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 3, 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.*

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Hello everyone. As the spring 2005 term rapidly becomes a memory, your IRB continues to be actively engaged in protocol review and board education. One of the federal mandates that allows maintenance of our institution's Federalwide Assurance is continuing board education. The SCSU IRB has engaged in several topic discussions this year including: research ethics and integrity; participant protections; and, the federal codes. From these experiences, research ethics emerged as a subject the board believed may hold some interest for the university community. This issue of the newsletter will focus on benchmarks of ethical research that fall directly under IRB purview.

Preface:
The discussion of research ethics which follows is based on a presentation by Ezekiel J. Emanuel, MD, PhD, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health, given at an advanced research ethics course sponsored by Public Responsibility in Medicine and Research , October 28, 2004, San Diego, California. The information addressed below is liberally drawn from this presentation.

Ethical Justification:
There are both historical and ethical justifications for the federal requirements that guide human participant research. This discussion will be concerned with the ethical justifications.

When human research results in generalizable knowledge that is used to improve health or increase understanding, participants in the research are a means to obtaining that knowledge and increased understanding. As a means, these participants can be easily exploited for the benefit of others. Ethical requirements for research are meant to minimize the possibility of participant exploitation. A series of ethical guidelines have been adopted by the United States federal government as requirements for research involving human participants. These requirements have become known as the "Common Rule." The "Common Rule" underlies all ethical considerations in human participant research and IRB review.

Eight Ethical Requirements:
The volumes written to produce the ethical considerations indicated in the "Common Rule" might be summarized by eight ethical requirements for human participant research: (1) collaborative partnerships; (2) social value; (3) scientific validity; (4) fair participant selection; (5) favorable risk-benefit ratios; (6) independent review; (7) informed consent; and, (8) respect for human participants.

(1) Collaborative partnerships : Research should involve the community in which it occurs. This may require: community participation in planning, conducting and overseeing the research; community advisory boards; and, participant advocates. In some cases the

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:

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"community" may be as large or larger than a township or as small as an institution.

(2) Social value : Research must lead to improvements or advancements in generalizable knowledge. The investigator must consider how study results will influence participants, the community and the world.

(3) Scientific validity : Research must be methodologically rigorous and practically feasible. The research must produce reliable and valid data that can be interpreted.

(4) Fair participant selection : The scientific objectives of the research, and not population vulnerability, availability, convenience, or privilege, should guide the selection of study participants. Groups should not be included or excluded from the study without scientific reason (inclusion/exclusion criteria).

(5) Favorable risk-benefit ratios : Four considerations emerge: (1) risks must be identified, assessed and minimized. Risk assessment must include but not be limited to the likelihood and magnitude of the following possible participant harms occurring as a result of the research: physical; psychological; social; economic; dignitary; and, legal; (2) potential benefits to the participants must be enhanced; (3) potential benefits to the participants must outweigh potential risks to the participants; (4) if risks outweigh benefits to the participants, then risks must be evaluated against the social benefit of the knowledge gained. If risks outweigh the social benefits, the study must not be completed.

(6) Independent review : Because investigators may have multiple legitimate interests, they may have potential conflicts of interest regarding research studies. Independent review of the research minimizes these conflicts. Independent review also assures society that it will not benefit from the abuse of research participants.

(7) Informed consent : Informed consent ensures that individuals decide if they wish to participate in research and whether the research fits with their own values, interests, and goals. For individuals who are unable to give consent conventionally, caretakers and investigators must be sure that the research fits with the participants interests. These four items must be considered when constructing a consent document: (1) competence of the participant; (2) full disclosure of information to the participant; (3) comprehension and understanding of the research and the terms of consent by the participant; (4) voluntariness of the decision to participate. The following eight items are required by code to be part of consent documents: (1) the title of the research, its purpose and duration; (2) knowable risks; (3) If a clinical trial, alternatives to treatment; (4) benefits to the participant; (5) confidentiality of collected data; (6) compensation for any injury incurred as a result of the research; (7) person to contact for questions about the research; and, (8) voluntariness and a right to withdraw.

(8) Respect for human participants : The ethical requirements of research do not end with a signed consent document. Ethical requirements also include: (1) active and continued protection of data confidentiality; (2) immediate and unimpeded permission for participant withdrawal; (3) in clinical trials research, providing new information to participants as the study progresses, and permitting continuing review of consent in light of new information; (4) active and continued monitoring of the welfare of participants as they engage in the study; and, (5) when appropriate, informing participants of what was learned from the research.

SCSU IRB Responsibilities:

The SCSU IRB is bound to follow federal codes regulating research with human participants. It is also morally, ethically, and institutionally bound to apply the strictest interpretations and extensions of the codes with respect to SCSU research activities and to do so in a manner that assures participant, investigator and institution protections.