

Institutional Review Board

Policy Manual

Revision 2.21

4/3/2017

Table of Contents

- 1.0 PURPOSE, REGULATORY OVERVIEW, AND INSTITUTIONAL POLICY 2
 - 1.1 INTRODUCTION AND PURPOSE 2
 - Review Guidelines..... 2
 - 1.2 LAWS, REGULATIONS, AND GUIDING PRINCIPLES 3
 - 1.3 INSTITUTIONAL POLICY AND IRB AUTHORITY 4
- 2.0 INVESTIGATOR GUIDELINES 7
 - 2.1 EDUCATION AND TRAINING REQUIREMENTS..... 7
 - 2.2 USING SSU DIRECTORY INFORMATION AND FERPA REGULATIONS 7
 - 2.3 FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA) 7
 - 2.4 HIPAA 9
 - 2.5 RESEARCH WITH CO-INVESTIGATORS..... 9
 - 2.6 RESEARCH COLLABORATIONS 9
- 3.0 MISCELLANEOUS INFORMATION FOR APPLICANTS..... 11
 - 3.1 INCIDENT AND ADVERSE EVENT REPORTING 11
 - 3.2 MASSACHUSETTS STATE REPORTING LAW 11
 - 3.3 DECEPTION AND DEBRIEFING 12
- 4.0 IRB MEMBERSHIP 15
 - 4.1 IRB EXECUTIVE COMMITTEE 15
 - 4.2 IRB COMPOSITION 15
 - 4.3 IRB COMMITTEE MEMBER REQUIREMENTS..... 15
- 5.0 COMPLIANCE AND REPORTING REQUIREMENTS 17

The Institutional Review Board (IRB) Policy Manual provides researchers with institutional, state and federal policy for conducting research with human participants. It is the responsibility of all researchers at Salem State University (SSU) to be familiar with both the IRB Policy Manual and Procedures manual and abide by the provisions provided herein. Please refer to the IRB Procedures Manual for further guidance.

1.0 PURPOSE, REGULATORY OVERVIEW, AND INSTITUTIONAL POLICY

1.1 INTRODUCTION AND PURPOSE

The purpose of this policy is to outline the responsibilities of the Institutional Review Board at Salem State University (SSU) and document the policies for the faculty, staff and students who conduct research with human participants at Salem State. The mission is to protect the rights and welfare of human participants in research. The policies outlined herein are in accordance with Federal Policy on the Protection of Human Subjects [DHHS Policy 45 CFR Part 46](#).

The IRB reviews and approves all research involving human participants that are conducted by Salem State faculty, administrators, staff, students, as well as others not affiliated with the university but who wish to conduct research at Salem State. Regardless of whether or not the data are collected on campus or off campus, and regardless of whether the research is federally funded or not, all research is reviewed by the IRB.

Both the university and the Principal Investigator(s) are responsible for ensuring the highest ethical standards are upheld for research with human participants. IRB approval of a research project means that the project satisfies the ethical guidelines for the protection of human participants, as set forth by the federal regulations and by the IRB.

IRB approval, however, does NOT mean institutional approval to conduct research.

Only research with human participants is under the purview of the IRB. Research is defined as: *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge* (45 CFR part 46 s. 102d).

All projects involving human beings conducted at Salem State, or by Salem State faculty, staff, students and others under the sponsorship of Salem State, must be submitted to the Salem State IRB for review. The process is required before any research can begin.

Review Guidelines

If your research meets one of the following criteria, it needs IRB review:

1. Does the project constitute research, based on the federal definition?
2. Will findings from the project be disseminated outside of the university?
3. Does the project involve a vulnerable population per 45 CFR 46?
4. Does the project involve any of the following:

Violation of Privacy: Collection of data concerning at-risk or socially questionable behavior (for example, questions about substance use or sexual activity) is viewed by many individuals as violations of privacy.

Legal Risks: Data concerning illegal behaviors may place individuals at risk of legal action, if (a) names can be linked to particular responses or observations and (b) the research has not received specific legal protection (e.g., by Certificate of Confidentiality).

Psychosocial Stress and Related Risks: Procedures that raise sensitive issues may generate stress for participants. For example, questions about at-risk behaviors may cause students to feel stress related to their self-image or contribute to perceived peer pressure.

Risks to Participants' Social Relations: Because relevant questions often request information about the behavior, or relations with, family members, peers, or authorities, some procedures may pose a risk to those relations if confidentiality is not adequately safeguarded.

