar with a member of the study team. If personal information about the potential subject is necessary in order to identify them as a potential participant (such as having a certain disease or medical condition) then the contact shall come from a person that they would expect to have that information about them (e.g., their doctor, a disease-related organization that they belong to, etc.).

## 5.C. Advertising

An investigator may not utilize any advertising material prior to approval by the IRB. All proposed advertising material must be submitted to the IRB for approval. This includes:

- Printed media advertisements
- Internet advertisements, including any information about the study to be posted on a website
- Social media posts
- Scripts of radio or television commercials
- Flyers, postcards, letters/email, text messages, pamphlets, brochures, or videos
- Any other written or verbal advertising materials

The PI must submit all advertising materials with initial Expedited/Full Board protocols (and Exempt protocols only if requested by a reviewer) or as an amendment to a previously approved Expedited or Full Board study. The IRB will employ the appropriate review mechanism (i.e., Expedited or Full Board) to review the advertising material based on its content. When reviewing, the IRB will assure that the advertising material:

- Is not unduly coercive (especially when targeted toward subjects who might be vulnerable to undue influence)

- Does not state or imply a certainty of favorable outcome or other benefits beyond which is outlined in the consent form or protocol
- Utilizes an appropriate typeface and visual effects
- Includes appropriate wording and presentation (especially for audio and video presentations)
- Does not provide misleading information to potential subjects
- Avoids portraying study procedures as "new", and does not use phrases like "receive new treatment" that might lead study subjects to think they are receiving a modality or treatment of proven worth
- Avoids use of the term "free treatment" when what is meant is that the study will not cost the subject anything
- Provides payment information in a manner that does not emphasize the payment amount by use of a larger or bolder type

Consistent with federal guidance in this area (FDA Information Sheets, 1998), the IRB limits the information that can be included in an advertisement to information that the prospective subject needs to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements (if appropriate):

- The name and address of the Principal Investigator, department and/or location of research facility
- The condition or area under study and/or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

## 5.D. Recruitment of Vulnerable Populations

The following populations are considered vulnerable: Students, Employees, Minors (under age 18)*, Pregnant Women, Fetuses, Neonates*, Individuals with Impaired Decision-Making Capacity, Non-English speakers, and Prisoners*. If the research involves any of these populations, the protocol should note the specific populations and any additional protections that will be provided.

*See the sections of this manual pertaining to these specific populations for additional information.

## 5.E. Recruitment of Minority, Marginalized, and/or Underrepresented Groups

Participants from minority, marginalized, and/or underrepresented groups must receive an equal share of the benefits of research and not bear a disproportionate burden.

## 5.F. Recruitment of FSC Employees as Research Participants

The use of employees as research participants may be permitted depending on the nature of the research and as long as they are treated as any other research subjects would be in compliance with federal, state, and institutional policy regarding the use of human participants in research. In most cases, investigators will not be allowed to recruit employees who work directly under their supervision. The final decision to allow employees as participants will be made by the IRB on a case-by-case basis.

Employees need additional protection because their position with regard to the investigator may make them vulnerable to undue influence. An employee who is asked to participate in a study that is being conducted by a professor, supervisor, or other person who has authority over them may feel compelled to comply with the request lest they be punished or deemed non-cooperative. The nature of the relationship between the prospective participant and the investigator may lead to a coercive recruitment environment. Employees who wish to become involved as research participants are subject to the same protections as any other human participants. A consent form (if applicable for a particular study) must be provided to all participants as there are no exceptions made for employees.

## 5.G. Recruitment of Students as Research Participants

The use of students as research participants may be permitted depending on the nature of the research and as long as they are treated as any other research participants would be in compliance with federal, state, and institutional policy regarding the use of human participants in research.

Students need additional protection because their position with regard to the investigator may make them vulnerable to undue influence. A student who is asked to participate in a study that is being conducted by a professor, supervisor, or other person who has authority over them may feel compelled to comply with the request lest they be punished or deemed non-cooperative. The nature of the relationship between the prospective participant and the investigator may lead to a coercive recruitment environment. Students who wish to become involved as research participants are subject to the same protections as any other human participant. A consent form (if applicable for a particular study) must be provided to all participants as there are no exceptions made for students.

College students who are under the age of 18 may participate in studies that are specifically approved for the inclusion of minors. Further, unless a waiver of parental permission has been requested by the investigator and granted by the IRB, permission of the parent of the minor participant will be required. Regardless of whether or not such waiver is granted, assent of the minor participant will be required. A waiver may be granted for studies for which the risks to the participants are determined to be minimal.

No student, minor or otherwise, can be required to participate in research studies as part of their course requirements, as research participation must be voluntary. Participation in a research study as part of a course or to earn extra credit is allowable as long as a comparable alternative is also offered, there is no penalty or undue burden in choosing the alternative, and it is described in the Research Information Sheet or Informed Consent process.

## 5.H. FSC Participant Pool (Psychology Department and School of Business)

The FSC Participant Pool is a mechanism to recruit and award extra credit to subjects for research participation. The pool is only open to FSC students currently enrolled in FSC Psychology or Business courses. Please contact the Participant Pool Administrators for more information.

## 5.I. FERPA Guidance on Using Educational Records for Research

- **Biometric Record**: As used in the definition of personally identifiable information, means a record of one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual. Examples include fingerprints; retina and iris patterns; voiceprints; DNA sequence; facial characteristics; and handwriting.
- **Educational Records**: Any record that can be linked to a student including grades, class assignments, advising notes, transcripts, video of students in class, online course discussions (FSC sanctioned platform), etc.
- **FERPA**: The Family Educational Rights and Privacy Act is a federal law that gives parents certain rights with respect to their children's education records. These rights transfer to the student when they reach the age of 18 or attends an educational institution beyond the high school level.
- **Personally Identifiable Information (PII)**: The term includes, but is not limited to the student's name, the name of the student's parent or other family members; the address of the student or student's family; a personal identifier, such as the student's social security number, student number, or biometric record; other indirect identifiers, such as the student's date of birth, place of birth, and mother's maiden name; other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; or information requested by a person who the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates.

- **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Research Participant (Human Subject)**: A living individual about whom an investigator (whether professional or student) is conducting research (i.e. obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens).
- **Research Protocol**: Documents describing the background, rationale, objectives, design, methodology, statistical considerations, and organization of a research project.
- **Wet Signature**: A person's name written in their own hand with ink.

## PURPOSE

In accordance with the provisions of the Family Educational Rights and Privacy Act (FERPA) (20 USC 1232g; 34 CFR Part 99), Farmingdale State College (FSC) has established the following guidelines for requesting and using educational records from FSC for research purposes. This is designed to ensure that research conducted by internal or external investigators using FSC educational records is FERPA compliant. These guidelines are for research purposes only. To obtain educational records for non-research purposes contact the applicable office (see chart below).

## GUIDELINES

For purposes of FERPA compliance, researchers interested in using FSC educational records containing personally identifiable information (PII) of students must obtain permission from the student to use those records prior to data collection.

Most research projects involving the collection of data from human subjects require prior review/approval from FSC's Institutional Review Board (IRB). Institutional permission to access FSC educational records for research purposes (if applicable) should be requested in conjunction with the IRB review process.

## PROCEDURES

Researchers may request select educational records by submitting a *Research Data Release Form* to the corresponding department (see chart below) for approval. Once the request has been approved, the *Research Data Release Form* is returned to the researcher. Requests for educational records derived from courses not taught by members of the research team also require written permission from the corresponding faculty member(s). If educational records with PII are requested through the Office of the Registrar, a copy of the executed *Release Authorization* (either hard copy or digital version) must be submitted with the *Research Data Release Form*. Researchers must maintain the approved *Research Data Release Form* and executed *Release Authorization* on file for at least 3 years after the project is complete. The destruction of documents relating to FERPA (as described in this document) must follow FSC's *Records Retention Policy* as posted on the college's website.

| Department | Educational Records | Dataset Options |
|---|---|---|
| Office of the Registrar (in conjunction with the Office of Information Technology) | Directory Information, Final Course Grades, Grade Point Averages, Student Transcripts | • Identifiable<br>• De-Identified* |
| Office of the Provost | Course Evaluations/Student Feedback Surveys (Administered via Axiom Mentor) | • De-Identified* |
| Office of Institutional Research | Student Survey Responses initiated by SUNY and/or FSC | • De-Identified* |

| * All records will be randomized or aggregated. |
|---|

Researchers with access to educational records including, but not limited to, grades, attendance records, and coursework samples (i.e. tests/quizzes, essays, term papers, class projects, etc.) in their capacity as FSC faculty or staff members may only access this information for research purposes if an executed *Release Authorization* has been collected from the student(s). Researchers must maintain all executed *Release Authorizations* on file for at least 3 years after the project is complete.

If a *Release Authorization* is not provided, the following data collection proposals may also be considered:

- In some circumstances, researchers may collect de-identified aggregate grade data from their courses themselves using certain functions in the College's Learning Management Systems. Please contact the Office of the IRB for more details.
- Researchers may request de-identified educational records from their own course(s) to be provided from other faculty or staff who also normally have access to these records and are not members of the research team by submitting a *Research Data Release Form* to that individual. Once the request has been approved, the *Research Data Release Form* is returned to the researcher. Researchers must maintain the approved *Research Data Release Form* on file for at least 3 years after the project is complete.
- Researchers may request that other Faculty (not members of the research team) voluntarily provide de-identified educational records from their own course(s) by submitting a *Research Data Release Form* to the faculty member(s). Once the request has been approved, the *Research Data Release Form* is returned to the researcher. Researchers must maintain the approved *Research Data Release Form* on file for at least 3 years after the project is complete. [If an executed *Release Authorization* has been collected from the student(s), identifiable information may be included. Researchers must maintain the executed *Release Authorization* on file for at least 3 years after the project is complete.]

