Institutional Review Board at Savannah State University

All institutions that conduct research using humans as research subjects and are awarded federal funds to conduct research are required by federal law to establish an active committee responsible for reviewing proposed research involving human subjects to ensure that the rights and welfare of the subjects are protected. To comply with this federal law, Savannah State University (SSU) has an established Institutional Review Board.

Projects involving human subjects at SSU must have IRB approval prior to project initiation. The SSU IRB reviews all research involving human subjects for the protection of the rights, welfare, and well-being of the subjects and the rights of the researcher and of the university.

The IRB is guided in its decisions by the Federal Policy for the Protection of Human Subjects (the Common Rule), published in the Federal Register on June 18, 1991, and by Federal Regulation 45 CFR 46, "Code for the Protection of Human Subjects in Research," published in the Federal Register in March 1983, and applicable ethical standards as published by professional groups and societies. SSU's IRB policy requires that all research involving human subjects, whether funded by an external organization or not, must comply with these regulations.

The Office for Human Research Protections (OHRP) has oversight over human subjects' research in programs funded by the HHS. In order to ensure the protection of these subjects' rights. Regulations regarding human subjects' research, including required training and education, are codified in 45 CFR 46.

SSU's research involving human subjects falls under the oversight of the HHS OHRP. The University maintains a Federal Wide Assurance (FWA) with the OHRP and has registered its Institutional Review Board (IRB) with the OHRP.

Organization of the IRB at SSU

The IRB consists of at least five individuals of diverse backgrounds (including cultural and racial) and having sufficient maturity, experience, and competency to ensure that the IRB will be able to discharge its responsibilities and that its determinations will be accorded respect by the University investigators and by the community served by the University. The IRB is comprised of members of several professions, including at least one practicing physician, scientist, ethicist or minister, and at least one person not otherwise affiliated with the university. The President of Savannah State University

appoints members and the IRB shall make periodic reports to the Associate Vice President, Research and Sponsored Programs.

Procedure for IRB Review

All proposals involving human subjects must be forwarded to the Chair of the IRB for review of application and materials. The SSU Chair of the IRB, who is assisted by the other IRB members along with the Administrative Systems Manager of the Office of Sponsored Research Administration, handles all administrative details for the IRB, including receiving applications, reviewing for completeness, logging, and reviewing them to determine the appropriate level of clearance for each. The IRB has authorized the Chair of the IRB to establish exempt status for projects after determining that there is minimal or no risk to participants and that safeguards for confidentiality and the methodology of obtaining informed consent are adequate. For certain other highly specific areas of research wherein risk to subjects' well-being is minimal, an expedited review process may be used. In this case, the Chair of the IRB and at least one other Board member reviews the application. If it meets all criteria, approval is granted. In the case of both exempt and expedited procedures, all Board members are notified in a timely manner of the actions taken by the Chair of the IRB. Should any member disagree with an action, a full IRB review is required.

All applications that do not qualify for either exempt or expedited review receive full board review. The protocols for all applications to be considered at a review meeting are forwarded to Board members at least one week before the date of the meeting. To hold a review, it is necessary that a quorum (a majority) of members be present. The Board may call consultants to advise on a complex protocol, or request that the researcher present the application. The Board may approve, approve contingent upon modification of elements of the protocol, or reject an application. In the latter case, the application is returned to the researcher with a statement of why it was deemed unacceptable and recommendations for modifications.

The Chair of the IRB, together with the researcher, prepares the human subjects research protocol documentation required in proposals to federal agencies and other sponsors.

Failure of the researcher(s) to comply with IRB policies and procedures may jeopardize University federal funding; therefore, it is not permissible for the researcher to initiate research involving human subjects prior to IRB approval. Failure to comply with IRB policies and procedures will result in appropriate action, including possible termination of the research.

Filing a Request for IRB Review

Savannah State University faculty, staff and students who are conducting research or related activities with human beings as subjects must conform with certain regulations prescribed by this procedure. To obtain a timely approval of research involving human subjects, the Request for IRB Review Package should be completed and returned to the SSU IRB Secretary for immediate action. A Request for Review is examined by the Chair of the IRB, who determines which approval category is appropriate (exempt, expedited review, or full board review) and informs the principal investigator(s) concerning any further action to be taken. In reviewing projects, the IRB decides whether the human subjects are at risk, and if so, whether the following criteria for approval have been satisfied.

1. Risks to subjects have been minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and to the importance of the knowledge that may reasonably be expected. The project director is prepared to obtain medical assistance in case of any unusual risk to the subject during the procedure(s).
3. Selection of subjects is equitable. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
4. Informed consent will be appropriately documented.
5. Where appropriate, the research plan makes adequate provisions for the date and time to ensure the safety of subject.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality.
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included in the research plan. *

*The SSU IRB does not approve of coercion in research. It will review and may approve applications that involve limited deception, with the proviso that subjects receive a comprehensive debriefing within a reasonable time frame.

IRB Review Categories

Research projects submitted to the IRB for approval are screened by the IRB Chair and placed in one of the three review categories:

1. Exempt. To qualify for this category, the research activity must meet the following criteria: a) the research involves minimal or no risk, b) the rights of potential subjects are fully protected, and c) the method of handling confidentiality and anonymity is adequate. This approval process usually requires 3-7 working days, so submit accordingly. Examples include surveys, questionnaires, interviews, educational testing, existing data, etc.
2. Expedited Review: Expedited Review is required when research activities involve no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories listed in 45 CRF 46.110 of the Federal Policy. This approval process could require 10 - 15 working days, so submit accordingly. Some of the examples include voice recordings, moderate exercise by healthy individuals, blood samples by venipuncture, weighting, electrocardiography, electroencephalography, etc.
3. Full Board Review: All projects involving human subjects that do not qualify for exempt review or expedited review must be reviewed by the full IRB at an official meeting. This complete approval process could require 1-1.5 months, so submit accordingly.

Regardless of the method of approval (exempt, expedited, or full board review), approval is required before any research project can begin.

Request for IRB Review

Faculty, staff, and students who plan to conduct research involving human subjects (including surveys) must submit a request for IRB review and approval to Dr. Deden Rukmana, Chair of the IRB. Approval by the IRB must be obtained before the research can be conducted.

The request should be submitted to:

Dr. Deden Rukmana
Chair, Institutional Review Board
Associate Professor and Coordinator, Urban Studies & Planning
Department of Political Science and Public Affairs
Savannah State University
Social Science Building, Room 139

3219 College Street, Box 20385
Savannah, GA 31404
Telephone (912) 358-3218
rukmanad@savannahstate.edu

The request for IRB review must contain the following elements. Electronic submission is encouraged.

1. Summary of research protocol
2. Copy of survey instrument
3. Informed consent form for participants
4. Completed request for IRB review form.