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 4, Number 2, Spring 2006

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

Vincent Avallone, Esq.–Attorney
Robert Axtell, Ph.D.–Exercise Science
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.*

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The IRB restarts protocol numbering with the beginning of each new year. To date, 45 new proposals have been submitted, a significant increase over last year's count for this period. It seems more persons are becoming research investigators and are following required IRB procedures for reporting research with human participants. A brief review of SCSU policy regarding IRB submissions indicates: **All studies in which human participants are to be recruited must come before the IRB for review.** The IRB wishes to thank investigators for following IRB policies and encourages continuing compliance with state, institutional and federal human research guidelines.

Do We Have Measures in Place to Protect Student Research Participants?

This question was posed in a recent *IRB Advisor* article involving departmental student participant pools (*IRB Advisor*, 2006). These student pools provide participants for studies when participation as a subject in research and/or completion of a research study is a course requirement. The article suggests that IRB's should take special interest in how student participant pools are run. Bradley Waite, Ph.D., and Laura Bowman, Ph.D., psychology professors at Central Connecticut State University, were interviewed for the article. Their suggestions are listed below and essentially present the SCSU IRB position on the use of student participant pools:

1. Students must be afforded a reasonable alternative to participation in departmental research in order to avoid potential coercion. The alternative should be "...equally demanding - not more demanding or less demanding..." and, "...reasonably attractive for those people who [do not] want to participate...."
2. In order to receive credit, students must show up at the study's appointed time and place. After they have determined what their participation will require, they may decide whether or not to participate. They may withdraw at this point and still receive some credit.
3. Investigators must inform students about the study and obtain consent from them according to guidelines and scripts provided by the IRB. Benefits, risks, voluntariness, privacy, confidentiality, and time involvement, among other consent document details, must be clearly and completely stated.
4. The potential for underage students (under 18 years) to appear in studies without parental consent must be controlled. Either a blanket parental consent statement for participation in all departmental sponsored research, or a study specific parental consent for each participation must be addressed by the investigator as part of IRB proposal submissions.
5. The department must consider the student research experience to hold valuable educational benefit. The department must make efforts to assure that after the study is completed, each student participant is properly debriefed regarding the significance of the research. When deception is part of the study, student participants must know clearly that deception was used, why it was used, and that participants are absolved of any complicity.
6. Procedures to maintain security and confidentiality of all student research data must be appropriately reflected in the IRB proposal submission.
7. IRB's reviewing studies that involve student pools "...should definitely look at those student subjects differently than the general population when it comes to risk and benefit."

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

Several members of the *IRB Forum* (email ListServe) have suggested that student participants should be considered an official vulnerable population because they can be seen as captive, easily manipulated, and overused as research subjects. As long as student participants who are offered credit for participation in research, whether in a pool or recruited individually, are afforded treatment according to the above guidelines, the SCSU IRB will review such proposal submissions with positive bias.

If you maintain a campus student participant pool it is expected that you have written guidelines that are at least as stringent as the ones presented here. If you have not done so already, please send a copy of your guidlines to: Dr. Frank Sansone, IRB Chair, 012B, Davis Hall. Thank you.

IRB Advisor, "Do you have measures in place to protect student participants?" Vol. 6, No. 1, 2006, pages 1-3: Thomson: American Health Consultants.

Departmental Human Participant Protocol Pre-review Prior to IRB Submission:
The IRB cannot be knowledgeable in all disciplines represented in on-campus human participant research. We rely heavily, therefore, on discipline expertise when evaluating such things as, applicability of the research question, adequacy of the research design, and appropriateness of the participant sample. The cover page of the IRB proposal application provides a space for the departmental chairperson's signature and the advisor's signature if the project is student research. By these signatures the IRB expects that the signatories are "...aware of the type and scope of human subject involvement in [the] project ...." Further, as a representative of the discipline in which the project is centered, it is expected that some review to assure basic discipline related research methodology and discipline specific guidelines for human study, prior to signing, has been accomplished.

Understandably this places great responsibility on the chairperson who should review each proposal and approve it for adequacy before it is sent to the IRB. In an attempt to mitigate these responsibilities the IRB suggests forming a departmental research review committee. The members of this committee would review all departmental human participant research proposals with regard to discipline specific concerns prior to submission to the departmental chair. In this way, both the departmental chair and eventually the IRB can consider proposals approved at the departmental research committee level as sound from a discipline's perspective.

A Few "Housekeeping" Items to Facilitate IRB Proposal Review:
1. Please be sure all of your identifying information is presented on the proposal cover page.
2. If you have indicated an IRB other than the SCSU IRB has reviewed, or will review, your project, be sure to give complete details. Include a copy of the IRB approval if available.
3. Please be sure each required signature appears in the proposal cover page on its appropriate line.
4. The IRB must have assurance that you, as the principal investigator, or your advisor, have the qualifications to conduct the study. Please do not leave this area blank.
5. Please be sure that your consent document follows the guidelines proposed by the IRB. They may be found on pages 12 and 13, and in Appendix B of the IRB proposal forms.
6. Please be sure to complete the on-line tutorial. Advisors should complete the tutorial as well.
8. Please be sure to include written indicators on agency letterhead from outside research sites, showing awareness of your study and granting permission to conduct your study at their site.
9. Please be sure to complete and sign page 15, the "IRB Application Form Submission and Order Check List." This will assure that all pages, signatures, and documents have been submitted.
10. Please do not staple documents or send them in folders. Please spell-out all acronyms.