During the IRB review process, researchers must provide the IRB with a detailed description of the process(es) that will be utilized by the non-affiliated faculty/staff member to de-identify the dataset prior to providing it to the researcher.

Additional procedures are outlined below:

- Researchers collecting educational records with PII must have the student complete a *Release Authorization* (either hard copy or digital version) prior to data collection. When collecting the hard copy version, the researcher must confirm the participants identity by their FSC ID card and witness their “wet” signature (digitally created signatures are not acceptable); otherwise the form must be notarized. This process is not required for the digital version as an authorized single sign-on is required.
- Once a student submits a digital *Release Authorization*, the resulting record will be sent directly to the researcher’s FSC e-mail account.
- If the researcher plans to retain the identifiable data for future research, the *Release Authorization* must specifically state each intended project.
- At times, de-identified records can still contain identifiable markers. If the de-identified information from educational records includes a code that allows information to be matched to a recognizable participant, an executed *Release Authorization* (either hard copy or digital version) must be obtained from each participant prior to data collection.
- Data that has been fully de-identified (with no links to PII) may be retained by the researcher. During the IRB review process, researchers must provide the IRB with a detailed description of the process(es) that will be utilized to de-identify the dataset.

- Researchers must either destroy all PII as soon as practicable after the completion of the study, or return all PII to FSC for proper destruction and disposal.
- If PII is collected without consent for any reason (e.g. exemptions, unauthorized access, etc.), a disclosure log must be submitted to Office of Administration and Finance.

*Directory Information*

FERPA does not require consent/parental permission for the release of Directory Information. FSC designates the following items as Directory Information: Student's Name, Address, Telephone Listing, Electronic Mail Address, Photograph, Degrees, Honors and Awards Received, Date and Place of Birth, Major Field of Study, Dates of Enrollment, Most Recent Educational Agency or Institution Attended, Participation in Officially Recognized Activities and Sports, Weight and Height of Member of Athletic Teams. Students may opt out of the release of this information by completing the Restriction on Disclosure of Directory Information Form. At FSC, the Office of the Registrar maintains the list of students who have opted out of the directory.

*Course Evaluations/Student Feedback Surveys (Administered via Axiom Mentor)*

Researchers who wish to collect information from course evaluations (Axiom Student Feedback Survey forms) from course(s) in which they were the instructor may do so by contacting the Academic Project Coordinator in the Office of the Provost and submitting a *Research Data Release Form*. Once the request has been approved, the *Research Data Release Form* is returned to the researcher. Researchers must maintain the approved *Research Data Release Form* on file for at least 3 years after the project is complete. Direct access to course evaluations is not permitted for research data collection. Only de-identified survey information will be provided; any identifiable information from freeform comments will be redacted. Researchers seeking to collect information from course evaluations from course(s) in which they were not the instructor must also submit written permission from the instructor(s) of the requested course(s).

*Exceptions*

An educational agency or institution may disclose personally identifiable information from an education record of a student without the consent required by 34 CFR 99.30 if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to: (A) Develop, validate, or administer predictive tests; (B) Administer student aid programs; or (C) Improve instruction (34 CFR 99.31(A)(6)).
In these cases, FSC administration must confirm (in writing) that the Principal Investigator has been tasked with conducting the research on behalf of the institution for one of the three purposes listed above, and the following federal regulations are satisfied:

- The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information;
- The information is destroyed when no longer needed for the purposes for which the study was conducted; and
- A written agreement between FSC and the researcher, educational agency, or external institution has been secured and which meets FERPA criteria (contact the Office of the IRB for guidance).

Exception requests must be included in the research protocol submitted to the IRB and will be reviewed on a case-by-case basis.

## 5.J. Incentives and Reimbursements to Research Participants

Incentives and/or reimbursements to research participants are not considered benefits. The amount and schedule of all incentives and/or reimbursements must be presented to the IRB at the time of initial application. Any incentive to research participants shall not be of such an amount as to be coercive or to present undue influence on the potential subject's decision to participate in the research. Prorated incentives should be provided at periodic intervals or checkpoints, but prorated amounts may sometimes be held until study end, for example when a study is brief and providing incentives to all participants at once is most efficient. The design of the prorated incentive schedule should

not be coercive or present undue influence on participants' decision-making about whether to remain enrolled (e.g., prorated payments weighted more heavily at the end, bonus payment given to participants who complete the entire study present undue influence to compete the study), and participants should always receive payment for the portion of the research they have completed.

Reimbursement for travel costs and time spent will be considered and approved by the IRB on a case-by-case basis related to the risk/benefit assessment of the study. Any reimbursement to research subjects shall be detailed in the consent form and shall always be prorated so that there is no bonus payment for remaining in the study.

Incentives to parents of minors who are research participants are not allowed. The IRB may approve reimbursement for travel-related expenses at a reasonable rate where appropriate. Incentives to minors may be allowed when the incentive is non-cash and is provided in a manner that can be understood and appreciated by the minor.

Payments to human subjects are considered "other" income and, as such, are subject to Internal Revenue Service (IRS) requirements for reporting. If the research is a sponsored program activity (i.e., grant funded) and involves incentives or reimbursements to participants, the investigator should contact the Office of Sponsored Programs Administration for additional guidance.

## 5.K. Raffles as Incentives for Participation in Research

Due to games of chance typically being highly regulated, investigators (both affiliated with FSC and not affiliated with FSC, but conducting research using FSC students, faculty, and/or staff as research participants) offering raffles, or other similar methods of reward, as incentive for participation in a research activity must comply with all applicable state and local laws regarding games of chance, and the raffle must be conducted in accordance with tax reporting requirements. Additionally, investigators must adhere to FSC requirements (listed below) regarding raffles used in research. Research conducted over the internet and international research must comply with the applicable laws of each location, including foreign locations.

FSC Requirements:

1. The funding source for raffle prize(s) must be disclosed to the IRB during the protocol review process and applicable clearance for the use of specific funds must be provided to the IRB:

| | |
|---|---|
| Investigator Personal Funds | Permissible. |
| FSC Bookstore Donations | Permissible. |
| External Donations | Contact the Office of Institutional Advancement for guidance and clearance. |
| Grant Funds | Contact the Office of Sponsored Programs Administration for guidance and clearance. |
| State Funds Expenditures | Non-allowable. Contact the Purchasing Department for further clarification. |
| ASC, College Foundation Funds, or Research Foundation Funds | Contact the custodian of these funds for guidance and clearance. |
| Other Types of Funds | Contact the Office of the IRB for guidance. |

2. Research participants shall not be required to pay to take part in the raffle.
3. Only persons 18 years of age or older may receive a raffle as an incentive for participation in research or assist in the conduct of a raffle drawing. If some research participants are under the age of 18, another form of incentive must be offered to those participants.
4. The chances of winning and the method of determining the winner(s) must be clearly communicated as

elements of the Research Information Sheet or Informed Consent procedure.

5. The value of the raffle prize must not be too great that it would be considered coercive to the research participants. Investigators should advise the winner(s) that they should consult their local tax reporting requirements.
6. If possible, the drawing should be conducted on campus. If possible, two or more members of the research team should be present for the drawing.
7. The winner(s) should sign for the prize(s) unless the data set is anonymous or has been de- identified and no link to participants' identities has been retained, and a Waiver of Documentation of Informed Consent has been granted.

# Section 6: Informed Consent

## 6.A. Definitions

| | |
|---|---|
| **Consent Form:** | Used to consent subjects 18 years or older. |
| **Research Information Sheet:** | An unsigned document providing prospective research subjects or the subject's legally authorized representative details regarding an Exempt research study such as the purpose of the research, collection and use of data, their rights as research participants, contact information for questions about the study, and other applicable information. |
| **Permission Form:** | May be given by parents of subjects 17 years or younger (since the subjects themselves cannot legally consent to being in the study). |
| **Assent Form:** | Used to obtain agreement from the minor subject (17 years or younger) to be in the study. |
| **Broad Consent:** | Consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes). |
| **Additional Definitions:** | |
| **Minor:** | Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. |
| **Assent:** | A minor's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. |
| **Permission** | The agreement of parent(s) or guardian(s) to the participation of their child or ward in research. |
| **Parent:** | A minor's biological or adoptive parent. |
| **Guardian:** | An individual who is authorized under applicable state or local law to consent on behalf of a minor to general medical care. |

## 6.B. Overview

Informed consent is not a single event or a form to be signed, but an ongoing educational process that takes place between an investigator and a prospective subject. The legally effective informed consent of the subject or the subjects' legally authorized representative shall be required, except when a waiver is granted under federal guidelines (as described below). All consent forms shall conform with federal guidelines (section 46.116) and Institutional requirements. General requirements for informed consent including the required elements of consent are provided in the federal guidelines and templates are provided by the IRB.

Federal guidelines state:

> *(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.*
> *(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.*
> *(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.*
> *(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.*

> *(5) Except for broad consent obtained in accordance with paragraph (d) of this section: (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. (6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.*

It is the responsibility of the investigator to ensure the subject comprehends the information given during the consent process. Consent must be sought under circumstances where the subject or the representative is given enough time to consider whether or not to be in the study and minimizes the possibility of coercion or undue influence. Information provided to the subject or representative must be written in simple language, so all aspects of the research (e.g., purpose, risks, and benefits) are clearly stated and an informed decision can be made. Potential subjects must have the opportunity to ask questions. The consent process must be obtained in such a way that the rights of the individual research subjects are not violated. An assessment of capacity may be required by the IRB regarding vulnerable populations.

