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 3, Number 1, Fall 2004

Meet the SCSU IRB

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

Members

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

Alternates

Cynthia McDaniels, Ph.D.–EDF
Mary Purdy, Ph.D.–CMD
Karl Rinehardt, Ph.D.–Exercise Science

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

Happy Autumn to all! The IRB sincerely hopes that your semester is going well as we all head toward mid-terms. During this past year several items have come to the board's attention regarding the IRB forms, the submission process, and the development of an acceptable informed consent document. In an attempt to resolve these issues, this issue of the newsletter will be concerned with IRB form updates, items most frequently forgotten or confused on the IRB forms, and, informed consent issues. This newsletter is not delivered to students. Advisors may wish to inform their research advisees of the online newsletter directory.

The on-line IRB forms have been updated as follows:

1. Proposal submission information has been modified to read: "For exempt research or expedited review, applications may be submitted at any time. Applications will be reviewed in the order of receipt. Allow at least two weeks for initial IRB response. For full board review during the academic year in any month from September through May, you must submit your application by 11:00 am on the first Monday of that month. If you require review during the summer months, your application must be submitted on or before July 15th. Applications received after July 15th will be considered in the subsequent September. Two hard copies of the IRB proposal should be submitted along with twelve copies of your research abstract on IRB Form # 2. Electronic application submission is not permitted. Allow at least two weeks after review for initial IRB response;"
2. The "Disposition Page," (former Form #2 on former page 5) has been eliminated;
3. The URL for The National Institutes of Health required tutorial for the protection of human research participants has changed. The new address is: http://cme.cancer.gov/clinicaltrials/learninghumanparticipant-protections.asp. Once at the site follow directions on the page.

SCSU IRB policy update concerning investigators from external institutions:

Investigators from external institutions who wish to recruit SCSU students, faculty, staff or administrators as research participants may do so without SCSU IRB review providing the recruitment activities are completely passive. Passive recruitment may involve activities such as: posting flyers on campus which meet SCSU IRB requirements (flyers may be posted only at sites approved by the Student and University Affairs Department); contacting potential participants by email as long as the email addresses are not supplied by the university and the content of the email has been approved by the SCSU IRB; contacting potential participants by direct mail as long as the mail addresses were not supplied by the university and the content of the recruitment letter has been approved by the SCSU IRB. Recruiting by phone or in person is not considered passive and is disallowed. If recruiting passively, external investigators must contact the SCSU IRB with their plans for recruitment and place on file with the SCSU IRB written IRB approval from their home institution. Once the SCSU IRB has cleared the recruitment plan, a letter indicating IRB acknowledgement will be sent to

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 Sansone, IRB Chair
voice: (203) 392-5958
fax: (203) 392-5968

e-mail
SansoneF1@SouthernCT.edu

campus address:
CMD, Davis Hall, 012B, SCSU

the investigator.

Investigators from external institutions who wish to aggressively recruit SCSU students, faculty, staff or administrators, and/or conduct research on the SCSU campus must obtain a SCSU faculty, staff or administrator sponsor and submit an SCSU IRB proposal. An IRB approval letter from their home institution must accompany the proposal.

Items most frequently forgotten or confused on IRB forms:

1. Appendix A: Investigators should read Appendix A, page 15, completely before filling out the forms;
2. Cover page: Faculty and staff members must have their departmental chair or supervisor sign the cover page of the proposal. Students must have their departmental chair and their advisor sign the cover page. If the investigator is the departmental chair, the school dean must sign the proposal cover page;
3. Page five: Your abstract must contain information that appropriately places your research into the context of your discipline;
4. Page six:
   a. If there will be recruitment advertisement of any sort, the IRB must approve the copy. This includes scripted statements made by regular mail, email, telephone, or by any other print or electronic media;
   b. The IRB must be informed of the location of participant recruitment.
5. Page seven:
   a. The IRB must be assured that the investigator or his/her advisor is qualified to conduct the research;
   b. The investigator must show proof the that an institution (if other than Southern) is aware of and approves the research that is planned to be conducted there.
6. Page thirteen: Please be sure to fill out and sign the "Education Certification" form. Be sure to include the online certificate obtained from the NIH tutorial.
7. Page fourteen: Please fill out and sign the "IRB Application Form Submission and Order Check-list."

Informed consent documents :

Informed consent documents must be constructed so that they are complete, accurate, and grammatically correct. When research is conducted off-campus the content and construction of these documents should represent the very best that our university can present to the public. Further, the research documents distributed to participants on-campus should also be carefully crafted because many times they serve as models to our students and colleagues.

Consenting is an educational process that takes place between the investigator and the prospective participant. It is the investigator's responsibility to ensure that each potential participant thoroughly comprehends the consent document, and to ensure that the necessary steps have been taken to assure that comprehension. Participants must be given sufficient opportunity to consider whether or not they wish to participate in the research. Consent must be given without coercion or undue influence.

Incompetent adults cannot give consent. Incompetence may include but is not limited to the developmentally delayed, the cognitively-impaired elderly, the unconscious or inebriated individual. Only authorized representatives can give permission for incompetent adults to participate in research. Evaluation of competence must be made on a case-by-case basis. In addition to obtaining permission from an authorized representative, provisions must be made for soliciting the assent of the incompetent adult.

The information given to prospective participants (or representatives) in the consent document must be in language they can understand. Technical language should be avoided. Further, the IRB encourages use of the "second person" when constructing consent documents. For example, instead of, "The participant will have a cuff placed on his/her left arm. . .," the sentence should read, "You will have a cuff placed on your left arm. . . ."