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 2, Spring 2005

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 New Year! The IRB hopes that your 2005 spring semester is proceeding enjoyably. During the summer and fall 2004 semesters, several concerns came to the board's attention regarding the IRB submission process. Even though we have discussed similar matters in the past, in continued attempts to make the IRB interaction as uncomplicated and hassle free as possible, this issue of the newsletter will address some student research information and a few "housekeeping" items. Please be advised: This newsletter is not delivered to students. Advisors may wish to show this issue to their research students and also inform them of our online IRB Newsletter Directory.

Student Research:

Professionals in human research protections, through the Applied Research Ethics National Association (ARENA), maintain a "member's only electronic mailing list" called "The IRB Forum." This forum daily provides a medium through which information regarding current concerns and issues in the field of human protections may be discussed on a national level. In a recent interaction, student research emerged as a hot topic.

The discussion began with the following questions (summarized): (1) If student research is not treatment related might an IRB review it less rigorously? (2) Should an IRB approve a student project that is so low powered or poorly designed that it is certain to develop no useful information? (3) How should an IRB handle student research that involves vulnerable populations and/or presents greater than minimal risk? (4) Should the IRB offer to work with students to make their projects more acceptable? These queries engendered a considerable response from the forum participants. (irbforum@irbforum.org, 2005)

Some of the replies are summarized as follows: (1) Student research should be dealt with in just the same fashion as any other research. Beyond serving to protect the study participants, students may be educated in the rigors of good research. It is not appropriate to permit students to do under-powered or poorly designed research even if the risk to participants is minimal. The reputation of the student's institution and its IRB rest upon the quality of the research design, conduct of the study, and the report written therefrom, whether eventually published or not. (2) We would feel as though we had failed if student's research experiences did not enable them to submit a well developed study for IRB review. What better way to educate students. (3) Reviewing all research with equal rigor allows the IRB to function as a shield for participants from unnecessary intrusions upon their time and privacy especially if those interactions will provide no useful information. The IRB might evaluate risk not only in terms of the potential for adverse events, but also in terms of the logistics and ethics of participation in the study. Studies that involve people should not be done solely as a learning technique. (4) A solution to these concerns might be to bring the faculty advisor into the picture. Their responsibilities should include counseling their students through the IRB process. (5) The IRB offering to work with students 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

improve the design of their research projects is laudable. (6) If no advancement is made on improvement of submitted IRB proposals, IRBs should not feel beholden to students. While a friendly IRB may encourage greater compliance, the IRB should not feel responsible for seeing that students graduate on time. Protecting human research participants must be the primary charge. (irbforum@irbforum.org, 2005)

It is interesting that faculty advisors and students from other institutions similar to ours, deal with the same ethical, practical, and logistical predicaments when interacting with their respective IRBs. The SCSU IRB will continue to work with departments, advisors and students in attempting to produce viable and useful research proposals. One of the ways that the IRB is able to assist the student investigator is through the *Modification Memo*. We hope that when the IRB suggests modifications to a proposal, or asks questions about the research, these suggestions will be received as sincere attempts by the IRB to improve the student's submission and by so doing, offer the student information about the IRB process and requirements. Please keep in mind that the IRB is pleased to make presentations to campus departments and classes.

A Few "Housekeeping" Issues:

1. *Qualifications of investigators*: There is a place in the IRB forms where qualifications of the investigator and, if appropriate, the investigator's advisor are requested (p. 8, #3). This information is critical to IRB review because it must imply that participants will be safe under a knowledgeable investigator's care during the conduct of the study. For example, if you wish to conduct a study that involves blood draws, the IRB has to be sure that the person who will collect the blood knows how to do it, and, if there are national or state certifications required to perform this activity, that this person has met those requirements. This concern applies to all types of interventions where there may be some participant risk even if minimal. It may be that a student will not have full qualifications to perform the research activity but can do so under the supervision of a qualified person. The IRB must be informed of such an arrangement and must know the qualifications of the supervisor(s).

2. *Who are your study participants*? Your proposal must indicate clearly the nature of your participant population. If, for example, your study involves evaluating changes in child behavior relative to placement in various public pre-school programs by asking parents, teachers, and school officials to complete an assessment questionnaire, your population is the group of persons responding to the questionnaire, not the children whose behavior may change as a result of program placement.

3. *Research variables*: If your study involves measuring the effects of routine treatment on a population of identified adult substance abusers (treatment they would receive even if your study was not being done) using a pre-post evaluative tool, the treatment cannot be considered as part of the dependant variable. Your research in this case is the pre-post testing. Your consent document therefore must not suggest that the treatment is part of the research. All of your proposal documents must convey that you are interested in the participant's responses to the evaluative instruments, prior to and after they receive their routine treatment. In many instances, this type of research can be considered a quality improvement or assessment evaluation and will generally be exempt from continuing IRB review. However, if you clearly state that treatment is part of the dependant variable in your study, and that the treatment would likely not be routinely administered, your research will undergo expedited or full review. The IRB will make this determination.

4. *Purpose of research*: For students, the stated purpose of their research cannot be to fulfill academic requirements. There must be a clear and viable purpose to the research based on established needs within the discipline that the study encompasses. The IRB must be informed of this need in the research abstract. In no way should consent documents or cover letters convey that the research is for academic purposes only.