Consent is an ongoing process that requires the investigator to keep subjects apprised of issues that arise which may affect their willingness to continue participation. The process of informed consent shall take place no more than 30 days prior to the initiation of the research. If more than 30 days has elapsed since the subject provided written consent, the process shall be repeated. In some cases, a revised consent form or addendum may be required by the IRB. There are certain circumstances where a subject may be asked to re-consent to participate in the research study.

The provision for obtaining Broad Consent as outlined in 45 CFR 46 is only allowed at FSC under limited circumstances; however, FSC Investigators are permitted to access previously collected data where Broad Consent was obtained from participants.

## 6.C. Exempt Studies

FSC requires each prospective subject or the subject's legally authorized representative be presented with a Research Information Sheet prior to their voluntarily participation in an Exempt research study (in rare cases a waiver may be granted). Documentation of this process (i.e., participant's signature) may be required. If this process will be conducted remotely, it must include a mechanism (e.g. downloadable link) for a research participant to retain a copy of the Research Information Sheet. Subjects who do not speak English must be presented with a Research Information Sheet written in a language understandable to them. A Research Information Sheet template is available for download on the Axiom IRB portal.

## 6.D. Criteria for a Waiver or Alteration of Consent

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent or waive the requirement for the investigator to provide an informed consent form for some or all subjects if <u>all</u> of the following is found and documented:

> (i) The research involves no more than minimal risk to the subjects;
> (ii) The research could not practicably be carried out without the requested waiver or alteration;
> (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

The PI must include a request for such a waiver or alteration in the IRB application and must provide justification for the request based on these criteria. If other federal agencies, such as the FDA, are involved in the study, that agency's approval criteria will be applicable.

## 6.E. Documentation of Informed Consent

Except where a waiver is granted, informed consent shall be documented for all Expedited and Full Board protocols by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A copy of the Informed Consent form shall be given to the person signing to retain. If applicable, additional authorizations may also be required (i.e., HIPAA, FERPA, etc.).

Consent is not valid unless the subject or the subject's legally authorized representative is fully informed about all the information in the consent document. Signatures on consent forms do not absolve the investigator of the responsibility to ensure that the subject or the representative is fully informed about the research. Once a subject agrees to participate, the subject or the representative must sign and date the consent form on the signature page. Although the HHS regulations do not require the consent form to be dated at the time it is signed, OHRP recommends that it be dated so that the IRB and others can document that informed consent was obtained prior to a subject's participation in the research.

Any investigator listed on the IRB approved protocol may obtain consent unless the research involves a participant receiving a medical/psychiatric intervention performed by a licensed professional. If the intervention can only be performed by a licensed professional, then the participant's consent must be obtained by an investigator possessing the same professional license.

Consent forms must be retained for all subjects enrolled in the study for at least 3 years, regardless of whether they withdraw or are withdrawn. A subject is considered enrolled at the moment they sign the consent form, whether or not they actually participate in the research or any of the procedures involved.

## 6.F. Criteria for a Waiver of Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Investigators may specifically request a waiver of the documentation of the informed consent requirements by providing information that supports one of the conditions stated above. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research or the IRB may require submission of a consent script that will be

used to verbally consent a subject. Both of these methods will need to comply with federal requirements regarding mandated elements of informed consent. If the Informed Consent process will be conducted remotely, the process must include a mechanism (e.g. downloadable link) for a research participant to retain a copy of the Informed Consent form (if applicable). An Informed consent template is available for download on the Axiom IRB portal.

## 6.G. Persons Authorized to Sign the Consent Form on Behalf of an Individual

Consent or agreement to participate in a research study shall be given by the individual who will be the research subject or a person who is permitted to act on behalf of that individual (a legally authorized representative). Persons consenting on their own behalf must be an adult over the age of 18 years who have the capacity to make a sound judgment regarding the risks/benefits of participation. For adult subjects incapable of consent to participation, the IRB may approve a process whereby permission may be obtained from the subject's legally authorized representative.

## 6.H. Research Including Minors

The parent or legal guardian shall be permitted to act on behalf of their child and give permission for their participation. However, the assent of a minor shall be obtained from any minor considered mature enough to understand, as determined by the IRB and with the investigator's judgment, unless the IRB determines that the assent requirement can be waived.

- **Exception to the Requirement to Obtaining Parental Permission** (in most cases). If the IRB determines that a research protocol is designed for conditions, or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). In such cases, an appropriate mechanism for protecting the minors who will participate as subjects in the research must be in place, and the waiver must be consistent with other applicable federal, state and local regulations.
- **Obtaining minor assent** (in the absence of a waiver). In determining whether minors are capable of assenting, the IRB must consider the ages, maturity, and psychological state of the minor involved. This judgment may be made for all minors to be involved in research under a particular protocol, or for each minor. The IRB may require documentation of assent, such that the minor is presented with an assent form to review and sign. The IRB may determine that the assent of the minor is not a necessary condition for proceeding with the research if:
  - The capability of some or all of the minors is so limited that they cannot reasonable be consulted.
  - The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the minors and is available only in the context of the research.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. Where research is covered by 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

## 6.I. Re-Consenting Subjects

The need to re-consent subjects when changes are made to a consent form for an ongoing study shall be determined by the IRB on case-by-case basis, depending on the nature of the protocol and the changes that have been made. In some cases, it may be appropriate to provide a subject with an addendum to the original consent form which provides the new information, or to verbally inform subjects of an administrative or other minor change (with documentation in the research record that such notification took place). If an addendum is used, it must clearly state that the information in the original consent form is still current and valid, and that the information in the addendum is supplementary.

Subjects shall be re-consented if (1) the consent form has been altered or amended since the subject signed the document and the changes include information that may affect the subject's willingness to participate in the research or (2) the subject was incapacitated at the time of enrollment (and the consent was signed by another authorized individual) and now has regained capacity. The same requirements for signatures and obtaining consent apply when re-consenting or presenting an addendum.

## 6.J. Non-English-Speaking Subjects

Federal regulations require that informed consent information be presented "in language understandable to the subject". Where informed consent is documented, the written consent document should embody, in language understandable to the subjects, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. For those consent forms that must be translated into a foreign language, an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study. The translated consent form and affidavit must be submitted and approved by the IRB before the consent form is used.

## 6.K. Illiterate Subjects

A person cannot speak or write can be enrolled into a research study if they are otherwise competent and able to communicate approval or disapproval. Federal regulations permit a short form written informed consent form stating that the required elements of informed consent have been presented orally to the subject, or the subject's legally authorized representative, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Unless a Waiver of Documentation of Consent if approved, the participant's verbal consent should be audio recorded; if non-verbal, it should be video recorded. If applicable, the short form is to be signed by the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Illiterate subjects who do not speak English should be verbally presented with consent information in a language understandable to them. All consent documents should also be presented in this language. For those consent documents that must be translated into a foreign language, an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study. The translated consent documents and affidavit must be submitted and approved by the IRB before the consent is obtained. The witness must be fluent in the language understandable to the subject.

## 6.L. Required Format of Consent Forms

Information given to a potential subject or a representative must be in a language understandable to them, and must include all of the elements required by federal regulation. Additional information should also be included as appropriate. The following guidelines will assist you in preparing a research consent form. Each selection should be tailored to meet the specific needs of the individual protocol.

General requirements for informed consent including the required elements of consent are provided in the federal guidelines and a template is available for download on the Axiom IRB portal.

Consent forms that are 3 pages or less in duration will be considered to meet the key information criteria summary requirement at 46.116(a)(5)(i). In general, consent forms that are longer than 3 pages should begin with a concise explanation of the following:
(1) The fact that consent is being sought for research and that participation is voluntary;

(2) The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
(3) The reasonably foreseeable risks or discomforts to the prospective subject;
(4) The benefits to the prospective subject or to others that may reasonably be expected from the research; and
(5) Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
Additional information may be required (when applicable). Consent forms that are extensive should include separate detailed descriptions of the items summarizes at the beginning of the form.

All FSC Informed Consent forms MUST:

- Be printed on official FSC letterhead (if hardcopy forms will be used).
- Include the Project Title, Principal Investigator, and [for Expedited and Full Board reviewed protocols] all Co-Investigators at the top of the first page.
- Include the term "Research Consent Form", centered and bold, at the top of the first page under the Investigator's name.
- Be written in lay language understandable to most adults.
- Use a font of 12-point equivalent or larger.
- Contain headings that clearly delineate each section (Expedited and Full Board reviewed protocols only).
- Include page numbers and a version date on the bottom of each page.
- Be formatted in such a way that the form is easy to read and follow (by using headings, indents, bolded types, tables, adequate margins and spacing, etc.)