If the proposal includes any of the above, a review is required. If the proposal does not involve any of the above conditions, an IRB review is not required.

Faculty are encouraged to contact the IRB administrator to determine if review is needed for course-related projects involving human participants. Projects without IRB approval may not be disseminated in written form or in public presentations outside of Salem State.

No applications for semester long courses will be accepted for review less than two weeks before the last day of classes.

IRB policies and procedures are reviewed and updated on an annual basis or as needed. Changes to federal regulations will be updated immediately and will supersede the current policy. Principal investigators are responsible for staying informed of IRB policies and procedures.

Research Integrity: In the event that the IRB determines that student or faculty-led human participants research has taken place without IRB approval (this includes but is not limited to lack of consent and recruitment of participants and data collection without IRB approval), the IRB Executive Committee will convene in order to cite the researcher under either the university's Research Integrity Policy or the Academic Integrity Policy.

1.2 LAWS, REGULATIONS, AND GUIDING PRINCIPLES

By federal regulations, the IRB is charged with the responsibility of reviewing and monitoring research involving human participants. Regulations fall under the governing authority of the [Department of Health and Human Services \(DHHS\)](#). Oversight ensures that researchers adhere to the ethical principles and guidelines for the protection of human participants in research, as outlined in the [Belmont Report](#) and [45 CFR § 46 of the Code of Regulations](#).

Guiding principles are defined in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research* by the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research (1979). The Belmont Report summarizes the requirements for ethical behavior in research with human participants including:

- **Respect for Persons.** -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
- **Beneficence.** -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.
- **Justice.** -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explanation. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

1.3 INSTITUTIONAL POLICY AND IRB AUTHORITY¹

SSU acknowledges and accepts the responsibility for protecting the rights and welfare of human participants recruited to participate in research activities. Requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all applicable research without regard to the source of funding.

SSU has established an IRB to review all research with human participants. Although federal guidelines require the IRB review federally funded projects with human participants, it

¹ Adapted with permission from University of Massachusetts Lowell IRB Policy and Procedures

permits the institution to determine the scope of IRB review for research involving human participants that is not federally funded. SSU requires that funded and non-funded research with human subjects be reviewed by the IRB prior to the initiation of the research, per our guidelines.

The involvement of human participants in research will not be permitted until the IRB has reviewed and made a decision on the research protocol. The IRB meets regularly to review research protocols. It is important to the institution that the IRB have a high level of respect from the research community in order to better fulfill its charge and develop trust between all parties concerned.

The President or designee is the Institutional Official (IO) and has responsibility for oversight of research with human participants. The IO recognizes that the IRB can only carry out its regulatory, educational, and ethical functions when there are sufficient resources and high-level support staff to communicate effectively with the research community and to ensure adequate protections of participants through oversight, including review and monitoring of approved research. Research that has been reviewed and approved by the IRB may be subject to disapproval, suspension, or termination by the IO or designee of the university but those officials may not approve research that has been disapproved by the IRB. For matters related to the execution of its duties and responsibilities, the IRB has direct access to the IO.

Funded research at SSU is conducted in accordance with the approved Federal-wide Assurance (FWA) on file with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) in which the SSU IRB #1 is designated as the IRB of record. The FWA is an assurance that SSU will comply with the federal regulations for the protection of human participants in research. It is a commitment, signed by the IO, that the institution will have written IRB procedures, provide review of nonexempt research covered by the FWA, obtain and document informed consent unless otherwise waived in accordance with the regulations, ensure that all collaborating institutions operate under an approved FWA, have formal written agreements of compliance from all nonaffiliated investigators, and the IRB will be provided with sufficient resources to fulfill these responsibilities. All sponsored research with human participants must be reviewed by the IRB.

In summary, SSU's institutional policy conveys the authority to the IRB to:

- Review all research studies involving human participants before their involvement may begin, per review guidelines;
- Require that faculty sponsors take ultimate responsibility for any student directed research. Only faculty may serve as a Principal Investigator; in select circumstances, administrators may serve as faculty principal investigators with permission from the IRB;
- Require revisions in research studies and consent documents as a condition of approval;
- Approve new research studies and the continuation of previously approved studies;
- Develop mechanisms for prompt reporting to the IRB of unanticipated problems occurring in approved studies, or in other studies related in context to the approved studies;

- Suspend or terminate a previously approved study, if necessary;
- Restrict aspects of a research study for the purpose of participant protections, if necessary.

