Update: Research Protection

A Publication of The Southern Connecticut State University Research Protection Program

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Special points of interest:

- New RPP Logo.
- IRB Submission Requirements — External Agencies.
- ORI Whistleblowing Issues.
- IACUC — OLAW Clarification.

Inside this issue:

New Logo For The SCSU Research Protection Program

Hello everyone. The staff of the Research Protection Program hopes that your spring term is progressing as planned.

A new logo has been adopted to identify the SCSU Research Protection Program. The logo shows a stylized, sweeping, dual bow, in green, over text displaying the words Research Protection and Southern Connecticut State University. The stylized dual bow was chosen to represent the overarching protection provided by the program to research activities at SCSU. The color green was chosen as a compliment to the old HRPP logo.

The new Research Protection Program logo.

The new logo appears on the last page of the "Update: *Research Protection*" Newsletter, and in the near future will be posted in the lower right hand corner of many RPP paper communications.

IRB Application Submission Requirements and Dates (Reprint)

Our records show that there continues to be some confusion regarding IRB submission requirements and dates. In an attempt to rectify this concern we are reprinting our message from last issue with some additional information.

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 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 human research participant recruitment.**

When to submit:

An application should be submitted for initial

IRB Application Submission Requirements and Dates (Cont.)

review **at the time you complete it.** At initial review it may be determined that your project can be exempted or expedited. If this is the case, you will receive a response from the IRB **within two weeks of submission**.

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 including the NIH tutorial completion certificate must be submitted. The cover page must be signed by all requested signatories. Electronic submission is not permitted.

IRB Requirements: External Agencies and Investigators

Research at External Agencies:

Faculty and students often conduct human subject research at locations away from the Southern campus. Investigators who do so should be aware of the following policies:

1. Investigators must document the permission of the agency to conduct the research at the off-campus location. This documentation must be on agency letter head, and be from an administrative official who will not be directly involved with the research. A letter from a student's field supervisor is not sufficient. In the case of schools, a letter from the building principal is acceptable. However, some school districts have policies that require the district superintendent or Board of Education to approve research. It is the investigator's responsibility to be aware of the policies of any outside agency with which they wish to work.

2. The recruitment of participants at an outside agency is also something that should be approved by the external agency. This also includes recruiting through online discussion lists or email lists. Some online communities have policies against using the resources for solicitation to minimize spam, and the recruitment of research participants, while done with good intentions, may not be welcome. In these cases, investigators should document to the IRB that recruitment using these electronic resources is acceptable to the users. This may be done by submitting correspondence with the moderator or a copy of the online community's policy regarding solicitation.

3. Some external agencies have their own IRB process. These agencies are likely to be hospitals, social service agencies, universities, or state agencies. Investigators are responsible for determining if additional IRB review is needed, and fulfilling the requirements of the external agencies' IRB policy. The SCSU IRB will not approve research that is subject to external IRB review without an indication of the external agencies' approval. It is recommended that the research first be presented to the external agency for review, and then to the SCSU IRB for review. This is for two reasons. The first is related to which IRB is best positioned to protect human subjects. The IRB system set up by the federal regulations operates with the philosophy of local control. That is, it is believed that a local agency is best positioned to under-

"The SCSU IRB will not approve research that is subject to external IRB review without an indication of the external agencies' approval"

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IRB Requirements: External Agencies and Investigators (Cont.)

stand issues relevant to the risks and benefits of the type of research that is conducted at the agency. The second is practical. The research could not be conducted without the external IRB's approval, even with the approval of the SCSU IRB, so the external IRB approval is critical.

Research by External Investigators:

Similarly, researchers from other universities often seek to recruit participants or conduct research at SCSU. We require such investigators to seek permission from this IRB before operating on our campus. If the recruitment is passive, such as by advertisement, external researchers must present information about their research with copies of the ads to the SCSU IRB. If the research is more active, such as recruiting in person or by using SCSU email, a closer examination of the research is made, and a full IRB application must be submitted. In both cases, evidence of the home university's IRB disposition is required. The full policy can be found on the SCSU Research web page at:

http://www.southernct.edu/grad/externalinvestigatorresponsibilities/

ORI: Web Resource Addresses "Whistleblowing" Issues

Below are excerpts reprinted from an Office of Research Integrity Newsletter regarding "Whistleblowing" issues. The article is authored by Sara Vollmer, University of Alabama at Birmingham. Although the piece is directed primarily to researchers and their students, the video link that the author and her colleagues developed might be used by instructors in research methods and ethics courses at SCSU.

"Deciding on what constitutes research misconduct and how to report it are probably among the most difficult decisions a researcher may have to make. With the increase in the incidence of research misconduct that is observed but appears to go unreported, it is clear that the dilemma of what to do will be faced by most researchers at some time during their careers."

"...we invited a team of administrators, scientists, philosophers, film makers, and an entertainer to work together to develop a video, "Whistle Blower." ...This new product is a video-driven illustration with lessons showing students how to anticipate the issues that would arise in a case of possible misconduct and to think ahead about what to do."

"We developed this video from an actual misconduct case that occurred at a major university last year. The fictional adaptation was first written by a focus group of faculty members; scriptwriters and an entertainer rewrote the case many times based on feedback from the scientists and administrators. The format of the video includes probing questions along with our responses. The answers were developed in cooperation with Nancy Matchett, Institute of Professional Ethics at the University of Northern Colorado."

"The authors of the site are Jeffrey Engler, Sara Vollmer, Harold Kincaid, Douglas Cromey, and Dean Bryan Noe from the University of Alabama, Birmingham; we thank the Council of Graduate Schools for funding."*

The site may be found at:

http://www.uab.edu/graduate/rcr/ndex.html

Tip: Type in answers as well as selecting answers with a mouse click.

*Vollmer, Sara, "New Web Resource Addresses Whistleblowing Issues." Office of Research Integrity Newsletter, Volume 17, No. 2, March 2009.

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Office of Research Integrity
NEWSLETTER

Research Protection
Southern Connecticut State University

Research Protection Program

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Institutional Animal Care and Use Committee (IACUC)

Nicolas Edgington. Ph.D., IACUC Chairperson

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 2001-2009.
- *Action Research,* Eileen Ferrance, LAB, Brown University 2000.

IACUC News: Designated Member Review—OLAW Clarification

Use of "Designated Member Review" (DRM) in IACUC protocol reviews: A clarification issued by The Office of Laboratory Animal Welfare (OLAW, January 8, 2009).

"The research community has raised questions regarding the action an IACUC may take when the committee reviews a proposed animal study at a convened IACUC meeting and determines that the study protocol does not meet its standards for approval."

"When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

*If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR), or returned for FCR [Full Committee Review] at a convened meeting .

*If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:

1. All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
2. In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW.

*If all members are not present and the IACUC lacks written standard procedures as described above, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR.

*If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so."

For more information please see:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html

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