Contact Information
An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject must be included in all FSC Informed Consent forms. For example: *If you have any questions about the research or would like a copy of the findings, you can contact [NAME OF PRINCIPAL INVESTIGATOR] at [PHONE/EMAIL]. This study has been approved by Farmingdale State College's Institutional Review Board. If you have any questions about your rights as a research subject, please contact Farmingdale State College's IRB at 934-420-2687 or IRB@farmingdale.edu.*

Voluntary Participation
The consent form must include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. This statement is particularly important for studies involving students to ensure a non-coercive recruitment environment. For example: *Your participation in this study is completely voluntary. If you choose not to join this study you will not be penalized or lose benefits to which you are entitled. If you join you may choose to withdraw at any time without prejudice to your future relationship with Farmingdale State College.*

Identifiable Private Information or Identifiable Biospecimens Statement
Include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

## 6.M. Additional Considerations

Possible Emotional Distress

If deemed necessary based on the level of risk, include the following statement*: If you feel distressed as a result of participation in this study, speaking with a qualified clinician may help. If you feel that you would like assistance, please contact Campus Mental Health Services at 934-420-2006 or your Primary Care Physician.*

Additional resources may be added to the statement above when applicable:

- Crisis hotline specific to research such as:
    - 988 Lifeline*: If you are concerned that you or someone else might be in danger of self-harm or dying by suicide, please call 988 (Suicide and Crisis Lifeline).*
- Contact information for local mental health clinics and/or research site specific mental health resource.

Blood Drawing

If the study involves blood drawing, include the following statement: *Some risks of blood drawing are temporary pain and bruising where the needle enters the skin, and sometimes, fainting and/or infection.*

Collection of Potentially Sensitive Information

If potentially sensitive information will be collected from participants, include the following statement: *Some of the questions that you will be asked are of a personal nature and may cause you embarrassment or stress. You may ask to see the questions you will be asked before deciding whether or not to participate in this research.*

Genetic Research

In studies involving genetic analysis of identifiable biological specimens (where inherited factors may be assessed in current or future proposed studies), include the following statement:
*The genetic analysis to be conducted on your tissue in this study may pose future risks that are unforeseeable at this time.*

Pregnancy Risk

If there are special risks to pregnant/nursing females, fetuses, and or females of childbearing potential, these should be discussed with special instructions regarding the need for effective birth control.

*Being a part of this study while pregnant may expose the unborn child to significant risks. Therefore, pregnant females will be excluded from the study. If you are a female who can become pregnant, a pregnancy test will be done before you start the study. If you are sexually active, you and your partner must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include surgical sterilization, approved hormonal contraceptives (such as birth control pills or Depo-Provera), barrier methods (condom or diaphragm) used with a spermicide, IUD, or abstinence. The investigator will discuss these options with you. If you do become pregnant during this study, you must inform the investigator immediately.*

Course Requirements

It is particularly important for studies involving students, whose participation may be included as part of a course, that participation is voluntary and there are alternatives to fulfilling the course requirements apart from the research study. The research study should be clearly described as one option to fulfill such course requirements, and the alternative option(s) should be detailed. For studies where the only alternative is not to participate in the research, but the study activity is also part of the course curriculum, include the following statement: *Although participation in [state activity] is required as part of the course requirements, your participation in the research study is voluntary. If you do not agree to participate in this research project, your information/data will not be collected by the Principal Investigator. You may choose to discontinue or otherwise not participate in the study without consequence. Choosing to participate or not to participate in this research project will not affect your standing in this course.*

Alternatives for Earning Extra Credit

If extra credit is offered to student participants as an Incentive, a disclosure of an appropriate non-research alternative to earning the extra credit that is equal in time and effort must be included in the Informed Consent Information.

Compensation for Research-Related Injury

For research involving more than minimal risk, the consent form must include an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. This is applicable if the study involves the potential for injury to the subject (e.g., physical, psychological, etc.,) including blood drawing protocols. The following statement may be used: *If you are injured from participating in this study, emergency medical personnel will be called to assist you. However, you will be responsible for the costs of such medical care and/or treatment, directly or through your medical insurance and/or other forms of medical coverage. No provisions have been made for financial payments or forms of compensation with respect to injuries.*

If no compensation will be provided, this must be stated as well.

If a research study involves the use of a product and the manufacturer of that product is sponsoring the study, in most cases assumes the responsibility for the costs of treatment of research-related injury to extent that the subject's third-party payer does not cover the costs (this would be detailed in the study contract). If so, this must be detailed in the consent form following the above statement. For example: *However, although the Farmingdale State College- SUNY will not be responsible for the costs of treatment cause by the study procedures or study product, the sponsor has agreed to pay for treatment of any research-related injury to the extent that it is not covered by your medical insurance and/or other forms of medical coverage.*

Data Collection/Reporting/Storage of Collected Information (Data)

- Fully Identifiable Information

  A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained must be included in the consent form. This section must include details on how the subject's identity will be kept confidential in connection with the research study. For example: *Your identity will be held confidential. The following procedures will be followed in an effort to keep your personal information confidential in this study…*
  *Absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. This means that there may be rare situations that require us to release personal information about you. To ensure that this research activity if being conducted properly, Farmingdale State College's Institutional Review Board (IRB) and/or applicable officials have the right to review study results, but confidentiality will be maintained to the extend allowed by law.*

  If participants will be identified in any resulting dissemination (i.e., presentations, publications, etc.) the following statement must be included in the Informed Consent Form: *You will be identified by name and the information collected from you will be attributed to you in resulting publications and/or presentations of this research study.*

- Coded Information

  If the data is coded, this section should describe the extent, if any, to which confidentiality of records that identify the subject will be maintained. For example: *Your identity will be coded by a random number, not by your name, social security number or other identifiable piece of information. The linking information will be kept separate in a locked file or computer and identifiers will be destroyed when the study is complete. All data will be kept in a secure location. If the results of the study are published, your name will not be used.*

- Anonymous Information

If participant information (data) will be collected anonymously with no links between the data and the participants' identities, the Informed Consent must state as such. For example: *Your data will be collected anonymously. No personally identifiable information will be collected from you.*

Note: The term *confidential* should not be applied to anonymous information.

## 6.N. Certificate of Confidentiality

Certificates of Confidentiality (CoC) protect research information by prohibiting certain disclosures and conditioning others upon consent of the subject (outlined in 42 U.S.C. 241(d) and in written policies of certain federal agencies such as NIH and CDC. Information protected under a CoC are protected in perpetuity and are immune from the legal process (not admissible as evidence and cannot used in any legal proceeding). However, a CoC does not prohibit voluntary disclosure of information by an investigator, such as voluntary reporting to local authorities of child abuse or a communicable disease, or voluntary disclosure by the subject.

CoCs are obtained as follows:

- CoCs are issued automatically when research is conducted or supported by NIH and fall within the scope of the NIH policy.
- CoCs are issued automatically when research is conducted or supported by the CDC and involves the collection of identifiable, sensitive information
- Research that is not supported by NIH or CDC may still have the protections afford by CoC through successful application to the FDA, HRSA, SAMHSA, or other authorized federal agencies or departments. Any person engaged in human subjects' research that collects or uses identifiable, sensitive information may apply for a CoC. For most research, CoCs are obtained through NIH. Additional information regarding research not covered by NIH policy is available on the NIH CoC website.

At FSC, the IRB Chair in consultation with the Office of Sponsored Programs Administration and the PI and/or the Project Director (if applicable) will determine if the federal policies and requirements apply to the research for automatic approval. In cases where the proposed research includes the collection of identifiable, sensitive information, the IRB may require an investigator to apply for a CoC if it is determined that a CoC is necessary to minimize risks and adequately protect subjects' privacy and confidentiality (whether federally funded or not).

When consent is obtained, the consent form should inform subjects that a CoC is in place and describe the protections and limitations. Investigators are responsible for representing in the IRB protocol that a CoC is in place, or that an application for CoC has been submitted or is pending. If pending, the IRB will condition final approval upon receipt.

# Section 7: On-Going Review of IRB Approved Activities

## 7.A. Overview

On-going reviews include, but are not limited to, continuing reviews, five-year continuing approvals, modifications, safety reporting, compliance audits, study closures, and any other activity that the IRB determines necessary for monitoring ongoing research. The IRB also has the authority to inspect records and to observe (or have a third party observe) the consent process and the research activity for any protocol that it approves.

## 7.B. Continuing Reviews (Not for Cause)

Once approved, the IRB shall conduct continuing reviews of all Full Board research and select Expedited research activities. When continuing review is required it is for the duration of the research, protocols do not require further annual reviews once the research has progressed to the point that it involves only one or both of the following: (1) Data analysis, including analysis of identifiable information or identifiable biospecimens or (2) accessing follow-up clinical data from procedures that subjects would undergo as part of a clinical care. PI's of protocols that have progressed to this point should complete the application for continuing approval in Axiom Mentor and indicate the appropriate continuation status (i.e., Data Analysis Only, Accessing Follow-Up Clinical Data and Data Analysis Only).

Approval Periods

- Exempt determinations do not expire.
- Expedited approvals are only assigned expiration dates if the research is FDA regulated or the IRB review team deems it necessary and provides a justification.
- Full Board IRB approval periods are granted on the basis of degree of risk associated with a particular protocol. An approval period will not exceed one year (minus 1-day). In the case of Full Board reviews, this one-year criterion commences on the date the application was reviewed by the full committee, not the date the application receives final approval. This means that if a protocol is reviewed by the Full Board and receives contingent approval (e.g., based on minor changes to the consent or protocol, or any other contingency), and then the investigator responds and meets the contingencies a short time later, the IRB will issue a final approval letter based on receipt of the revised materials, but the approval period began on the date that the committee convened and issues the contingent approval.

Certain projects may require review more often than annually based on other factors other than degree of risk (e.g., past history of non-compliance with a particular investigator may require more stringent oversight by the committee).

