STOCKTON UNIVERSITY

PROCEDURE

General Assurances Statement: Protection of Human Rights in Experiments

Procedure Administrator: Provost
Authority: Code of Federal Regulations Part 46
Effective Date: May 17, 1978; May 18, 1978; November 9, 2009
Index Cross-References: Policy I-52.5: Committee on the Protection of Human Subjects
Procedure File Number: 1035
Approved By: Dr. Herman J. Saatkamp, Jr., President

I. PURPOSE:

Stockton University is committed to the pursuit of excellence in teaching, research, and service. In an effort to maintain these pursuits and permit progress of research activity, Stockton has established an Institutional Review Board for the Protection of Human Subjects (IRB) specifically for the purpose of protecting the health, welfare, safety, rights, privileges and the best interests of all human subjects participating in research. Stockton gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46) better known as the "Common Rule." In doing so, the ethical principles which guide projects involving individuals in studies or experimental research will be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk but not less than annually. The IRB must review all applications that: a) will be conducted by or under the supervision of staff or faculty, or b) will involve Stockton staff, faculty or students, or c) will be performed on the campus or involve Stockton equipment or facilities.

All researchers submitting IRB applications are required to demonstrate proficiency in knowledge about how to protect human subjects by completing the online training and submitting certificates of that training with the application. Online training is available through the Stockton website.

II. PROCEDURE:

A. The University will follow a review process for all proposals involving the use of human subjects, regardless of whether or not the project has received funding support. This will apply to internal activities as well as those seeking external or governmental support. Individuals seeking approval will complete an application package available on the University website which includes the information outlined in Part B which follows which then should be sent to the IRB for review and approval. Students seeking approval must have the signature of a supervising faculty member in the appropriate discipline. Individuals responsible for the research activity must wait for approval from the IRB before beginning the project.

1. Applications that require a review by the full committee shall be submitted to the IRB two weeks prior to the review/meeting date of the IRB. Governmental proposals often must be reviewed before submission to the agency. Applications that request an exempt or expedited review may be submitted at any time. The review category is defined by the federal government and is based on the level of risk involved for the human participants.

2. During a full committee review, the IRB members will examine and discuss the application and make a written recommendation to the project director as to whether or not the application should be approved. The IRB may suggest modifications and/or request additional information before a final determination. Once approved, the application is signed by the Chair, date stamped and filed. Approvals are valid for one year. If a project continues beyond this anniversary date, the researcher must formally apply for a renewal.

3. Projects involving applications for outside funding must be routed through the normal internal approval procedure for proposals and ultimately approved by the President.

B. The application form is available on the University website and should be thoroughly completed and signed before submitting to the IRB for review. While the application requires more information than outlined below, its basic details include: A general description of the project, including beginning date and duration of the project, and location.

1. The names and titles of the investigator(s).

2. Identification of the target study group, especially noting any vulnerable populations. A description of the background and purpose of the proposed study, including a literature review of relevant research.

3. A full and detailed explanation of procedures and methods to be followed involving human subjects, including any procedures which are experimental.

4. Detail of anticipated physical, mental or emotional risk to the subjects of the research or a statement explaining why there are no risks anticipated.

5. Description of measures to be taken to protect confidentiality of the data and the subject's rights to privacy.

6. Informing human subjects about their rights and privileges and the activities of the study is a continuous process that should be regularly communicated throughout the project period. In addition to this open-ended process, the mechanism to fully inform participants at the beginning of a project should include a written and sometimes verbal message. This informed consent form must consist of the following:

    a. A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.

    b. A description of any attendant discomforts and risks reasonably to be expected.

    c. A description of any risks that might result from participation. And if risks are anticipated, contact information for appropriate assistance.

    d. A description of any benefits reasonably to be expected.

    e. Acknowledgement of compensation participants might receive or costs they may incur as a result of the study.

    f. A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

    g. An offer to answer any inquiries concerning the procedures, and a phone number and email of the researcher or faculty sponsor given to participants to take away, in case there are questions later.

    h. An instruction that participation is voluntary and the person is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

This process requires each subject to acknowledge consent to participate by signing a form, checking a box for online participation or by other verifiable means which indicates one's willingness to participate.

III. COMMITTEE STRUCTURE

A. The IRB shall consist of at least five faculty members who have expertise in research involving human subjects and who have been nominated by their Dean to the IRB. As required by federal regulations, the IRB must also include at least one male and one female member, at least one scientist and one non-science member, and at least one member of the community who is unaffiliated with the University. This member shall be invited by the Provost to participate on the IRB. The chair of the IRB shall be a member of the IRB and serve at the invitation of the Provost. All members must receive training and become certified in the protection of human subjects.

B. The IRB will meet monthly or as necessary and a quorum will be defined as a simple majority of the total membership (3). No IRB member shall be involved in the review of a proposal in which he/she has a conflicting interest, except to supply requested information.

C. The IRB shall continually review its activities, procedures and competence and will promptly act to supplement or replace any of its members with competent personnel when and if such action is found necessary. Outside expertise may be called upon at any time.

D. Records of all IRB actions will be maintained in the Grants Office for compliance and inquiry.

IV. COMMITTEE RESPONSIBILITIES

Upon receipt of an application package, the application will be distributed depending on the level of review requested - exempt, expedited or full committee. Regardless of the review category, all categories require fulfillment of research protocols, including the need for the consent of participants where applicable. IRB members will individually review the materials, and record their findings on a review form. If an application correctly requests an exempt review, the application will be read by the IRB chair who may request another member also review. If approved, the chair will sign the application, and this decision will be recorded and communicated in writing to the applicant. If the application correctly requests an expedited review, it will be reviewed by at least two IRB members who will recommend to the Chair that it be approved or not; their decision will be recorded and communicated to the applicant in writing. If the application requires review by the full committee, the IRB members each read the application and meet together for discussions. Regardless of the level of the review category, the review process is to determine:

1. That the safety, health, privileges, rights and welfare of the subjects are maintained.

2. Whether or not there is risk for the subjects involved.

3. That, if risk to the subject is involved, (a) the risks are outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained; (b) the risk is not extreme.

4. That legally effective informed consent will be obtained by adequate and appropriate methods.

In case of a negative decision, or request for modification or more information by the IRB, a written explanation will be communicated to the applicant. The IRB may also call upon professionals both inside and outside of the University for opinions concerning possible harm to human subjects when warranted.

(Please note: Special guidelines apply to research involving drugs, pregnant women, fetuses, possible impregnation or prisoners. Refer to Code of Federal Regulations 45 CFR 46.)

Approval History:

	Date
President	11/09/09