



Update: Research Protection

A Publication of The Southern Connecticut State University Research Protection Program

Volume 2, Issue 1, Fall 2008

Something New—A Research Page Link From SCSU's Home Page

Special points of interest:

- New Research Page.
- IRB Submission Requirements.
- Update NIH Tutorial.
- Research Misconduct Case Summary.

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Greetings. The RPP staff hopes that your fall term has been enlightening and that activities for closing out the semester are progressing as planned.

Research activities at Southern can now be accessed directly from the SCSU Home Page. On the home page upper horizontal menu bar, the word "RESEARCH" appears as a new clickable link. The link takes you to the new Southern Research Page.

With the exception of the "ATHLETICS" page, the new research page design parameters mirror the other links found on the SCSU Home Page menu bar. Background colors, fonts, a photo bar, left and right vertical menus, and a central picture and text, present coordinated viewing which incorporates the SCSU web architecture.

On the Research Page, the left-hand vertical menu offers links to critical information regarding: sponsored programs and research; graduate and undergraduate research activities; dissertation and thesis information;

policies for the responsible conduct of research; and research protection requirements for human and animal studies (IRB, IACUC). Links to the current IRB tutorial requirement, RPP educational resources, and the "Update: Research Protection" newsletter directory, are also provided.

A link to *The SCSU Research and Scholarship Advisory Committee* is featured in the upper right-hand corner of the page. This link provides critical research information for faculty regarding: CSUS research funding opportunities and conferences; faculty bibliographies; faculty scholar awards; and much more.

The right-hand vertical menu on the Research Page presents links to SCSU research centers, Southern research entries found on the World Wide Web, and links to Federal and professional research organizations.

Thanks for development of the page go to: Betsy Beacom, Rick Callahan, Patrick Dilger, and Paul McKenzie, all from the Department of Public Affairs.

IRB Application Submission Requirements and Dates

Who should submit:

SCSU faculty, staff, and students, who engage humans as participants in research on the SCSU campus must submit an IRB application for research review. Further, SCSU faculty, staff, and students who, under the auspices of SCSU, conduct research with human participants at institutions external

to SCSU must submit an IRB application for research review.

Classroom research may be exempt from formal IRB review. Please see *Course Instructor Certification* information online at: <http://www.southernct.edu/grad/research/institutionalreviewboard/hrpp/>.

Research conducted by investigators not

IRB Application Submission Requirements and Dates (Cont.)

directly connected to SCSU must follow the IRB *External Investigator Responsibilities* found online at: <http://www.southernct.edu/grad/externalinvestigatorresponsibilities/>.

An IRB research application must be submitted, reviewed, and assigned an “Exempt” or “Approved” disposition prior to any SCSU human research participant recruitment.

When to submit:

An application should be submitted for initial review **at the time you complete it**.

Full Review Submissions:

Academic Year: If initial review determines the need for full board review, during the academic year in any month from September through May, applications received prior

to or on the first Monday of the month will be full reviewed during that month (usually on the third Friday of the month providing a quorum of board members is available).

Summer: Applications requiring full review received after the first Monday in May will be reviewed according to the academic year schedule provided a quorum of board members can be achieved. Applications unable to receive full review during the summer will be considered for full review on the third Friday in the subsequent September.

What must be submitted:

Two hard copies of the entire application must be submitted. The cover page must be signed by all requested signatories. Electronic submission is not permitted.

Cover Page Application for Human Research Review

(This must successfully complete the full review. Please do not bring this application. See Form #1 for detailed information. You must receive the Institutional/Departmental Review of the "Packet for Human Research Review" prior to and during the construction of your application.)

1. Principal Investigator: [Name] [Title] [Dept.] [Phone] [Fax]

2. Please Check Status: SCSU Faculty SCSU Staff SCSU Student Graduate Undergraduate

3. Other (Please attach explanation. Insert in Item #1 after this page):

4. Study Address: [City] [State] [Zip] [Home Phone] [Work Phone] [E-mail] [Fax]

11. Department: [] 12. Sponsor/Advisor: []

13. Project Title: []

14. Classification: Human Department of [] Other (Please attach explanation. Insert in Item #1 after this page)

15. Research Type: Faculty Research Doctoral Dissertation Master's Thesis Special Project Graduate Fellowship Honor's Thesis Independent Study Creative Project Other (Please attach explanation. Insert in Item #1 after this page)

16. Funding Agency: SCSU Other (e.g. State, Federal, Corporation - Please attach explanation. Insert in Item #1 after this page)

17. External Agency Review (Only "Yes" has project been reviewed by an external human research review panel): Yes No

18. Location of Data Collection: []

Warning: Before initiation of the review of the application and scope of human participants involvement in this project, the Principal Investigator must complete the following information in this application to the maximum extent possible.