2.0 INVESTIGATOR GUIDELINES

2.1 EDUCATION AND TRAINING REQUIREMENTS

Faculty, staff, graduate and undergraduate students submitting proposals to the IRB must obtain training through the Collaborative Institutional Training Initiative (CITI), Social Behavioral module, and present CITI certification as part of their IRB proposal as supporting documentation. The NIH Office of Extramural Research training “Protecting Human Research Participants” may be substituted.

The Salem State IRB offers training on the protection of human research participants for all investigators submitting protocols for review. This training is offered through the CITI Program, a web-based program for research with human participants. Directions for registration and use may be found on the [IRB website in Canvas](#).

Non-SSU personnel who wish to conduct research at Salem State must provide proof of completion of the appropriate CITI program course.

The CITI social and behavioral course ***Social and Behavioral Investigators*** includes modules chosen by the university's IRB that provide coverage of the ethical principles and procedures for conducting human subject research. Students will find specific training modules set up for their use including, but not limited to: Students in Research, Internet Research, Research with Children, Informed Consent, and Defining Research with Human Subjects.

As a condition of federal funding, this program meets the federal mandate for instruction.

2.2 USING SSU DIRECTORY INFORMATION AND FERPA REGULATIONS

Researchers who intend to use SSU's student data from the university Registrar or department of Strategic Planning and Decision Support must consult and seek permission from those entities. The IRB does not determine whether these entities can or should share student data. These data may include student grades, exam grades and SAT scores, among other types. This consultation must address whether these data can be both generated and released, assuming IRB approval would be obtained. Data used for internal university evaluations does not constitute human participants research. If the Registrar or Strategic Planning and Decision Support consent in writing to the use of these data, the researcher may submit an IRB proposal for review. It is the responsibility of the researcher to obtain the necessary waivers if necessary. This is discussed further in the next section.

2.3 FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA)²

² SOURCE: <http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

The Family Educational Rights and Privacy Act (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.

Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth their view about the contested information.

Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):

- School officials with legitimate educational interest;
- Other schools to which a student is transferring;
- Specified officials for audit or evaluation purposes;
- Appropriate parties in connection with financial aid to a student;
- Organizations conducting certain studies for or on behalf of the school;
- Accrediting organizations;
- To comply with a judicial order or lawfully issued subpoena;
- Appropriate officials in cases of health and safety emergencies; and
- State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

More information on FERPA at Salem State can be found with the [Registrar's Office](#).

2.4 HIPAA³

The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased. The Rule balances an individual's interest in keeping his or her health information confidential with other social benefits, including health care research.

In general, the Privacy Rule requires an individual to provide signed permission before the "covered entity"⁴ can use or disclose the individual's private health information for research purposes. There are certain circumstances, however, in which an individual's authorization is not required. In these cases, the covered entity must provide a proper documentation of the waiver of authorization.

For additional information on research involving health information, please refer to the National Institutes of Health's [information](#) on health services research and the HIPAA Privacy Rule.

2.5 RESEARCH WITH CO-INVESTIGATORS

Currently, the Salem State IRB application process only recognizes one principal investigator (PI) per research study, no matter how many research sites and investigators may be involved. The PI of record should submit the IRB application.

In the case of student research, the faculty sponsor is the principal investigator and therefore will be fully responsible for the project.

In multi-site studies for which Salem State is the coordinating institution, the principal investigator assumes the responsibility for the conduct of the study at each performance site and by each site-specific principal investigator.

2.6 RESEARCH COLLABORATIONS

Any research project involving Salem State University or Salem State personnel must have Salem State IRB approval and an IRB agreement with the lead institution.

Letter of Agreement

³ U.S. Department of Health and Human Services, National Institutes of Health's *Institutional Review Boards and the HIPAA Privacy Rule*.

⁴ Covered entities are defined in the HIPAA rules as: 1) health plans; 2) health care clearinghouses; and 3) health care providers who electronically transmit any health information in connection with transactions for which the Department of Health and Human Services has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. Researchers are covered entities if they are also health care providers who electronically transmit health information in connection with any transaction for which the Department of Health and Human Services has adopted a standard.

When proposed projects involve collaboration with an internal entity or an organization external to the university, a letter of agreement must be obtained by the researchers for submission to the IRB prior to the initiation of the project.

For projects involving the collection of sensitive data from specific Salem State populations or entities internal to the university (e.g., Women's Center, Veterans Center, etc.), the IRB will determine whether a letter of agreement is needed.

