



Update: Research Protection

A Publication of The Southern Connecticut State University Research Protection Program

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SCSU requires integrity, moral and ethical conduct in all research performed by its faculty, students and staff. The Research Protection Program (RPP) is responsible for assuring conformity with both university and federal mandates for research design and investigator behavior. Divisions of the RPP include: The Office of Research Integrity (ORI); The Institutional Review Board (IRB); The Institutional Animal Care and Use Committee (IACUC); and, Educational Resources.

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Dear Colleagues,

The main news regarding research protection has to do with personnel changes related to the early retirement program. Dr. Frank Sansone retired (again) from the University. He held the title of Director of the Research Protection Program, and also was the Research Integrity Officer and an IRB Member. Frank had been a member of the Communication Disorders Department and IRB Chair before his first retirement, but continued in the RPP program to ensure continuity in the program. Through Frank's work, research protection at SCSU has become an outstanding program, and is one of which we can be proud. As a retiree however, his term of employment was limited, and his term ended over the summer, leading to his second retirement. His knowledge of the regulations which guide the IRB and underlie research protection is encyclopedic, and his commitment to facilitating research while protecting participants is known nationally. I remain the IRB Chair, and have assumed the responsibilities Frank has held in the RPP. Due to his excellent mentorship, the transition has been seamless, but I am learning that I have much more to learn to approach Frank's level of expertise, and I am grateful for the opportunity to have worked closely with him for nearly three years.

The recent retirement incentive has also changed the IRB membership. Dr. Michael Perlin (Public Health), and Mr. Dave Denino (Counseling Ser-

vices), have both retired. The wealth of knowledge that these two dedicated professionals brought to the IRB will be sorely missed. To fill out the IRB membership, Dr. Cynthia McDaniels (Educational Foundations), Dr. Richard Cain (Public Health), and Dr. Karen Remedios (English) have been appointed to the committee. Also, Dr. Sandra Bulmer (Public Health) has been appointed as an alternate member. Dr. Richard Cain's research focuses on social inequalities and social problems and how these concepts lead to health disparities. His primary focus involves the study of stigma and its impact on the quality of life and wellness among people living with HIV disease. His secondary focus is adolescents and health-related fitness. Dr. Sandra Bulmer conducts research on topics related to physical activity, women's health, and college student wellness. She specializes in the use of qualitative and community-based participatory research methods. She also serves as a reviewer for several public health journals and for grant applications with the National Institutes of Health. Dr. Karen Remedios' areas of research are Modern British literature and postcolonial literature with a focus on South Asia, West Africa and the Caribbean. These scholars bring a wealth of experience and knowledge to the IRB, and they have the legacy of the retiring members to guide them.

Jerry Hauselt, IRB Chair

IMPORTANT UPDATE! Please change your documents!

The 203-392-5958 phone number for the RPP is **no longer in service**. Researchers are asked to update any forms that they use that may include this number, including any informed consent documents. This is deemed a minor change, and no Request for Revision paperwork is required for this change to occur. The sole RPP phone number is 203-392-5243. The RPP and IRB fax number remains 203-392-5221.

If research is “exempt” why does it need IRB review?

In October 2009, The Office for Human Research Protection (OHRP) issued revised information about the determination of research as “Exempt.” In order to be exempt, research must fit entirely within certain regulatory definitions. Furthermore, our institutional policy is that research involving children can not be exempt. At SCSU, the most commonly used exemption definitions are a) research using educational tests, survey procedures, interview procedures, or observation of public behavior provided that the data are anonymous and any privacy risks are minimal, and b) research using existing data if the sources are publicly available or the data are anonymous. For the 2008-2009 academic year, 235 new research applications were submitted and 116 (49.4%) were found to be exempt in one of the categories mentioned above.

The guidance issued by OHRP clarifies the apparent paradox of the exemptions...if research is exempt from the regulations, why must it receive an official review? The answer lies in preventing a conflict of interest. The guidance (OHRP, 2009) states that “OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt.” This importance of maintaining objectivity in research is not alien to human subjects researchers, who often take great pains to prevent participant bias or experimenter bias from contaminating their data. For example, we often keep those in contact with participants unaware of the hypotheses so that their actions do not create an artifact in the data. Similarly, the determination about the research must be made independently.

Therefore, the meaning of the word “exempt” in relation to research does not mean that “the rules” do not apply. It should be taken to mean that the research is anonymous, of minimal risk, and exempt from further IRB review as long as no changes which affect the cost/benefit ratio are made.

Office of Human research Protections. (2009). FAQ: Exempt research determination. http://www.hhs.gov/ohrp/policy/exempt_res_det.htm

IRB and IACUC News

IRB. Greetings! So far this calendar year, the IRB has processed over 200 new protocols. This is on pace with last year’s total of 235, which was one of the busiest in the history of this IRB. In order for things to continue to run smoothly, and to facilitate timely processing of protocols, please keep the following in mind when preparing a submission. First, all materials for the IRB should be taken to the School of Graduate Studies Office, EN B110, where they will be recorded and logged into our system. Second, please check to make sure that all supplemental materials (education certificates, letters of agreement, and informed consent documents) are attached to the application. Third, a detailed description of your research is critical to fully understanding the research. Fourth, please contact us if you have any questions. EN A110 (203 392-5243).

IACUC. The SCSU Institutional Animal Care and Use Committee (IACUC) is a federally mandated committee responsible for tending to the care and welfare of vertebrate animals (i.e., animals with a backbone) used in field and lab research as well as teaching purposes. Relying on the experience, training and expertise of its members, the IACUC oversees all SCSU animal research programs, facilities and procedures. All research involving animals must be reviewed by the IACUC prior to project initiation.

IACUC protocol submissions for spring should be submitted before or during March 2010.

Other IACUC responsibilities include:

- Semiannual review of animal study areas to assure Public Health Service guideline compliance.
- Maintenance of appropriate policies and procedures for animal care and welfare.
- Investigation of concerns involving animal care and use.

Reporting Research

A llegations of research misconduct and the basis for them should be communicated confidentially and preferably (but not necessarily) in writing to the Research Integrity Officer (RIO).

Jerry Hauselt, Ph.D. is currently serving as SCSU RIO (Office: EN A 110 A-B; Voice: (203) 392-5243; FAX: (203) 392-5221; Email: hauseltw1@Southernct.edu)

The HHS ORI Whistleblower’s Bill of Rights may be found at:

http://ori.hhs.gov/misconduct/Whistleblower_Rights.shtml