Copies of the consent/permission/assent documents signed by the last subject enrolled (with the subject's name and signature redacted), and updated human subjects training certificates (if applicable) are required for continuing review submissions. If any new modifications are proposed as part of the continuing review process, a Request for Modifications application should be submitted concurrently with the Request for Continuing Review application.

An IRB-approved research project may be periodically renewed over a five-year period beginning on the date of the original IRB approval, after which time a five-year application will need to be submitted for review, incorporating all amendments, updated consent, permission, and/or assent forms, funding information, etc. that have occurred since the study's inception. This resubmission will be treated like a new protocol.

An expiration reminder letter will be sent to the investigator sixty (60) days before study expiration. The investigator must submit an application for continuing approval (annual report) in Axiom Mentor at least thirty (30) days before study expiration. For continuing approval, the IRB reviews all new information submitted by the investigator and determines whether it results in a change to the risk/benefit ratio of the study. Specifically, the IRB will review the recruitment process, informed consent process, and the continuing protection of human research participants.

Consistent with federal requirements (45 CFR part 46), if continuing approval is not issued before the expiration date, all research must stop. No human participant activity may take place on or after the research expiration date unless the IRB finds it is in the best interest of individual subjects to continue participation in research interventions or interactions. Note that human participant activity includes the use, study, or analysis of identifiable information. If there is a lapse in approval, the investigator will be sent a notice that the protocol has expired and that no human participant activity including enrollment, recruitment, or analysis of identifiable data may take place on or after the expiration date. The investigator will have thirty (30) days from the date of the expiration notice to obtain continuing approval for the research or it will be administratively closed by the IRB. If the study is closed by the IRB, the investigator must submit a complete, new protocol for the IRB to review the research.

Note: Federal regulations require that the IRB notify the funding agency of any suspension or termination of a research project.

All completed protocols (Exempt, Expedited and Full Board) should be terminated in Mentor.

## 7.C. Modifications

Investigators must promptly submit to the IRB an official request for review of any proposed changes to previously reviewed Exempt, Expedited, and Full Board research via Axiom Mentor. Changes to existing protocols must first be reviewed by the IRB prior to commencement of the revised study as they may impact the risk/benefit ratio of the protocol. When changes are implemented to eliminate an immediate hazard, or to change logistical administrative aspects of the trial, the IRB must be notified of the change as soon as possible.

Minor amendments are defined as (1) changes that do not alter the overall risk-benefit profile of the study; (2) changes that would not potentially affect the willingness of enrolled subjects to remain in the study, or the willingness of potential subjects to enroll in the study; and (3) changes that do not alter the scientific validity of the study design.

- All modifications to Exempt protocols are reviewed by a member of the IRB (preferably the original reviewer of the research).
- Minor modifications to Expedited protocols are reviewed by a member of the IRB (preferably a member of the original review team). Major modifications to Expedited research are reviewed via the Expedited review process.
- Minor modifications to Full Board protocols are reviewed via the Expedited review process. Major modifications to Full Board research are reviewed at a convened meeting under the Full-Board review process.

IRB approval of modifications does not change the expiration date for the protocol (if applicable).

## 7.D. Protocol Deviations, Problems, and Events

- **Protocol Deviation:** a circumstance that occurs during the course of the study that does not adhere to the IRB-approved protocol (which may include the protocol, consent, recruitment and/or subject materials). A protocol deviation may be major or minor.
- **Unanticipated Problem:** Unexpected events that occur during the course of the research activity that can negatively impact the risks to research subjects or others (e.g., an investigator realizes that they or the research staff did not follow, or have not been following, IRB-approved protocol procedures (potential risk to subjects); an investigator's laptop or other electronic device with stored data, which contains identifiable information, is lost or stolen (potential risk to subjects' confidentiality); etc.).
- **Adverse Event:** an unfavorable physical or psychological occurrence in a human subject research participant.

- **Unexpected Adverse Event:** Any adverse event and/or reaction that is not anticipated either specifically or in severity by the investigators.
- **Serious Adverse Event:** A death, a life-threatening event, or an event that results in any of the following outcomes: inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. It is also defined as a significant medical event that requires medical or surgical intervention to prevent death, a life-threatening event, or one of the other outcomes listed above (e.g., allergic reaction, seizures, psychiatric disorder). If the event is unanticipated (i.e., not identifiable specifically or severity in the risks section of the most current IRB-approved consent form for the study) AND there is a reasonable possibility that the event was caused by the subject's participation in the study (e.g., not caused by expected disease progression) then the event is considered to be an **Unanticipated Serious Adverse Event**.

Once the study is initiated and ongoing, investigators are responsible for prompt reporting to the IRB of any protocol deviations and/or anticipated or unanticipated events or problems involving risks to subjects or others. The IRB, in its initial determinations, assesses the risk/benefit ratio inherent in a given proposed research activity involving human subjects.

The IRB will assess the relationship of these deviations/events/problems to the subjects' participation in the study as these negative effects may obviously affect the risk/benefit ratio. As a result of the assessment, the IRB may determine that the study protocol and/or consent forms need to be updated, and/or currently enrolled subjects need to be informed of the new information to determine whether or not they wish to continue. In some cases, the IRB may determine that the risk to subjects has changed enough that the study must be stopped (perhaps temporarily until a thorough assessment can be made).

Please refer to the following table for reporting requirements related to protocol deviations. All reports should be submitted through Axiom Mentor:

| **Category** | **Reporting Requirement:** Farmingdale Subjects | **Reporting Requirement:** Non-Farmingdale Subjects |
|---|---|---|
| Protocol Deviation or Unanticipated Problem | Report to IRB within 3 working days of occurrence. | Report to IRB within 3 working days of occurrence. |
| Anticipated Adverse or Serious Adverse Event | Include summary report at the time of study renewal as part of the progress report. Events should be presented individually. | Attach cumulative summary report at continuing review. Events can be presented in summary form. |
| Unanticipated Adverse or Serious Adverse Event | Report to IRB within 2 working days of occurrence. | Report to IRB within 2 working days of occurrence. |

***Note**: Investigators are responsible for complete compliance with all federal agencies and/or other sponsors' adverse event reporting requirements, where applicable. If an investigator receives correspondence from applicable federal agency or a sponsor mandating reporting of information to the IRB, these requirements will override the guidelines in the above table. If a federal agency or sponsor of a particular study includes more stringent reporting timeframes, the sponsor's guidelines will override the institutional guidelines.*

All deviations/events/problems will be initially reviewed by the IRB Chair to confirm that the reported incident has been categorized correctly. An initial determination regarding immediate action will be made, and the PI will be notified regarding steps to be taken to ensure proper protection of the rights and welfare of research subjects (if necessary). A full review will then be completed (see procedures below), and the PI will be notified regarding any required additional steps.

a. Exempt Protocols: Reviewed by the Chair or an IRB member (preferably the original reviewer).
b. Expedited Protocols: Based on the initial review, the IRB Chair will determine it will be reviewed by one or two members of the IRB (preferably original reviewers).
c. Full Board Protocols: Based on the initial review, the IRB Chair will determine it will be reviewed by one or two members of the IRB or be brought to the attention of the full committee for their review and action. If immediate action is not required, the reported information may, at the discretion of the Chair, be placed on the agenda for full review at the next IRB meeting.

As a result of review, the protocol and/or consent form may need to be revised to include the possibility and likelihood of the problem/event, or subjects who are currently enrolled in the study may need to be made aware of the problem/event. Additional modifications to the protocol may be required in order to mitigate the problem/event from reoccurring. A corrective action plan from the PI and an application for modifications to the protocol should be submitted at the time of reporting, if the PI believes such action is warranted, prior to IRB review.

If the definition of an Unanticipated Problem/ Unanticipated Serious Adverse Event is met, the IRB Coordinator will confirm that the appropriate notifications have been made (e.g., to the sponsor or governing authority) and appropriate documentation has been filed. When appropriate, regulatory bodies (including OHRP and FDA, etc.) will be notified by the IO.

## 7.E. For-Cause Compliance Audits

- **Non-Compliance**: Failure to comply with any of the federal regulations and/or the regulations and policies of the College; failure to follow IRB determinations and/or implementation of protocol changes without prior IRB approval. Non-compliance issues may range from minor to serious and may be isolated or continuing (related or non-related).
- **Serious Non-Compliance**: Non-compliance that is determined by the IRB Chair or the convened IRB to increase risks to subjects, decrease potential benefits, or compromise the protection of human participants.
- **Continuing Non-Compliance**: A pattern of noncompliance that, in the judgement of the IRB Chair or the convened IRB, suggests a likelihood of non-compliance will continue without intervention, or where non-compliance has continued even when IRB intervention has occurred. Continuing non-compliance includes failure to respond to a request to resolve a non-compliance issue.

If a potential issue/problem is brought to the attention of the IRB (prompted by information obtained from sources such as internal/external whistleblower(s), regulatory agencies, community member(s), industry sponsor(s), study team member(s), research participant(s), etc.), a preliminary review will be conducted by the IRB Chair (or in the Chair's absence the IO). Reports of non-compliance (including the description and personnel involved) must be submitted to the IRB, either verbally or in writing, within 10 working days of discovery. Complainants may choose to remain anonymous. The IRB may request information from the PI beyond regular progress reports in order to ensure that the rights and welfare of research subjects are protected.

Based on the preliminary review findings, if non-compliance is deemed by the IRB Chairperson to have occurred, but is minor, this determination is reported in writing to the PI. A corrective action plan may be deemed necessary. If the PI refuses to agree to the corrective action plan, the issue will be referred to a convened IRB meeting.