The letter of agreement should be signed by a person of authority at the external or internal entity, should state the names of the researchers, should indicate the basic nature of the research and indicate support for the conduct of such research. The letter of agreement must be on the letterhead of the external or internal entity. A scanned copy of the original is appropriate for submission to the IRB. The letter of agreement must be obtained before the IRB can approve an investigation.

Research Collaborations with Multiple Institutions - For collaborations in which Salem State will serve as the lead institution, SSU IRB review is required. Salem State personnel who wish to collaborate with a principal investigator at another institution as a co-investigator should contact the PI or IRB at the lead institution for their review requirements. In certain cases including federally sponsored projects, one IRB will serve as the IRB of record for both institutions. Such an agreement will require a Collaborative Institution Authorization Agreement signed by the signatory officials at each institution.

In all collaborations, IRB approval does not mean a researcher has access to the sample population. Access needs to be granted by the appropriate office before data collection can commence.

3.0 MISCELLANEOUS INFORMATION FOR APPLICANTS

3.1 INCIDENT AND ADVERSE EVENT REPORTING⁵

Any unanticipated problem involving “risk” that ultimately results in harm to the participant and is related to a research intervention encompasses a reportable adverse event. “Problems involving risk” could indicate that only the possibility of harm occurs rather than actual harm. However, loss of research records that contain identifiable private information would be a reportable event. Procedures for prompt reporting of unanticipated IRB Policies and Procedures events that involve risk to the participant or others must be established by the principal investigator. Typically, only events that are very serious and related to the research are reported to DHHS or the Food and Drug Administration as adverse event reports. Any unanticipated incident that occurs during a research activity should be reported to IRB as soon as possible to assist the PI in determining whether the protocol should be revised to prevent any similar subsequent incidents.

Adverse event or incident reports should be submitted to the IRB Administrator and IRB Chair. The report should provide the IRB with a reasonably detailed analysis of the event and allow the IRB to assess the situation and determine whether the protocol requires modification to minimize risk, whether the consent form should be revised, or if participants should be contacted to re-consent to participate in the research study. Adverse events can be internal (those that occur at SSU and are served by the SSU IRB) or external (those that occur at external unaffiliated study sites). The event report should include:

- Description of the event in sufficient detail as to allow an informed review of the occurrence (description, causality, prognosis);
- Explanation as to why the event is unexpected and related (for internal adverse events a report is required if the event meets both criteria only);
- Explanation as to why the event is unexpected and related and serious (for external events a report is required if the event meets both criteria only);
- Description of changes to the protocol to minimize further risk, or the rationale if no changes are required;
- Description of changes to the consent or the rationale if no changes are required;
- Description of the plan to re-consent current participants or the rationale if no re-consent is required. Risk/benefit analysis update: explain why the overall risk/benefit relationship of the research is still acceptable in light of the information concerning this adverse event report.

3.2 MASSACHUSETTS STATE REPORTING LAW

Students, faculty and staff will all comply with the following Massachusetts General Laws related to the mandatory reporting of child maltreatment, elder abuse/neglect or someone exhibiting harm to self or others:

- Part I, Title II, Chapter 19a, Section 15 (on elder abuse)
- Part I, Title XVII, Chapter 119, Section 51A (on child maltreatment)

⁵ Adapted with permission from University of Massachusetts Lowell IRB Policy and Procedures

- Part I, Title XVII, Chapter 123, Section 12 (on reporting harm to self or others)

Any questions about mandatory reporting should be directed to the university's Office of Human Resources & Equal Opportunity.

In studies where there is the possibility of information concerning child maltreatment, elder abuse/neglect or harm to self or others, the informed consent form must include the following language:

"The information provided to the researcher will be kept confidential with the exception of the following information, which must be reported under Massachusetts law such as suspected cases of child or elderly abuse and information that individuals intend to harm themselves or others."

3.3 DECEPTION AND DEBRIEFING

Introduction

Salem State University's Institutional Review Board is guided by 45 CFR 46 (Common Rule). The SSU IRB acknowledges that deception and incomplete disclosure may at times be necessary when researching social and human behavior to avoid study bias or explore hypotheses requiring participant misdirection. At the same time, the IRB considers research involving deception a matter of particular seriousness. With deception, participants cannot give true informed consent. The IRB must thus, to preserve research ethics, give special consideration to studies involving deception through alterations to the informed consent process. These guidelines discuss deception and incomplete disclosure in research and stipulate the requirements of such alterations so as to preserve ethicality.

