



Update: Research Protection

A Publication of The Southern Connecticut State University Research Protection Program

Volume 1, Issue,1, Fall 2007

Special points of interest:

- Different Newsletter format and title.
- New! Office of Research Integrity.
- What is research misconduct?
- Responsible research conduct expectations at SCSU.
- Reporting research misconduct.
- Processing misconduct allegations.

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Changes

Hello everyone. There have been some significant changes in the research protection area within the past few months. Most obviously has been the change in title and format of our newsletter. The former *IRB Newsletter* has been up-dated and reformatted to include new aspects of campus research protections. The title of the newsletter has been changed to *Update: Research Protection*. We are considering this first issue to be Volume 1, Issue 1, under the new title. The former Human Research Protection Program (HRPP) title has been shortened to Research Protection Program (RPP) to reflect the expanding role of research protections in SCSU research activities.

Beyond involvement with activities of the Institutional Review Board (IRB), the re-named Research Protection Program (RPP) now incorporates the SCSU Institutional Animal Care and Use Committee (IACUC), and the SCSU Office of Research Integrity (ORI). Further, the RPP provides educational resources regarding research protection

across all of its divisions.

We hope that the new *Update: Research Protection* newsletter will portray the dynamic activity of our program and will encapsulate crucial issues regarding research protections and research integrity. In subsequent issues, we plan to have information on each RPP division, highlighting critical elements which may be of interest to the university community.

In this issue, the Office of Research Integrity will be featured because its responsibilities may be viewed as embracing all aspects of research protection.

The Office of Research Integrity promotes and monitors the responsible conduct of research for all SCSU **human and non-human research**, acts on substantive allegations of research misconduct, and serves as the office of the Research Integrity Officer (RIO). The information that follows offers a more extensive examination of the office and its authority and responsibilities.

Office of Research Integrity (ORI) Authority

The SCSU ORI follows The U.S Dept. of Health and Human Services' (HHS) Public Health Service (PHS) Policies on Research Misconduct found in *The Federal Register*, at Title 42, Part 93 (2005). Further, the SCSU ORI observes processes presented in the HHS and PHS *ORI Handbook for Institutional Research Integrity Officers* (2005), and to

the *ORI Introduction to The Responsible Conduct of Research* (2005). The SCSU ORI participates in the HHS ORI Assurance Program and has established administrative policies for responding to allegations of research misconduct that comply with PHS Regulation 42 CFR Part 93 and accepted institutional procedures.

Federal Definition of Research Misconduct

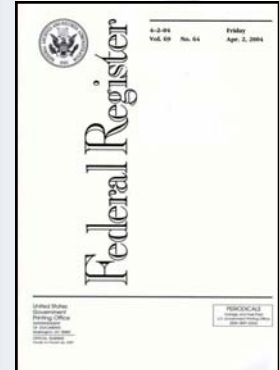
The federal codes, 42 CFR 93 at § 93.103, define research misconduct as... “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results:

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person’s ideas, processes, results,

or words without giving appropriate credit.

- Research misconduct does not include honest error or differences of opinion.”

Recognizing that institutions may have research integrity requirements in addition to the federal definitions, the codes make allowances for individual institutions to “... have internal standards of conduct different from the HHS standards...an institution may find conduct to be [potentially] actionable under its standards even if the action does not meet...[the HHS ORI]...definition of research misconduct.”



Responsible Research Conduct at SCSU

Considering federal policies and institutional elements regarding responsible conduct in research, it is expected that investigators, conducting research under the auspices of SCSU, will refrain from engaging in federally defined research misconduct, and at a minimum, observe the following common ethical values:

- Honesty – convey information truthfully;
- Accuracy – report findings precisely;
- Efficiency – use resources wisely;
- Objectivity – let facts “speak for themselves” and avoid improper bias;
- Protect human participants in research –submit research involving humans to Institutional Review Board (IRB) review;
- Attend to the welfare of laboratory animals– submit research involving animals to Animal Care and Use Committee (IACUC) review;
- Follow discipline specific ethical codes regarding research investigator conduct;

- Foster professional self-regulation in research – set an example of responsible research conduct for students, colleagues and the public;
- Report instances of research misconduct when they occur.

Adherence to these basic tenets provides groundwork for research integrity and is expected to promote responsible conduct in research at SCSU. Violation of these ethical values and/or federal research misconduct codes may be considered actionable according to SCSU policies and procedures.