If the IRB Chairperson deems non-compliance as greater than minor, the Chair has the authority to suspend a protocol if a deficiency or situation poses a risk to subjects. The IRB will notify the IO in writing with a summary of the issue(s) and ask that a For-Cause Audit be conducted. The IO will notify the PI in writing that an audit has been requested. The letter will outline the reason(s) for the request and detail any information that is needed. The PI will be given adequate opportunity to respond. The Chair will arrange a time to review the investigator's study files and any other information necessary for the conduct of the audit. The IRB shall be kept apprised of any such action at their

next meeting. Instances of serious or continuing noncompliance may be referred to the convened IRB for review at the discretion of the IRB Chair or IO.

If the audit indicates continued monitoring or suspension is required to ensure the safety of study subjects, the IRB Chair may act accordingly without convening an IRB meeting; however, no protocol may be permanently terminated without the concurrence of the committee at a convened meeting. As a result of audit, the protocol and/or consent form/ Research Information Sheet may need to be revised to include the possibility and likelihood of any identified problems/events, or subjects who are currently enrolled in the study may need to be made aware of identified problems/events. Additional modifications to the protocol may be required in order to mitigate the identified problems/events from reoccurring including:

- Submission of a corrective action plan from the PI;
- Re-Training in human participants research;
- Modifications to the study's continuing review cycle; etc.

If the non-compliance is deemed by the IRB to have occurred, but is not serious, the IRB determination is reported in writing to the PI. A corrective action plan may be deemed necessary. If the PI refuses to agree to the corrective action plan, the issue will be referred to a convened IRB meeting.

If the non-compliance is deemed by the IRB to have not occurred, the IRB determination is reported in writing to the PI.

## 7.F. Suspension or Termination of IRB Approval of Research

Federal regulations state: *An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.*

OHRP will be notified if the study is a subject to DHHS regulations or subject to a DHHS Federalwide assurance, and other federal agencies will be notified as required by the agency.

Additional consideration will be made of actions needed to protect the rights and welfare of current or former participants enrolled in study. Information may be provided to the participants concerning the suspension/termination including procedures for withdrawing from the study, follow-up care (outside of the research), reactivation of study activates, etc. Revised Informed Consent information may also be required to be provided to participants.

## 7.G. Closure of Protocols

Regardless of its review type, the completion or termination of a protocol, premature or scheduled, is a change in activity and should be reported to the IRB via Axiom Mentor.

Research is permanently closed if all the following conditions are met:

- No new subjects are enrolled; and
- There are no more interventions or interactions with enrolled subjects.

*Additionally*:

- Protocols approved prior to January 21, 2019 will remain governed by the pre-2018 Common Rule, and are considered active if human participant activity including the use, study, or analysis of identifiable information is on-going.
- Protocols approved on or after January 21, 2019 may be closed if the research has progressed to the point that it involves only one or both of the following: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

## 7.H. Separation from the Institution

If an investigator is separating from the FSC (i.e., no longer will be employed by the institution), the investigator is required to contact the IRB before the separation date regarding transferring their duties as the Investigator to another individual at FSC (modification request) or to close the protocol. The transfer of duties or the closure of the protocol must be done prior to the PI's separation date; otherwise, the protocol will be automatically closed by the IRB.

# Section 8: Research Involving Pregnant Women, Human Fetuses, and Neonates (Subpart B)

## 8.A. Definitions

- **Dead Fetus**: A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- **Delivery**: Complete separation of the fetus from the woman by expulsion or extraction or any other means.
- **Fetus**: The product of conception from implantation until delivery.
- **Neonate**: A newborn.
- **Nonviable Neonate**: A neonate after delivery that, although living, is not viable.
- **Pregnancy**: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
- **Viable**: As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

## 8.B. Overview

This subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates. The IRB shall review research covered by subpart B and approve only research which satisfies the conditions of all applicable sections of this subpart. Each of the exemption categories may be applied to research subject to subpart B if the conditions of the exemption are met.

*Note: Viable neonates are considered minors, and are therefore covered by Subpart D (Section 9: Research Involving Minors (<18 years of age)*

## 8.C. Research Involving Pregnant Women or Fetuses

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

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part,

except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children as defined in 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

## 8.D. Research Involving Neonates

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

- The IRB determines that:
    - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
    - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained [in accord with subpart A], except that the waiver and alteration provisions of 46.116(c) *Additional elements of informed consent* and (d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens* do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally

authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

## 8.E. Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

## 8.F. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of 46.204 or 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

# Section 9: Research Involving Prisoners (Subpart C)

## 9.A. Definitions

- **Prisoner**: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- **Minimal Risk**: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [Note: This definition differs from the definition of minimal risk in Section 1 and is unique to research with prisoners].

## 9.B. Overview

***Note**: All investigators who are planning research involving prisoners should consult with the Office of the IRB to discuss the specific requirements for this category of research. FSC does not permit research that includes participants who are prisoners to be determined as Exempt.*

All research involving prisoners shall be conducted and reviewed in compliance with the special requirements as set forth in subpart C, as summarized below. Inasmuch as prisoners may be under certain constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, additional safeguards exist for the protection of prisoners involved in research activities. These concerns apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who becomes prisoners after they become enrolled in the research.

A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board. It is anticipated that research with prisoners at FSC will occur infrequently. When research involving prisoners is reviewed by the IRB, a consultant shall be called in to assist in the review of the protocol. This individual shall represent the prisoner population and shall be someone with the appropriate background and experience to serve in that capacity.

## 9.C. Duties of the Institutional Review Boards Where Prisoners Are Involved

In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

- The research under review represents one of the categories of research permissible under 46.306(a)(2);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

- Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.
(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

## 9.D. Permitted Research Involving Prisoners

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

- The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under 46.305 of this subpart; and
- In the judgment of the Secretary the proposed research involves solely the following:
    - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    - Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    - Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or
    - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

# Section 10: Research Involving Minors (<18 years of age) (Subpart D)

## 10.A. Overview

Minors are considered a vulnerable population because their emotional and intellectual capacities may be limited and they are not of legal age to give informed consent. The IRB is responsible for assuring that all FSC investigators who conduct research with minors comply with special requirements set forth in the federal regulations.

All research involving minors as subjects shall be placed into one of the following four categories of risk. The IRB shall review and approve only research which satisfies the conditions of all applicable sections of subpart D.

- Research not involving greater than minimal risk. (46.404)
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (46.405)
- Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (46.406)
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (46.407)

## 10.B. Exempt Categories

FSC does not typically permit research that includes participants who are minors to be determined as Exempt; however, exceptions for minors will be considered on a case-by-case basis. Otherwise, if the research includes participants who are minors, FSC requires the protocol to be referred to Expedited review.

## 10.C. Requirements for Permission by Parents or Guardians and for Assent by Minors

See Section 6: Informed Consent

## 10.D. Research with Students

College students who are under the age of 18 may participate in studies that are specifically approved for the inclusion of minors. Further, unless a waiver of parental permission has been requested by the PI and granted by the IRB, permission of the parent of the minor participant will be required. Regardless of whether or not such waiver is granted, assent of the minor participant will be required. A waiver may be granted for studies for which the risks to the participants are determined to be minimal.

No student, minor or otherwise, can be required to participate in research studies as part of their course requirements, as participation in such activities must be voluntary. Participation in a research study to fulfill course requirements or to earn extra credit is allowable as long as a comparable alternative is also offered and there is no penalty or undue burden in choosing the alternative.

## 10.E. Additional Policies Regarding Minors

FSC adopts and will comply with and enforce all aspects of the *SUNY policy 6505 Child Protection Policy* as written. FSC's *Child Protection Policy* is posted on the college's website (as mandated by SUNY policy 6505). If a research protocol involves minors, the PI is required to complete a *Request to Conduct Programs/Activities Involving Children*. The study team may be required to meet additional requirements. If a research protocol involves minors present in a laboratory, please see FSC's policy *Minors in Laboratories* which is posted on the college's website.

- **Laboratory/Lab**: A research or clinical setting where scientific research or instruction is conducted. Laboratories often contain hazardous materials (e.g., hazardous chemicals, biohazardous agents, etc.)

and/or physical safety hazards (e.g., moving machinery parts, extreme temperature, electrical apparatus, etc.). For purposes of this section, a laboratory does not include dry or computational laboratories or any other laboratories where no hazardous chemicals, radiation or biological materials are handled or stored and where no physical safety hazards are identified.

## 10.F. Wards

Minors who are wards of the state or any other agency, institution, or entity can be included in research approved under 46.406 or 46.407 only if such research is: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

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

# Section 11: Research with Biological Specimens (including Genetic Research)

## 11.A. Definitions

- **Anonymous Samples:** Biological material that were originally collected without identifiers and are impossible to link to their sources.
- **Anonymized Samples:** Biological materials that were initially identified, but have been irreversibly stripped of all identifiers and are impossible to link to their sources.
- **Genetic Tests:** The analysis of human DNA, RNA, chromosomes, proteins or other gene products to detect disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes.
- **Identifiable/Coded Samples:** Specimens that can be linked back to the subject who provided them.
- **Prospective Collection:** Proposed research involves specimens that do not exist "on the shelf" when request is made to the IRB for approval. The specimens will be collected once IRB approval has been granted.
- **Retrospective Collection:** Proposed research involves specimens that already exist, i.e., already collected and are "on the shelf", stored or frozen at time of protocol submission to the IRB. This type of research will often involve a third party (e.g., tissue bank or registry, Department of Pathology etc.). In this instance, the third party will likely have the tissue coded with respect to subject identity.

