RESEARCH HUMAN PROTECTION PROGRAM

IRB

# the IRB newsletter

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

The SCSU Institutional Review Board – Volume 5, Number 1, Fall 2006

## 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
W. Jerry Hauselt, Ph.D.-Psychology
Shirley Girouard, Ph.D.–Nursing
James Mazur, Ph.D.–Psychology
Michael Perlin, Ph.D.–Public Health
Jaak Rakfeldt, Ph.D.–Social Work
Frank Sansone, Ph.D.–CMD

Alternates

Marianne Kennedy, Ph.D.–CMD/Assemt.
Cynthia McDaniels, Ph.D.–EDF
Mary Purdy, Ph.D.–CMD

## 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

HELLO EVERYONE. THERE HAVE BEEN SOME CHANGES IN THE IRB OFFICE LOCATION AND PERSONNEL. The IRB office is currently located in the School of Graduate Studies, EN B 110 D. We expect that this is a temporary location and anticipate relocation to our new office in EN A 110 A-B before the end of this semester. After several years of productive service, Dr. Karl Rinehardt has stepped down as an IRB alternate member. Dr. Marianne Kennedy has changed her participation from IRB member to alternate. Dr. W. Jerry Hauselt (PSY) has been appointed to the board as a member and co-chair. Dr. Frank Sansone is now serving as Human Research Protection Program (HRPP) administrator and IRB co-chair. Dr. Hauselt is in the process of assimilating the IRB policies and procedures and is currently reviewing new IRB proposals. Dr. Hauselt and Dr. Sansone have recently returned from an IRB conference presented in Washington, D.C. where both attended short courses and meetings designed to up-date IRB personnel regarding federal human research protection regulations. Select items from the conference that pertain to the type and complexity of the research activities at SCSU will be presented below.

## Studies Involving Children: SCSU IRB Policy and Failure to Submit IRB Research Protocols:

The following is a restatement of information provided in a prior SCSU IRB Newsletter (Vol. 2, No. 3, Spring 2004): "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 . . . (45 CFR 46.401(b))." The current SCSU IRB institutional policy requires that all research with children be reviewed by the IRB no matter the level of perceived risk or type of research activity. This policy must supercede privileges given under the SCSU IRB *Course Instructor Certification* program. Whenever research involves children the SCSU IRB must determine the level of review and disposition. Research with children will almost always be submitted to an expedited or full review.

It may be that SCSU professors in some disciplines who do research with children or advise students who study children, consider this research to be exempt based on the research type and the minimal or no risk paradigm mentioned above. These professors fail to submit IRB protocols when appropriate. We mention this because only a few IRB research protocols have been received from persons in campus disciplines where children are perceived to be one of the main populations of academic inquiry. Please receive these comments in light of the requirements imposed on the Human Research Protection Program to assure campus-wide compliance with federal, state and institutional policies regarding human participant research. If you or your students will be engaging in research that involves children, please submit an IRB proposal for

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 E. Sansone,
Human Research Protection Program Administrator and
IRB Co-Chair, or
Dr. W. Jerry Hauselt
IRB Co- Chair
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review and disposition. If you are unsure whether or not your study activities require IRB review please contact the IRB office by voice or e-mail. We will be happy to help you.

Participant Notice of Research Involvement:

There are several acceptable ways that research participants may be informed of their research involvement. The following should be considered as appropriate notification formats and principles:

*Informed Consent*: The informed consent document is a critical piece of an IRB proposal. It helps to safeguard human research participants against: unethical research practices; coercion to participate; undue influence; and undisclosed risks of participation, among others. The consent document insures that prospective human research participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. Informed consent is one of the primary ethical requirements of human participant research, protecting both the research participant whose autonomy is respected, and the investigator, who otherwise may face legal hazards.

*Child Assent/Parent Consent*: When children are used as research participants, a parental consent (permission) form must be developed and signed by the parent or legal representative of the child. Furthermore, an assent document must be constructed for the child participants to sign when the children: (1) are able to read and understand; or, (2) are able to be read to and understand; and, (3) have decision making ability. The assent document must be written at a level the children are able to comprehend. If the language of your parental consent form is at the reading/comprehension level of your children research participants, the parental consent form may also be used as an assent form if a place is provided for the child to sign. The assent must be signed without the possibility of parental coercion.

*Cover Letters*: The use of an informed consent document in some research may actually jeopardize participants' confidentiality and/or anonymity unnecessarily. For example, a researcher employing a signed consent document in an anonymous survey, may inadvertently be providing the only link to the participants identity thus compromising confidentiality and anonymity. Please be advised however, the researcher is not freed of the responsibility of informing participants about the research activity. In such cases, cover letters, which are unsigned documents that contain most if not all of the elements of an informed consent document, can be used. The cover letter must include language that informs potential participants that **the return of the survey indicates their consent to have the data included as part of the research**. Cover letters can not be used to replace consent/assent documents in research involving children. The IRB makes the final decision on the appropriateness of cover letter use.

*Waiver of Informed Consent*: When a researcher wishes to use a cover letter rather than a consent document, a request to have the consent document waived must be included in the IRB application. A justification for the waiver must be provided.

A Few Housekeeping Items:

1. Please do not staple pages of the protocol or other information submitted.
2. Please be sure to obtain all signatures required on the cover page of the proposal.
3. Please be sure to complete and sign the SCSU IRB "Education Certification" form and submit the NIH tutorial "Completion Certificate."
4. Please carefully proofread any documents that will be transmitted to participants.
5. Enclose letters of permission to engage in research from external agencies.