Please note: The final item in this list signifies that failure to report knowledge of research misconduct is considered an ethical violation. Anyone who witnesses research misconduct whether involved in the research or not, should report it.

“...it is expected that investigators... will refrain from engaging in federally defined research misconduct and...observe... common ethical values...”



Reporting Research

Allegations 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).

Frank E. Sansone, Ph.D. is currently serving as SCSU RIO (Office: EN A 110 A-B; Voice: (203) 392-5958; FAX: (203) 392-5221; Email: Sansonef1@Southernct.edu)

The complainant may not remain anonymous but will be protected under *The HHS ORI Whistleblower's Bill of Rights*. Further, the professional reputation of investigators named in allegations will be rigorously pro-

tected unless found guilty, at which time case activity may be made public.

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

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



Dr. Frank Sansone
Research Integrity Officer

Processing Allegations of Research Misconduct

- Preliminary Assessment - The RIO determines if allegations contain sufficient information to proceed with an inquiry.
- Inquiry - The RIO makes a prefatory evaluation of the evidence, testimony of the complainant and key witnesses to determine if there is sufficient evidence of possible misconduct to warrant an investigation.
- Investigation - The RIO, along with institutional officials, appoints an ad hoc committee. The committee explores the allegations

in detail, and examines the evidence in depth, to determine if actionable misconduct has been committed, by whom, and to what extent. The committee reports findings and recommended institutional actions to the institution's deciding official.

- Decisions - Based on a preponderance of the evidence, the institution's deciding official will make the final determination whether to accept the investigative report, its findings, and the recommended institutional actions.

"The committee explores the allegations...and examines the evidence...to determine if actionable misconduct has been committed..."

Actionable Research Misconduct

A finding of actionable research misconduct requires that:

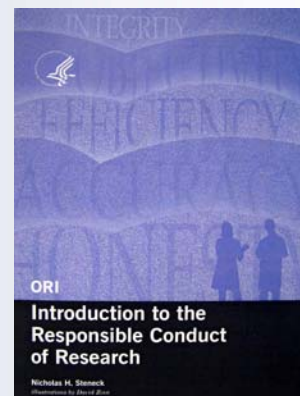
- "There be a significant departure from accepted practices of the relevant research community; and,
- The misconduct be committed intentionally, knowingly, or recklessly; and,
- The allegation be proven by a preponderance of the evidence."

References for all ORI items:

Code of the Federal Register 42 part 93, 2005

ORI Handbook for Institutional Research Integrity Officers, United States Public Health Service, 2005

ORI Introduction to The Responsible Conduct of Research, Nicolas H. Steneck, U.S. Department of Health and Human Services' Office of Research Integrity, 2005





The SCSU Research Protection Program

Frank E. Sansone, Ph.D., Administrator
 Research Protection Program,
 Research Integrity Officer

Institutional Review Board (IRB)

W. Jerome Hauselt, Ph.D. IRB Chairperson
 Frank E. Sansone, Ph.D., Associate IRB Chair
 IRB Members:

Dr. Barbara Aronson	Mr. Vincent Avallone
Dr. Robert Axtell	Mr. David Denino
Dr. Marianne Kennedy (ALT)	Dr. James Mazur
Dr. Cynthia McDaniels (ALT)	Dr. Michael Perlin
Dr. Mary Purdy (ALT)	Dr. JaaK Rakfeldt

Institutional Animal Care and Use Committee (IACUC)

Nicolas Edgington, Ph.D., IACUC Chairperson
 IACUC Members:

Dr. Rosalyn Amenta	Dr. Deborah Carroll
Dr. George DeMarco, DVM	Dr. Brian Hurlbut
Dr. James Mazur	Dr. Dina Moore
Ms. Layne Ochman	

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.

Visit us online at: www.GradStudies.SouthernCT.edu. Click on Research.

Educational Resources (Partial Listing):

- *Introduction to The Responsible Conduct of Research, Nicolas H. Steneck, U.S. Department of Health and Human Services' Office of Research Integrity, 2005*
- *PRIM&R Research Protection Conferences, Short Courses and Workshop Proceedings 2001-2007*
- *Prior Newsletters (available online)*
- *Research Protection PowerPoint Presentations*

IRB and IACUC News

IRB

Greetings! So far this calendar year, the IRB has processed over 185 new protocols. This is on pace with last year's total of 247, 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 animals used in research. 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.

Other IACUC responsibilities include:

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



Dr. W. Jerome Hauselt, IRB Chair



Dr. Nicolas Edgington,
 IACUC Chair