## 11.B. Overview

All research involving genetic research and tissue banking shall be given special considerations with regard to the unique risks presented by such research, and according to current regulations governing such research. In genetic research and research using biological specimens there are potential health, societal, emotional, and legal issues to consider.

## 11.C. Retrospective Studies

Research involving the use of existing data (derived from biological specimens) or discard biological specimens must be approved prior to the initiation of the protocol used to analyze the data or utilize the specimens. This is considered a retrospective study, or a study involving discard specimens, and while there are no clinical procedures involved, the use of data previously collected or discarded specimens from human subjects is considered research and must be approved by the IRB prior to the research.

- Anonymous Data: When submitting the application materials to the IRB, the investigator should include a written agreement between the third-party entity and the investigator ensuring that the code will not be released to the investigator under any circumstances.
- Coded/Fully-Identifiable Data: The investigator and the IRB must consider issues of added risk (e.g., confidentiality, etc.) of whether consent can be waived or if it must be obtained from the subject.

Retrospective Study Review Category:

Exempt Category 4: *Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met*:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);

## 11.D. Prospective Studies

In prospective research, the investigators have the responsibility to communicate with the potential subjects, obtain informed consent, and maintain confidentiality to the extent permitted by law. If results are to be given, subjects should be offered counseling as appropriate, since results from such research could lead to adverse psychological outcomes, social stigmatization and discrimination. In certain cases, subjects should be given the option to determine whether they want to be informed of the results of their testing. The disposition of their samples should be included in the consent process; if samples are to be stored for future studies, subjects must be informed of how long storage is planned.

Note: In no case should results from a genetic test be given to subjects without proper validation of the test and certification of the laboratory performing the test.

Prospective Study Review Categories:
Will the biological samples be labeled such that they can be traced back, in any way, to the subject (via direct identifiers, or via codes)?

*If the answer is NO*:
Non-physical (e.g., breaches of confidentiality, etc.) risks are deemed minimal. If the specimens were collected:

- **Prospectively:** study will either undergo Expedited or Full Board Review (depending on the physical risks associated with the collection procedure (e.g., blood drawing, biopsy, cheek swab, lumbar puncture, etc.).
- Regarding informing the subject of the test results, possible consent language in the procedures section may include:
  *Because this is research information will be collected anonymously, individual test results will not be shared with you or your doctor.*

*If the answer is YES*:
Will the test result be able to provide information that has known clinical significance for diagnosis or prediction of a disease state for either the subject or the subject's family members?

*If the answer is NO*:
The non-physical risks are deemed minimal (i.e., they are theoretical in that clinical significance may be determined in the future, with risks being a breach of confidentiality and the subject not knowing that this private information now exists). The study will qualify for Expedited or Full Board review depending upon the physical risks of the collection procedure.

- Regarding informing the subject of the test results, possible consent language in the procedures section may include:
  *Results from testing of your tissue will not be understood unless we pool it together with data from other study subjects. Because this is research, the clinical significance (if any) of your individual results may not be understood for years. Therefore, individual test results will not be shared with you or your doctor.*

*If the answer is YES*:
The non-physical risks associated with this study constitute MORE THAN MINIMAL RISK. Study must be reviewed by the Full Board, regardless of the physical risks associated with the specimen collection procedure. The non-physical risks, that are more than minimal, are as follows (and should be considered when drafting the foreseeable risks section of the consent document):

When subjects already have the disorder for which biological testing is being done:

Risks may include possible breaches of confidentiality (affecting insurability, employability, etc.) and (where applicable) unintentionally uncovering incidental genetic information (e.g., non-paternity, hereditary risks, risks of future diseases). Benefits could include confirmation of clinical diagnosis, where applicable, or else indicate clearly that no direct benefit exists for the subject.

When subjects are not yet known to have the disorder for which biological testing is done:
Risks include those above, as well as (where applicable) psychological risks, determination of the possible presences of a heritable disorder (in themselves or their current/future offspring, accordingly). This research activity could also be of direct benefit, e.g., giving the subject the ability to inform family and to make appropriate lifestyle and reproductive choices; offering the potential for more effective intervention). Further:

- If there are hereditary implications, genetic counseling by a genetic counselor or other qualified health care provider is required prior to participation in the study. Consent should indicate who will cover the cost of counseling.
- There is an obligation to inform the subject of the test results in a timely manner after they are known. However, the subject should be offered an opt-out option (to not be told).
- Consent document must indicate that the result of the research testing must not be used as the basis for clinical decision making, and the subject should seek confirmation of research test results in a certified clinical laboratory.

PI wishes to contact subjects if and when the clinical significance of the results becomes clear:
Possible consent language includes:

- *If, in the future, findings from this study are confirmed by the scientific community and have definite implications for your health (or your children or future offspring), we will make a best effort to send you a letter describing the general results and offering ways to obtain care and/or counseling. If you initial here _____, it means you do not want to be contacted if future findings become relevant to you.*

## 11.E. General Issues to Consider in Biological Specimen Research

If the banking of biological specimens is proposed within the context of a larger research study, the following issues may be addressed within the main research consent form, but the actual request for consent to bank the tissue should be separated out from the request to consent for the main study. This can be achieved by adding yes/no statements (with a signature or initial lines) before the signature lines of the main consent.
For example:

1. *Do you agree to allow use of extra blood obtained from this study/extra tumor from your surgery for use in future research, the purposes of which are unknown at this time? If you agree, any future studies using your sample will be subject to further regulatory review*.
2. *Do you agree to allow someone to contact you in the future to ask you questions about your health or to ask you to participate in more research?*
3. At the time of the proposed activity, is it the intent of the investigator or the company collaborator/sponsor to produce a commercially valuable product? If yes, disclose in the consent form whether or not the subject or his/her heirs will receive a portion of the profits. Note that consent forms cannot contain language through which the subject is made to waive, or appear to waive, any of his/her legal rights. An acceptable example of consent language is:
   *We may, in the future, be able to produce a commercially valuable product from the work done on samples collected from subjects in this study. It is not our intention to pay you of your heirs, for profits derived from such a product.*
4. What happened to the specimen(s) and/or cell lines generated, and the data derived thereof, if the subject decides to withdraw from the study? Is the tissue removed from the study analysis or from the tissue bank? If so, state so in the consent. If it is not the intention to remove the sample or any data derived from it, state so in the consent.

5. How long will the biological specimen be kept? It is acceptable to indicate, in the consent form, that the specimen will be kept for an indefinite amount of time.
6. If a new study proposes secondary use of biological specimens, i.e., use of samples collected for a previously conducted study, an assessment will be made by the IRB regarding whether or not the consent that was obtained for the first study is applicable to the second. If the purpose of the new study differs significantly from the purposes stated in the original study, and the specimens are identifiable, obtaining new consent will be required, unless the consent waiver criteria are met.
7. Given the study aims and risks, the IRB will determine if the investigator should obtain a study-specific Certificate of Confidentiality from the NIH to protect against disclosure required by issuance of a subpoena. This is an extra protection for confidentiality if the study can potentially generate information that is particularly sensitive (ex. HIV status, history of alcoholism, possible mental illness, etc.) and is available for all studies regardless of funding source).

# Section 12: Research with Medical Devices

## 12.A. Overview

All research studies involving the use of an investigational device, or the investigational use of an approved device, must be reviewed and approved by the IRB prior to initiation. A medical device is defined, in part, as any health care product (including software such as apps and algorithms in certain circumstances) that does not achieve its primary intended purposes by chemical action or by being metabolized. Research investigations of medical devices must comply with the Food and Drug Administration (FDA) and Institutional Review Board (IRB) regulations.

## 12.B. IRB Review of Medical Device Studies

Any device studies submitted to the IRB must include information regarding any FDA review that has taken place to date. If the device has not already been classified as either Significant Risk or Non-Significant Risk, the IRB will make this determination. When doing so, the IRB will consider the sponsor/investigator's description of the device, reports of any prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria. The IRB will consider the sponsor's risk assessment in its determinations, but reserves the right to disagree with the preliminary classification.

In the case that a submitted protocol involves a medical device, an IRB member with health care credentials will be included as part of the initial review team, and an IRB consultant will advise the IRB throughout the review process.

# Section 13: Research Integrity Policy

## Policy Purpose

It is the purpose of this policy to instill and promote the principles of professional integrity; to prevent scientific misconduct; and to discover and censure instances of misconduct when they occur. This policy sets forth the requirements necessary to ensure compliance with laws and regulations regarding research misconduct.

## Persons Affected

Faculty, Staff

This policy applies to funded and unfunded scientific research and scholarly writing conducted by any member of the Farmingdale State College faculty or staff. It is not intended to address issues, such as the conduct of students in fulfilling course requirements or students involved in research, which are covered in the Academic Integrity Policy and Student Code of Conduct.

## Policy Statement

Farmingdale State College (hereinafter "the College") shall maintain high ethical standards in scholarly work, prevent misconduct where possible, and promptly and fairly evaluate and resolve instances of alleged or apparent misconduct.

Federal Research misconduct is monitored by the U.S. Department of Health and Human Services Office of Research Integrity. Federal Register section 65 FR 76260 requires all agencies which conduct or support Federal research to follow the Federal Policy on Research Misconduct.

The United States Public Health Service (PHS) regulation, "Public Health Service Policies on Research Misconduct," at 42 C.F.R. 93.301 requires that all institutions renew their research misconduct assurance by annually submitting a report to the Office of Research Integrity (ORI). All allegations of fabrication, falsification, and/or plagiarism received by an institution, including allegations that do not make it to the inquiry or investigation phase, must be reported.

