RESEARCH HUMAN PROTECTION PROGRAM

the IRB newsletter

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The SCSU Institutional Review Board – Volume 2, Number 3, 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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Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable research participants. The codes list children, prisoners, pregnant women, mentally disabled persons, and the economically or educationally disadvantaged as vulnerable populations *(45 CFR 46.111).* Edward Bartlett from the Office of Human Research Protections (OHRP) suggests interpretation of the code might be expanded to include: those engaged in illicit behavior; immigrants; graduate and undergraduate students; military enlistees; and the elderly (Bartlett, 2004). The regulations define "vulnerable" as persons susceptible ". . . to coercion or undue influence . . ." when deciding to participate in research. The codes require that ". . . additional safeguards . . . [be] included in the study to protect the rights and welfare of these [participants]." Several departments on campus engage in research that require the use of vulnerable populations as participants. This issue of the IRB Newsletter will discuss children as research participants, a frequently employed vulnerable population.

Children

Generally, research involving minimal or no risk, conducted with children in established or commonly accepted educational settings, using normal educational practices is exempt from continuing IRB review. However, the codes are clear that survey and interview procedures, and some forms of observational procedures even if they are at the minimal or no risk level, are never exempt from IRB review and require strategies to protect participants. All research with children that is determined to be above the minimal risk level must be reviewed by the IRB and must employ special protections *(45 CFR 46.401(b)).*

Minimal Risk: The federal definition of minimal risk is as follows, ". . . the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests." Researchers must be aware not only of the magnitude of harm but also the likelihood of it occurring *(45 CFR 46.102(i)).*

Special Protections:

In research involving no greater than minimal risk, the investigator must employ adequate provisions for soliciting the assent of the children and the permission of their parents or guardians. The decision whether or not to require assent may be made by the investigator but the IRB may overrule the investigator regarding the need to employ assent. In determining the need for assent the investigator and the IRB must take into account the age, maturity and psychological state of the children involved *(45 CFR 46.404, 408).*

In research involving greater than minimal risk, with the prospect of direct benefit to the participant, the investigator must clearly justify that the risk is less than 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:

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

anticipated benefit to the participant, and that the relation of the anticipated benefit to the risk is at least as favorable to the participant as that presented by available alternative approaches. Generally, risk level may be determined through review of prior research. Further, investigations which present greater than minimal risk to children should first be attempted with adults. The investigator must make adequate provisions to solicit the assent of the child and the permission of parents or guardians *(45 CFR 46.405).*

In research involving greater than minimal risk where there is no prospect of direct benefit to individual participants, but where there is a possibility of gaining critical generalizable knowledge, the investigator must clearly establish that the risk is only a minor increase over minimal risk, and that any intervention experiences are reasonably commensurate with those inherent in the children's actual or expected medical, psychological, social or educational situation. The investigator must make adequate provisions to solicit the assent of the child and the permission of their parents or guardians *(45 CFR 46.406).*

If participants cannot be protected under any of the conditions cited above (for example, if risk is greater than a minor increase over minimal risk), and the IRB determines that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, the proposal must be submitted to the Secretary of the Department of Health and Human Services for review and approval. Otherwise, the project will be disapproved at the local level *(45 CFR 46.407).*

Informed Consent: Parents and guardians must be completely informed regarding the nature of the research in which their children will participate. All of the informed consent requirements listed in the codes must be considered when developing a consent document. Information regarding consent requirements may be found in **Appendix B** of the SCSU IRB proposal template. Parental consent, when it is accompanied by a child's assent, is sometimes referred to as parental permission. In either case, all consent requirements must be considered.

Child Assent: Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be considered assent *(45 CFR 46.402(b)).* The investigator is responsible for initially determining if an assent document is required. Consideration must be given to the child's ability to understand the research, and if written assent is desired, the ability to read and understand the assent document. Investigators must acquire knowledge about the thresholds of competence, judgement and capacity of their prospective participants (McCormack 2004). Assent may be obtained verbally by script, with a witness present, or by signature on an assent document. A verbal assent script and a child's assent document must be crafted with care. Consideration must be given to the complexity of the language used and the break-down of study constructs into understandable units. The IRB must approve all assent scripts and documents.

Cited:

Bartlett, Edward, *Regulatory Overview of Vulnerable Subjects*, Presentation at "Recognizing and Protecting Vulnerable Subjects," Orlando, Florida, April 2004.

McCormack, Norma, *Special Considerations for Adolescents in Research*, Presentation at "Recognizing and Protecting Vulnerable Subjects," Orlando, Florida, April 2004.

The Federal Register, Part II, *Federal Policy for the Protection of Human Subjects: Notices and Rules*, *45 CFR Part 46*, Government Printing Office, Tuesday, June 18, 1991.

Consulted:

OHRP, *Protecting Human Research Subjects: Institutional Review Board Guidebook,* NIH, Government Printing Office, 1993.