19. Principal Investigator	Date
20. Advisory Sponsor (Required for Student Research Documentation)	Date
21. Dept. Chairperson	Date
22. School Dean (Required only if subject is interdisciplinary)	Date

IRB Odds and Ends

We have just returned from a conference sponsored by PRIM&R (Public Responsibility in Medicine and Research), a national organization devoted to facilitating scientifically valuable and ethical research. It was clear from hearing the comments of other IRB Chairs and staff members that SCSU's program for complying with the Federal regulations governing human research is effective. A large part of this success is due to the vigilance and professionalism of our faculty and student researchers. Thank you for your diligence.

As we get ready for a new year and semester, here are a few items that may be of interest to investigators:

Update your training: Investigators are reminded to check the date on the Completion Certificate from the required NIH online training course. If the completion date is three years ago or later, the course must be retaken. The course has recently been updated by the NIH, and accordingly, has a new address. The link to the course can be found on our revised website.

New IRB member: The IRB welcomes Dr. Jessica Kenty-Drane (Sociology) as a new Alternate Member. Dr. Kenty-Drane was appointed in the fall semester to replace Dr. Marianne Kennedy, who was promoted to Associate Vice-President for Assessment, Planning, and Academic Programs. Dr. Kennedy served on the IRB for seven years,

as an Alternate. We wish her well in her new position.

Download the revised application: The IRB Application continues to be a work in progress, and has recently been redesigned to make the application easier to complete for researchers while highlighting the information reviewers need to determine the level of research risk. The accompanying instructions file also has been changed to facilitate the process. These changes should also significantly reduce the use of paper. For example, twelve copies of the Abstract are no longer required. Additionally, the application has been reformatted to more effectively make use of printed pages. As changes are periodically being made to the application, investigators are encouraged to **download the application for each new submission**.

Paper documentation: Federal regulations require the IRB to maintain its records for a period of three years. Currently, we do not have the capability to do this electronically, and must maintain a paper trail of our determinations and correspondence. Therefore, our ability to conduct reviews by email is limited. Please keep this in mind when an application is submitted.

Rolling review: Initial review of applications is ongoing, and if a research project is found to be exempt or of minimal risk, a disposition letter is normally sent within two weeks of submission. It is only when a proposal is found to be of MORE than minimal risk that the published deadlines are in effect.

“Update your training... check the date on the Completion Certificate from the required NIH online training course. If the completion date is three years ago or later, the course must be retaken.”



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SCSU Annual Report on Possible Research Misconduct

Each year the Health and Human Services' Office of Public Health and Science (PHS) requires registered institutions to submit an *Annual Report on Possible Research Misconduct*.

"Institutions are required by regulation to submit the annual report to maintain their research misconduct assurance. If the assurance is not maintained, the institution becomes ineligible to receive PHS support for research, research training, and related research activities.

"Filing the annual report requires officials to state whether their institution has a policy

that conforms with the PHS Policies on Research Misconduct (42 C.F.R. 93), update their institutional contact information, and report the number of research misconduct allegations received involving PHS-supported research or research training and the subsequent number of inquiries and investigations conducted."*

SCSU continues to meet this PHS obligation. Happily, to date, no instances of research misconduct at SCSU have required reporting.

*Quoted material was extracted from: *The Office of Research Integrity Newsletter*, Vol. 16, No. 4, September 2008, pg. 3.



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Federal Office of Research Integrity: Misconduct Case Summary

The Federal Office of Research Integrity (ORI), in its quarterly newsletter, publishes case summaries of research misconduct investigations that have reached the level of censure by the Department of Public Health and Science (PHS). "*Update: Research Protection*" will present facets of these cases when there are aspects of a case that may have import to SCSU investigators.

