RESEARCH HUMAN PROTECTION PROGRAM

the IRB newsletter

A Publication of the Southern Connecticut State University Human Research Protection Program

The SCSU Institutional Review Board – Volume 5, Number , Spring 2007

Meet the SCSU IRB

Below are listed the current members and alternates of the SCSU Institutional Review Board. They unselfishly volunteer their time to assure fair treatment to human research participants at SCSU.

Members

Mr. Vincent Avallone, Esq.–Attorney
Robert Axtell, Ph.D.–Exercise Science
Mr. David Denino, LPC, NPC–Counseling
W. Jerry Hauselt, Ph.D.-Psychology
Shirley Girouard, Ph.D.–Nursing
James Mazur, Ph.D.–Psychology
Michael Perlin, Ph.D.–Public Health
Jaak Rakfeldt, Ph.D.–Social Work
Frank Sansone, Ph.D.–CMD

Alternates

Marianne Kennedy, Ph.D.–CMD/Assemt.
Cynthia McDaniels, Ph.D.–EDF
Mary Purdy, Ph.D.–CMD

Prior Newsletters

The IRB encourages you to view prior IRB Newsletters. Information in these missives may assist you in reducing application construction and submission hassles. Newsletters may be found online at the School of Graduate Studies web site under Research> IRB Newsletter Directory.

SCSU School of Graduate Studies
Visit us online at:
www.GradStudies.SouthernCT.edu

The Human Research Protection Program (HRPP) and The Institutional Review Board (IRB) offices are now located in Engleman Hall, A wing, Room 110 A-B. There are two direct phone lines into the offices, 203 392-5243 (HRPP main), and 203 392-5958 (Dr. Sansone's university line). A dedicated FAX number has been assigned to HRPP/IRB - 203 392-5221. Using this number, FAX transmissions will be received directly in the HRPP/IRB offices. Please be advised: HRPP correspondence, IRB protocols and correspondence, must continue to be sent to The School of Graduate Studies, Engleman B 110. The School of Graduate Studies' office staff will be available to receive correspondence and protocols during regular school business hours. IRB protocols will continue to be entered into the School of Graduate Studies' IRB data base and then transferred to the HRPP/IRB offices for review and disposition. When staff is available, the HRPP/IRB offices' door will always be open and you are all invited to drop by and say hello.

Compliance Issues Continue

Conditions Mandating IRB Review: By federal code, the SCSU IRB is mandated to determine the eligibility of human research conducted under the auspices of SCSU. All investigators claiming SCSU as their professional address, whether part or full time, are required to follow the institution's review policies regarding human participant research (there are separate requirements for non-affiliated investigators). With respect to when an SCSU individual should submit a project for IRB approval, briefly, our review policies indicate, submit when the following two conditions are evident:

1. the project is considered research. Federal guidelines and SCSU policies indicate a project is considered research when it is, ". . . a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Generalizable knowledge is defined as ". . . knowledge that can be applied to populations outside the population studied." For example, when a fundamental goal of the project is to learn something that may impact people other than the research participants the knowledge gained is considered generalizable (*CFR Title 45, part 46*).

2. the project involves "A living individual about whom an investigator… conducting research obtains data (1) through intervention or interaction with [an] individual, or (2) [through] identifiable private information (*CFR Title 45, part 46*). Identifiable private information frequently involves retrospective studies of previously collected information.

Failure To Submit For Review: Our experience with submission issues has indicated that, for some, the above conditions are considered quite specific and, depending on

Education

The IRB can provide Human Research Protection educational information in the form of CD's, video tapes, and PowerPoint presentations. These materials may be borrowed for classroom use by instructors or may be presented by the IRB.

INFORMATION

For information regarding educational materials or any other aspect of the IRB please contact:

Dr. Frank E. Sansone,
Human Research Protection Program Administrator and
IRB Co-Chair, or
Dr. W. Jerry Hauselt
IRB Co- Chair
Voice: (203) 392-5958
VOICE: (203) 392-5243
FAX: (203) 392-5221

the type of project planned, provide an easily determined direction for submission. For other potential investigators, the conditions seem too general and therefore encourage developing interpretations of the requirements that result in failure to submit when necessary. The IRB strongly encourages individuals who are unclear about whether a project requires IRB submission, to forego personal interpretation and seek IRB guidance.

We mentioned in a previous newsletter that IRB submissions have steadily increased over the past six years. The 2006 submissions topped 247. It seems as though more and more SCSU investigators are perceiving the importance of their responsibilities to insure critical aspects of human participant protections have been addressed in their projects through IRB review. However, it has come to our attention through interaction with current investigators, students, and the Office of Sponsored Programs and Research (SPAR), that human participant research is being conducted by some SCSU employees without regard to IRB interaction or review. Southern's institutional policies regarding human research are clear: (1) when the two conditions for submission are evident research must be submitted for review; (2) when questions arise regarding interpretation of the two conditions, contact the IRB (Instructor Certification guidelines remain in effect).

Federal Requirements: Requests for federal funding of institutional research proposals involving human participants must be accompanied by a Federal Wide Assurance (FWA) number. The FWA is a proprietary number assigned to individual Institutional Review Boards (IRB) only after successful evaluation of submitted application materials and accompanying documentation (e.g. Health and Human Services (HHS) IRB registration information) by the federal Office of Human Research Protection (OHRP). The FWA must be renewed every three years. If SCSU is to continue to request money for projects involving human participants from the federal government, our FWA must be maintained. As part of the application process the institution, through its IRB, must assure OHRP ". . .that all of its activities related to human subjects research, regardless of funding source [interpreted to mean no funding source if applicable], will be guided by the ethical principles in . . . The Belmont Report." Further, SCSU has elected to . . .apply. . . [The Common Rule and subparts B, C, and D, of the HHS regulations at 45 Code of Federal Regulations (CFR) part 46] . . . to all of its human subject's research regardless of funding [or no funding] source of support. . ." The SCSU IRB policies and procedures are based on the Belmont Report and the Common Rule documents. All of the IRB forms are derivatives of these documents and provide the IRB with information to make informed decisions regarding the propriety of human participant research.

Please Share Your Knowledge with Colleagues and Students: Often, information in newsletters does not seem to get to the persons who need to have it. The IRB is requesting you to share this information with individuals whom you believe are doing research or contemplating research for which IRB interaction is not planned. Legally, when human research is conducted under the auspices of SCSU and has not been reviewed by the SCSU IRB, both the investigator and the institution are placed in jeopardy. Research privileges can be terminated at the federal level and funds may be withheld for all institutional research projects. Further, research activity may be barred across the entire campus. Morally and ethically, all investigators engaged in human research have a fiduciary responsibility to assure participants that their protection from research harms supersedes the investigators desire for research results. The IRB provides research oversight and assists investigators in meeting their moral and ethical fiduciary responsibilities. Thanks in advance for your help.

Code of Federal Regulations: Title 45, Public Welfare, Department of Health and Human Services, National Institutes of Health Office for Protection From Research Risks, Part 46, Protection of Human Subjects, Effective August 19, 1991.