

## **Institutional Review Board Policy      Salem State University      Fall 2011**

### **Introduction:**

By federal regulation, the IRB is charged with the responsibility of reviewing and monitoring human subjects research.

The IRB reviews and approves all research involving human subjects conducted at Salem State prior to beginning the research. This includes research, whether conducted on or off campus, which is conducted by Salem State faculty, administration, staff or students, as well as others not affiliated with the university who wish to conduct research at the university. This applies whether the research is federally funded or not.

Oversight ensures that the ethical principles and guidelines for the protection of human subjects in research, as outlined in the Belmont Report and 45 CFR 46 of the Code of Regulations, is adhered to. We encourage you to take advantage of training materials on this web site and to contact the IRB if you have any questions.

### **What is Research?**

Research is defined by federal regulations as "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

According to the regulations, a human subject is a "living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information."

If you have questions about what constitutes human subjects research, contact the IRB Administrator or the IRB Chair.

### **Who Needs Review?**

All research 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 Institutional Review Board (IRB) for review. The process is required before any research can begin.

### **Review and Post Review Process:**

**Review Timetable** The IRB will determine the level of review. Exempt and expedited applications will be reviewed within two weeks of submission. Applicants that require full committee review are done monthly during the academic year and on an as-needed basis during the summer. Committee members and meeting schedules are available at [salemstate.edu/academics/irb](http://salemstate.edu/academics/irb)

**Notification** All notifications to the Principal Investigator and Sponsor regarding questions, approvals and denials are by email.

**Extension of Approval** According to federal guidelines, approval for a project can be for a maximum of one year. Multi-year projects must seek annual renewal. If an approved project is or will not be completed by the project's end date specified in the application, the Principal Investigator must apply for extension of the original approval using the Modification Request Form.

**Modification of Previously Approved Protocol** Any modifications to a previously approved protocol need review by the IRB to ensure the modification meets the requirements of the originally approved projects. Minor changes to the protocol can be addressed on the Modification Request Form. Extensive changes to any previously approved protocol are best addressed by submitting a new application.

### **Levels of Review:**

1. Exempt Review: Certain projects, such as those that involve only survey, questionnaire or interview procedures and anonymous participation, may be categorized as no risk and may be exempt from the Federal Policy for the Protection of Human Research Subjects. The IRB Chairperson will determine if the application meets the exempt criteria. No research with participants under age 18 can be exempt.
2. Expedited Review: Applications that involve no more than minimal risk to human subjects may be eligible for an expedited review by the Chairperson of the IRB.
3. Full Review: Applications that involve more than minimal risks or those in which the identity of participants is at risk require a full IRB review.

### **Consent or Disclosure:**

**Informed Consent:** Informed consent must be obtained from all human research participants. This generally means a participant must either: (1) sign consent form (sample attached) explicitly agreeing to participate in the research or (2) be read a disclosure statement (see section below). When a consent form is used, a copy of this signed consent form must be offered to the participant to keep. Consent for any potential participants under 18 years of age, or persons not competent to give informed consent, must be obtained from parent(s) or guardian(s). Investigators should keep copies of consent forms in a locked file cabinet for three years after the completion of the project. For research conducted with minors in a classroom, consent may be waived if the primary or secondary school has a blanket consent form on file signed by the minors' parent(s) or guardian.

Such consent forms should include the following information:

Paragraph 1: Sponsor or auspice and purpose of research

Paragraph 2: Time commitment, potential risks/benefits, what will occur in the research session

Paragraph 3: Voluntary participation and right to withdraw

Paragraph 4: Maintenance and limits of confidentiality

Signatures

Paragraph 5: Contact information or investigator and IRB

Disclosure statement instead of consent form: If the research involves only survey, questionnaire or interview procedures where the participants will remain anonymous (no names given) and there are minimal risks involved in participation, a disclosure statement describing research procedures may substitute for the consent form. The disclosure statement may be read, or a copy provided, to participants. A disclosure statement is not sufficient if participants are tape recorded, even if risks are minimal. Disclosure statements should contain the same information as the consent forms, but they need only be read or given to participants. No signatures are required.

**Human Subjects Training:** Collaborative Institutional Training Initiative (CITI)

Web-based training program for research with human subjects: The Salem State University Institutional Review Board offers training on the protection of human research participants for all investigators submitting protocols for review. This training is through the Collaborative Institutional Training Initiative [CITI program](#).

The social and behavioral modules chosen by the university's IRB provide coverage of the ethical principles and procedures for conducting human subject research. It includes modules on Good Clinical Practice, Health Information Privacy and Security (HIPS) and Responsible Conduct of 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. This training is optional for those not receiving Federal funding. Faculty may also use the training modules for classroom use and discussion, especially in research and graduate courses.

**Massachusetts State Reporting Law:**

In studies where there is the possibility of information concerning child/elder abuse 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: Suspected cases of child or elderly abuse and information that individuals intend to harm themselves or others.

**Record Keeping and Retention:**

In accordance with federal regulations, the Office of Sponsored Programs and Research Administration maintains Institutional Review Board applications and records for three years before they are destroyed. During the 2010 academic year, records were maintained both electronically and on paper. Going forward, we will strive to maintain only electronic records.