The case presented below involves a graduate student (respondent), in the Department of Social and Decision Sciences and Psychology at Carnegie Mellon University (CMU).

"Based on reports submitted by CMU..., the respondent's own admission..., and additional analysis conducted by the ORI..., PHS found that [the respondent] engaged in the following acts of scientific misconduct:" (The summary shows misconduct across several studies that were published under various titles.)

1. "Respondent altered the main dependent variable (life events: life expectation)...and variables of ease of thought generation so that the reported study results are largely unsupported...."
2. "Respondent falsified cortisol values and possibly cardiovascular measures and optimistic appraisals (as measured by the [Life Orientation Test] LOT), so that a large portion of the mediation analyses...does not reflect the data actually collected and analyzed for the study...."
3. "Respondent falsified the [data] analysis [regarding] participants' responses to manipulation

check items (including the data for self reported fear)....

4. "Respondent falsified the main dependent variable (reservation price, [Becker-DeGroot-Marschak Mechanisms] BDM) in the electronic file for 48 of...175 subjects participating. Respondent directed the alteration of the paper files for those subjects in order to match the electronic file."

Censure:

"The respondent entered into a voluntary Exclusion Agreement [3 year duration] in which [it was]... agreed...."

1. "To exclude...self from serving in any advisory capacity to PHS...."
2. "...[That] any institution that submits an application for PHS support for a research project on which the respondent's participation is proposed...must...submit a plan for supervision of the respondent's duties to the funding agency for approval...."
3. "... [To] ensure [that] any institution employing [the respondent]...submits...with each application for PHS funds...in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived...."
4. "[That the respondent] write ORI-approved letters to...collaborators and coauthors...; and [journal] editors...stating what...[was] falsified/fabricated...."*

CMU censure of the respondent was not presented.

*Quoted material was extracted from: *The Office of Research Integrity Newsletter*, Vol. 16, No. 4, September 2008, pgs. 6-7.

"The Federal Office of Research Integrity... publishes case summaries of research misconduct.... The case presented... involves a graduate student...in the Department of Social and Decision Sciences and Psychology at Carnegie Mellon University...."





The SCSU Research Protection Program Personnel

Frank E. Sansone, Ph.D., Administrator
 Research Protection Program (RPP),
 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. Jessica Kenty-Drane (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. Steven Wilson VMD	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. Click on "RESEARCH," upper horizontal menu
 SCSU Home Page.*

Stop in to see us: Engleman Wing A, Room 110 A-B

Phone: 203 392-5958/5243

Hours: M-TR, 8:00am - 10:30am

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 2001-2008*
- *Prior Newsletters (available online)*
- *Research Protection PowerPoint Presentations*

IACUC News

Veterinary Care:

According to CFR 1985, Title 9, Subchapter A, and PHS 1996, Policy on Humane Care and Use of Laboratory Animals, a doctor of veterinary medicine, who is American College of Laboratory Animal Medicine (ACLAM) certified or has training or experience in laboratory animal science and medicine or in the use of species handled at an institution, must be a member of the Institutional Animal Care and Use Committee (IACUC).

Dr. George DeMarco, VMD, ACLAM, Associate, Yale University School of Medicine, Section of Comparative Medicine, ended his association with Southern's IACUC, August 31st, 2008. He had served the IACUC for almost a year. The RPP staff wish him success in his new endeavors.

Dr. Steven R. Wilson, VMD, DAACLAM, Associate Research Scientist, Section of Comparative Medicine, Yale School of Medicine, has replaced Dr. De Marco. He began his duties

September 1st, 2008. The RPP staff welcomes Dr. Wilson to the Southern Research Protection Program.

Safe Purchase:

From time-to-time, investigators working with animals require the use of drugs in their research. The Federal Office of Laboratory Welfare (OLAW), and The State of Connecticut, require safeguards for storage of these controlled substances.

This summer a Mesa Safe (MBF3820) was purchased that meets OLAW requirements and the specifications indicated in Connecticut Statutes' Sec. 21a-262-1, and 21a-262-10. It was installed in the Engleman animal facility.



Happy Holiday's

From the Research Protection Program Staff



Dr. Nicolas Edgington,

IACUC Chair

Biology

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