Definitions

- "Deception" occurs when a researcher gives false information about any aspect of the research to the participant;
- "Incomplete disclosure" occurs when the researcher does not disclose the true purpose or nature of the research;
- "Debriefing" happens after the research and includes explaining the deception to the participant, responding to the participant about the use of deception, and obtaining true informed consent.

*Examples of deception*⁶:

- Participants are told they are working with a group of other participants on a task, but in actuality, they are the only participant in the study. The other "participants" are actually confederates or research staff acting as participants.

⁶ Examples taken from Northwestern University's IRB, retrieved from <https://irb.northwestern.edu/sites/irb/files/documents/deception-incomplete-disclosure-guidelinesrevised652015.pdf>

- Participants are told they scored poorly on a task, when in actuality, they are scored poorly regardless of their performance.

Examples of incomplete disclosures:

- Researcher instructs the participant to complete a puzzle; however, the researcher does not mention to the participant that the puzzle cannot be completed.
- Participants are told that the questionnaire they are completing measures anxiety. In reality, the questionnaire is a combination of questionnaires whose purpose is to measure both depression and post-traumatic stress disorder.

Policy

Research which includes deception in the study design must provide the following information:

- **Justification for the use of deception:** The American Psychological Association's code necessitates that the research demonstrate the potential for substantial scientific and educational value. The researcher must further explain why there is no viable alternative procedure. In the application the researcher should provide information on similar uses of deception in similar studies, including description of any harm arising from such studies. If there is a possibility of short-term psychological distress for participants, the researcher must explain how distress will be diminished: for instance, during a debriefing process.
- **Pain or severe emotional distress:** Researchers are prohibited from using deception when there is a reasonable risk deception may lead to extreme emotional distress or physical pain.
- **Debriefing:** As soon as possible after the deception, researchers must apprise participants of the deception or incomplete disclosure and provide them with an IRB-approved debriefing document. Debriefing should consist of a personal interview so that participants may ask questions as needed and also a written debriefing statement. There may be conditions when a debriefing statement alone may be used. The researcher should provide a script for debriefing interviews during the IRB review process.
- **Waiver of Consent:** The IRB must approve an alteration to the consent form process. An alteration can be granted if the IRB documents all of the following (see §45 CFR 46 (d)):
 1. The research involves no more than minimal risk to the participants;
 2. The waiver or alternation will not adversely affect the rights and welfare of the participants;
 3. The research could not practically be carried out without the waiver or alteration, and;

4. Whenever appropriate, the participants will be provided with additional pertinent information after the procedure.

- **Privacy and Confidentiality:** Research protocols must discuss specific procedures which will be used to protect the confidentiality of the data collected. Participants must be given an opportunity to disallow the use of their data after it is collected.
- **Waiver of use of collected data:** Participants must be provided the option of disallowing the use of participant data after they learn the true nature of the research methods.

Debriefing Recommendations

Researchers are strongly encouraged to debrief participants as soon as possible after the research. Below, please find some general recommendations for the debriefing document to be provided to all research participants:

- Document title should read “Debriefing Statement”;
- Document should contain study title;
- Provide complete contact information for the principal investigator (name, address, phone, and email);
- Thank participants for their time and efforts;
- Discuss the purpose and rationale for the study in the simplest terms possible; avoid using complicated terminology;
- Explain the components of the study that involved deception and why deception was justified;
- Explain how data will be used and provide participants the opportunity to disallow use of their data;
- If deception involved audio or video recording of participants, participants have the right to refuse permission to use the recordings in the study. The researcher must destroy recordings within 24 hours after the participant informs the researcher of his/her decision.

4.0 IRB MEMBERSHIP

4.1 IRB EXECUTIVE COMMITTEE

In addition to the full IRB committee, an Executive Committee will function as a working group tasked with managing the day-to-day operations of the IRB process. The Executive Committee will consist of the IRB Chair, the IRB's senior university administrator, and the IRB administrator.

4.2 IRB COMPOSITION

Effective January 2015, Salem State University's IRB committee composition is as follows: 12 total members (including the IRB administrator, *ex-officio*): 7 faculty (one from each MSCA academic area unit (e.g., Area A, Area B, Area C, Area D), plus three additional faculty from any academic area); 1 university administrator; 2 administrators from Student Life; and 1 external member. Members may serve for two consecutive three year terms, and after cycling off for one year, may be reappointed.

