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-

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.

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