



the IRB newsletter

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

The SCSU Institutional Review Board – Volume 2, Number 2, Spring 2004

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
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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Welcome back to the 2004 spring semester. The IRB hopes that it will be a productive and enlightening term and that any human participant research you may be engaged in will be guided by human research protections implemented by the SCSU Institutional Review Board (IRB). The current newsletter is directed to assisting you in preparing IRB proposals and in understanding some of the underlying principles that inform the IRB. From time-to-time topics will be selected for discussion that have particular application to the types of research in which SCSU investigators most frequently engage. This newsletter will address survey and classroom research.

Survey Research

Several university academic departments and administrative offices engage in survey research. This form of research is often considered to present little if any risk to participants and therefore questions arise as to the necessity of IRB review.

Possible Harms: Information extracted from a survey frequently offers a glimpse into the private life of an individual and may therefore precipitate participant harms as serious as the physical risks associated with clinical trials used to evaluate drugs or medical devices. These harms might include: inadvertent disclosure of private medical problems or sexual preference; psychological trauma as a result of reading or revealing information; boredom or frustration as a result of the inconvenience of participation; social embarrassment or rejection if considered part of an identified group associated with the survey; economic privation in the form of job, credit or insurance loss; and legal concerns if the survey purposefully or inadvertently discloses illicit behavior (Oakes, 2002).

IRB Policy: The SCSU IRB policy is to review all survey research. The IRB will determine the level of participant risk and suggest, if needed, ways to minimize the risk. However, survey activities that are employed to determine if operations within SCSU are being performed in line with established standards (Quality Assessment) or, with the goal of improving SCSU operations with respect to established standards (Quality Improvement), are generally considered non-research and need not be submitted to IRB review (Amdur and Speers 2002).

Proposal Submission: The IRB must receive from the principal investigator, enough information regarding the study so that an informed decision may be made regarding the level of risk to participants. The principal investigator must be cognizant of the possible risks to participants that the survey being employed can inflict, and address them fully in the proposal. A copy of the survey instrument must accompany the proposal.

Exempt Status: Most survey research at SCSU will be exempt from IRB continuing review, however, the IRB must make this determination not the investigator. Surveys with children as participants are never exempt unless a teacher is using a survey to evaluate his/her own teaching effectiveness and the data collected will be used for this purpose only.

Informed Consent: Standards for informed consent in survey research are the same as those for other forms of research. DHHS gives two conditions in which consent may be waived by

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 IRB: (1) the only document linking the participant with the research is the consent form and a possible breach of confidentiality may be present; (2) the research presents no more than minimal risk and does not involve procedures for which written consent is normally required outside of the research context. The IRB may request that a written statement regarding the research be provided to the participants (like a cover letter). Return of the survey in cases of a waived informed consent document would constitute participant consent.

Surrogate Surveys: Surrogate surveys are instruments that ask a participant to give information about another. In these cases, the informant and the person about whom information is offered must be considered separate participant populations. Informed consent requirements and all other ethical considerations and protections the law provides must apply to both participant groups. Oakes (Oakes, 2002) suggests, “. . . that investigators get informed consent from both primary and surrogate subjects when a breach in confidentiality could result in meaningful harm.”

Privacy and Confidentiality: Confidentiality indicates that data extracted from survey instruments will be protected information and will be employed only according to the terms presented in consent documents or implied in cover letters. Information sought from participants that falls outside consented surrendered data extracted from the survey constitutes a violation of privacy. Researchers must be aware of these distinctions and must recognize that they are responsible for assuring the confidentiality of participant data and for maintaining participant privacy (Oakes, 2002).

Oakes, Michael, J., Survey Research (Chapter 10-6, pgs. 428-433), in Institutional Review Board: Management and Function, edited by, Amdur, Robert, and Bankert, Elizabeth: Jones and Bartlett, Boston. 2002.

Amdur, Robert, and Speers, Marjorie, Identifying Research Intent (Chapter 4-3, pgs. 118-124), in Institutional Review Board: Management and Function, edited by, Amdur, Robert, and Bankert, Elizabeth: Jones and Bartlett, Boston. 2002.

Classroom Research

Is “research” conducted in the classroom by teachers really research and therefore non-exempt and subject to IRB review? To assist in answering this question a distinction must be made between teaching and educational research. Teaching is performed to help students learn and is conducted with the understanding that the welfare of the individual student is paramount. Educational research is performed to contribute to the body of knowledge about education, and the welfare of the individual student participant is not of primary interest (Deramond 2003).

Exempt Activities: Teaching activities which may be exempt from IRB review would be those that would have taken place even if the teacher was not studying his/her own practice or if the data collection procedure would have been used as part of normal educational activities. Combining teaching and research to generate knowledge in the context of improving one's own practice is generally exempt (Deramond 2003).

Outsider Research: An identified researcher investigates teaching practice to change/ improve/ document someone else's teaching. This type of research is usually conducted in a partner relationship with a university or research institution and is generally not exempt (Deramond 2003).

Non-exempt Activities: Research involving extraordinary educational practice and educational tests if the results can be linked to individual students and may be potentially harmful, are generally not exempt (Deramond 2003).

IRB Policy: The SCSU IRB policy is to review all educational research with the exception of teacher's evaluating/documenting their own practice to change/improve their own teaching. All other classroom research should be submitted to the IRB so it may determine the level of participant risk and suggest, if needed, ways to minimize the risk.

Deramond, Helene, U.S. Department of Education, presentation at 2003 PRIM&R conference, Washington D.C. entitled, Is it Research if it's in the Classroom?