The Salem State IRB committee composition conforms to the IRB membership requirements spelled out in 45 CFR § 46.107. The IRB Committee includes at least five members and considers members with varying backgrounds, with a diverse representation in race, gender, and culture. The committee also includes at least one member whose primary concerns are in scientific areas, and at least one member whose primary expertise are in non-scientific areas. The committee also includes at least one external member who is not affiliated with the institution and who is not an immediate family of a person affiliated with the institution.

4.3 IRB COMMITTEE MEMBER REQUIREMENTS

Qualifications for Membership

Faculty who are appointed as members of the IRB must have the relevant research experience necessary to review IRB proposals. Preferred qualifications for faculty membership include having at least one successful IRB proposal of their own and at least one publication or presentation that includes research with human participants within the last five years.

CITI Training

IRB committee members are required to complete human subjects training through the Collaborative Institutional Training Initiative (CITI), a web-based training program for research with human subjects. Committee members are required to complete the CITI training within one month of appointment to the committee. Appointed committee members who have not completed their CITI training within one month from the date in which the IRB Committee is charged will be required to step down from the IRB Committee.

Application Reviews

The IRB reviews all research with human participants to ensure that the research is conducted in accordance with all federal, state, institutional, and ethical guidelines.

Although federal guidelines require that the IRB review federally funded projects, the IRB may determine the scope of IRB review for research involving human participants that is not federally funded.

IRB members are not permitted to review (whether the initial review or a continuing review) applications in which the member has a conflicting interest. For instance, an IRB member may not review his or her own research, or research which presents a conflict of interest.

Proposals beyond minimal risk are reviewed by the convened Committee. In order to be able to review proposals, all new members of the IRB Committee will participate in IRB proposal review training process with the IRB Chair and/or IRB Administrator. This process is designed to orient members to the challenges of reviewing human participants research protocols. After the training is complete, new members will review as a second reader to the IRB Chair and/or IRB Administrator for their first year. After that point, new members will be able to function as a primary reader. If an appointed faculty member has not completed their IRB proposal review training within six weeks of the completion of their CITI training, they will be required to step down from the Committee.

Convened Meetings

The IRB committee meets monthly during the academic year, from September to May. During the summer, the committee meets on an as-needed basis.

IRB Applications that require full committee review are reviewed monthly during the academic year and on an as-needed basis during the summer. Committee members and meeting schedules are available on the IRB's Canvas site.

Action involving a committee vote requires a quorum (i.e., the presence of a majority of IRB members). IRB actions are decided by a simple majority vote.

Other Responsibilities

IRB Committee members are required to sign a confidentiality and conflict of interest agreement upon joining the committee. This agreement ensures that members hold IRB research in confidence and meet federal, state, and institutional conflict of interest laws. The IRB committee is also responsible for various other tasks related to research participants. This includes but is not limited to: a review of IRB policies and procedures; and on-campus instruction of the IRB requirements and process.

5.0 COMPLIANCE AND REPORTING REQUIREMENTS

Noncompliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, the policies or procedures set forth by the Institutional Review Board (IRB), or institutional policies that govern research with human participants.

Even in the absence of intent, an unapproved research protocol or otherwise noncompliant research activity may place a research participant at unnecessary risk. Such noncompliance may be determined to be in violation of SSU's Research Integrity Policy.

Examples of Noncompliance:

1. Conducting human participant research without IRB approval (e.g., before approval; after the expiration of an approval);
2. Disregarding or otherwise violating IRB approved informed consent procedures (e.g., failing to obtain consent or assent, using unapproved or outdated consent, assent, or informational sheets; missing signatures; and failing to document the consent process);
3. Deviating from the protocol approved by the IRB;
4. Modifying an approved protocol without IRB consent;
5. Failing to report or tardily reporting unanticipated problems;
6. Failing to maintain adequate records;
7. Failing to train research team members in the proper procedures;
8. Failing to follow the recommendations by the IRB to ensure the safety of research participants.

Serious noncompliance involves one or more of the following:

1. Bringing harm to the research participants;
2. Exposing research participants to a significant risk of substantial harm;
3. Compromising the privacy and confidentiality of the research participants;
4. Causing damage to the scientific integrity of the research data that has been collected;
5. Engaging in willful or knowing noncompliance;
6. Disregarding ethical principles adversely;

Please refer to Salem State's research integrity policy for full guidance.