The College will annually report to all funding and sponsoring agencies as follows:

1. Assurance that the institution has established an administrative process for reviewing, investigating, and reporting allegations of misconduct in science in connection with sponsored research.
2. Provision of such aggregate information on allegations, inquiries, and investigations as funding and sponsoring agencies may prescribe.

Every member of the College community has the responsibility of reporting misconduct in scientific work. Employees and individuals who report suspected or detected allegations of misconduct shall not suffer discharge, demotion, suspensions, threats, harassment, discrimination, or other forms of retaliation for making such reports in good faith. Intentional use of this policy or associated procedures to make false allegations may result in disciplinary action.

If sufficient information exists, the College will refer the matter for investigation and disciplinary action as may be appropriate under the applicable collective bargaining agreement. The disciplinary process and potential outcomes are described in the applicable collective bargaining agreements.

If necessary the College may disclose proven or confirmed misconduct to funding agencies, collaborating scientists and institutions, journal editors, professional associations, and licensing boards.

Where there is reasonable indication of possible criminal violations, University Police must be notified immediately, as well as the Director for the Research Foundation and Sponsored Program Operations for sponsored research. The Director for the Research Foundation and Sponsored Program Operations will notify SUNY Research Foundation and the appropriate funding agencies within 24 hours of this determination. Where Public Health Service (PHS) grants are involved, the PHS Office of Scientific Integrity will be notified.

This policy will allow such distinctions to be made in a manner that minimizes disruptiveness and protects the conscientious, honest scientist from false or mistaken accusations.

The procedures for the institutional handling of allegations of scientific misconduct have four stages: inquiry, investigation, formal finding, and disposition of the matter.

Alleged reports of misconduct in research activities must be reported to the Research Integrity Officer (RIO). The Provost, in consultation with the President, has appointed the Associate Provost as the College's Research Integrity Officer. If there is an actual or perceived conflict of interest, a different RIO will be appointed. The responsibilities of the RIO include:

1. To serve as a resource for inquiries regarding misconduct in research.
2. To receive and review formal written complaints of suspected and detected misconduct in research.
3. To maintain records of all complaints, related documents, and institutional responses.
4. To conduct inquiries and submit recommendations concerning investigations to the Provost and the Risk and Compliance Office.
5. To inform the Director of the Research Foundation and Sponsored Program Operations of misconduct involving sponsored programs. The Director will notify the sponsoring and funding agencies as appropriate.

Precautions shall be taken against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

## PROCEDURES

### Inquiry

Individuals are responsible for reporting allegations of research misconduct in good faith to the Research Integrity Officer (RIO). Reports must be made in writing and submitted to the RIO.

The RIO will review the written report of the alleged misconduct.

The RIO will then conduct an immediate inquiry into allegations of misconduct in order to determine whether there is a substantial basis for initiating a formal investigation into the alleged misconduct.

The RIO will make every effort to safeguard all individual reputations and the integrity of the research and maintain confidentiality. Every effort shall be made to protect the interests, privacy, position and reputation of those who in good faith report apparent misconduct and others who testify.

In the conduct of this inquiry, the RIO may consult with legal counsel, faculty, staff, and other sources for pertinent data.

The RIO, in consultation with the Provost and the Director of the Research Foundation and Sponsored Program, will take appropriate administrative actions to protect all funds and ensure that the purposes of the Federal financial assistance are being carried out.

The RIO will notify the faculty member or other investigator whose research is the subject of the complaint that a complaint has been lodged, the nature of the complaint, and the procedures to be followed. The affected individual(s) will be granted confidential treatment to the maximum extent possible, prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

The inquiry shall be conducted in confidence with the purpose of separating unfounded allegation(s) from those of a substantive nature and shall be completed within 60 days of the initial receipt of the allegations. At the completion of the inquiry, a written report shall be filed with the Provost with an assessment as to whether or not the allegation(s) is/are warranted and why such a determination had been made. If circumstances clearly warrant an extension of the sixty (60)-business day limit, a record of the inquiry shall include documentation of the reasons for exceeding the sixty (60) business days. If the activity includes NSF funds, interim status reports may be required if the Inquiry goes longer than 90 days.

The Provost shall determine on the basis of the written report of the inquiry, and any other consultation deemed necessary, whether the allegations warrant a formal investigation. In either case, the basis for the decision will be fully documented. Such records shall be maintained in a secure manner by the RIO for a period of at least three years after the termination of the inquiry and shall, upon request, be provided to authorized representatives of sponsoring and funding agencies.

If the decision of the Provost is that no investigation is warranted, the Provost will notify all those concerned of this determination. Final decisions made by the Provost regarding the outcome of the inquiry will be communicated to the President.

## Investigation

If the decision of the Provost is that an investigation is necessary, it shall be undertaken formally within 30 days of the completion of the inquiry.

When applicable, after administrative and legal consultation, the Research Foundation, the granting agency and any other parties potentially affected by the investigation will be informed of the decision to conduct an investigation.

The Provost will take interim administrative actions, as appropriate, when necessary to protect research funds, human subjects, or equipment.

During the course of the investigation, funding and sponsoring agencies are to be apprised of any developments which disclose facts that may affect current or potential funding for the individual(s) under investigation or that the funding agency needs to know to ensure appropriate use of funds and otherwise protect the public interest.

The Provost will appoint a Research Integrity Committee to conduct the investigation and prepare an investigation report. The committee shall be composed of impartial members with appropriate expertise to evaluate the allegations. The committee should have the following membership:

1. Research Integrity Officer (Chair)
2. Director for the Research Foundation and Sponsored Program Operations
3. Dean or Director of appropriate area
4. Ethics Officer

The Research Integrity Officer shall:

1. Inform the subject of the investigation of the accusations and that formal investigation will be conducted and invite the subject to make a written response to the allegations.
2. Consult, as the need arises, on an ad hoc basis with faculty and staff members for pertinent data.
3. Inform collaborator(s) in the research project under investigation and give them the opportunity to comment.
4. Immediately proceed to collect and secure all materials necessary for the investigation.
5. Complete the investigation within 120 days, whenever possible.

During the course of the investigation, the Research Integrity Committee will:

1. Receive and review relevant documents, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.
2. Interview all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations. Complete

summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.
3. Seek additional information as deemed necessary.
4. Consult, when appropriate, with expert(s) from outside the institution.
5. Record and document all relevant information obtained in the course of the investigation. This documentation is to be made available to the appropriate officials of sponsoring agencies when requested.
6. Analyze and summarize the results of the investigation.
7. Prepare and submit a written report to the Provost, including a summary of the investigation, findings, and recommendations for further action.

## Finding

At the conclusion of the investigation, the Provost will:

1. Submit a written report to the President of the results of the investigation. Included in this report will be:
2. A statement of accusation.
3. A statement of the findings.
4. An indication of the evidence or lack of evidence of misconduct.
5. An evaluation of the seriousness of any misconduct found.
6. Recommendations for further action.
7. Send a copy of the report to the subject of the inquiry who has ten (10) business days from receipt of the report to submit a response to the President.
8. Include any written response by the subject of inquiry as an addendum to the report.

## Reporting Requirements

1. An institution's decision to initiate an investigation must be reported in writing to the appropriate officials of the sponsoring and funding State or Federal agencies on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the application or grant number(s) involved.
2. An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the sponsoring agency.
3. The institution is expected to carry out its investigations through to completion, and to diligently pursue all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements, a report of such planned termination, including a description of the reasons for such termination shall be made to the appropriate funding and sponsoring agencies.
4. The final report submitted to the sponsoring agency will describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.
5. If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the sponsoring agencies written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. If the request is granted, the institution must file periodic progress reports as requested by the sponsoring agency.
6. The institution is responsible for notifying sponsoring agencies if it ascertains at any stage of the inquiry or investigation that any of the following conditions exist:

a. There is an immediate health hazard involved;
b. There is an immediate need to protect Federal (or State) funds or equipment;
c. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is/are the subject(s) of the allegations as well as his/her co-investigators and associates, if any;

d. It is probable that the alleged incident is going to be reported publicly;
e. There is a reasonable indication of possible criminal violation. In that instance, the institution must inform the sponsoring agencies within 24 hours of obtaining that information.

## Disposition

The President, upon receiving the report from the Provost and any response statement by the accused, will make a final determination regarding whether sufficient information exists to that misconduct has occurred and refer the matter to his/her designee for investigation and disciplinary action, or other action, as may be appropriate under the applicable collective bargaining agreement.

Consideration will also be given to formal notification of other concerned parties, not previously notified, such as:

- Sponsoring agencies, funding sources
- Co-authors, co-investigators, collaborators
- Editors of journals in which fraudulent research was published
- State professional licensing boards
- Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated
- Professional societies
- Where appropriate, criminal authorities

## Definitions

- **Scientific Misconduct:** "Misconduct" or "Misconduct in Science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
- **Inquiry:** An inquiry is an information-gathering and initial fact-finding to determine whether an allegation or apparent instance(s) of misconduct warrant an investigation.
- **Investigation:** An investigation is a formal examination and evaluation of all relevant facts to determine if an instance of misconduct has taken place. If misconduct is confirmed, the investigation should determine the seriousness of the offense and the extent of any adverse effects resulting from misconduct.

## Related Documents

Academic Integrity Policy
Student Code of Conduct

## Responsible Office

Provost's Office

## Policy History

Approved Date: 12/19/2022