Update: Research Protection

A Publication of The Southern Connecticut State University Research Protection Program

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Special points of interest:

- New RPP web pages.
- New IRB Application Packet.
- IRB Application reminders.
- RPP Policy Statement.
- ORI definition of research.
- IACUC to use new USDA pain scale in new protocol forms.

Inside this issue:

Changes—New Research Protection Program Web Pages

Hello everyone. The RPP staff hopes that you have had a productive spring semester and that preparations for the end of term are progressing well. Again, there have been some significant changes in the research protection area within the past few months. The most significant change involves the addition of RPP web pages to the School of Graduate Studies (SGS) website. These pages should provide research investigators, instructors of research methods courses and their students, and persons interested in assuring the responsible conduct of research, a locus for obtaining critical RPP information and accessing useful links.

To access the RPP pages, from the SCSU home page click on "ACADEMICS" on the horizontal menu. From the "ACADEMICS" page, click on "School of Graduate Studies" (lower right under "GRADUATE"). Once at the SGS site, click on "RESEARCH" on the right of the horizontal menu. This will take you to the SGS research page. On the research page, the upper part of the left-hand menu presents the RPP selections.

The left-hand menu offers pages for the RPP itself, the divisions of the RPP, an external investigator policy link, a link to the currently required IRB tutorial, and the new *"Update: Research Protection"* and the old *"IRB Newsletter"* directory. The RPP web pages will be monitored on a weekly basis and revisions will be made as needed.

Future additions to the pages will include access to the policies and procedures of the SCSU Office of Research Integrity including Research Integrity Officer responsibilities, the policies and procedures of the Institutional Review Board, and The Institutional Animal Care and Use Committee.

The Institutional Review Board page must be accessed in order to navigate to crucial IRB protocol application information. IRB operating principles, tutorial links, and links to the new "IRB Application Packet For Human Research Review" may be found on this page.

The New IRB Application Packet for Human Research Review

From the IRB page, you may elect to go to the "IRB Instructions and Forms Selection Page." At the top of the page you will be informed of the following: "On June 1st, 2008, the current 'Application for Protocol Review' will expire. After this date, the new 'IRB Application Packet for Human Research Review' must be used. You may begin to use the new instructions and forms now if you wish." The new packet is presented in two sections. Section one, "Application Instructions," should be downloaded, printed, and used for reference as you fill out the "Application Forms." Section two, "Application Forms," presents the new forms in both a PDF or MS Word format. Selecting

The New IRB Application Packet for Human Research Review (Cont.)

the MS Word format allows the user to enter information directly into the forms.

Application Instructions: These pages present the Table of Contents for the entire application packet, a tutorial completion reminder, form-by-form directions for completing the application, and, if necessary for your research, detailed instructions for developing "Participant Notice of Research Involvement" documents. IRB reviewers will expect that you have used the Application Instructions to complete your application and will evaluate research proposals accordingly.

Application Forms: Bolded items in the Table of Contents indicate forms which must be included in your application. Each form is numbered in red in the upper right corner. The appearance of the forms has changed. Query and response segments are placed in a grid format. Queries are placed against a grey background (further instructions are in red), while responses may be typed into a white background. Starting points for responses are indicated by grey blocks.

When completed, forms must be printed for hardcopy submission to the School of Graduate Studies, EN B, Rm. 110. Electronic submission is not permitted because original signatures are required on the forms. Questions? Contact the RPP office EN A, Rm. 110, 203 392-5958/25243.

Assuring IRB Applications are in Good Order Prior to Submission

The IRB recognizes that investigators put considerable time and effort into their research, and are eager to begin participant recruitment soon after application submission. Applications received in "good order" are often processed within two weeks. "Good order" means that the application is complete with all supporting documents and signatures, and the application questions are addressed thoroughly and clearly. Below are listed suggestions to put your application in "good order" and speed review:

1. Please remember that the IRB reviewers are probably not experts in your research area. More detail and explanation on what is intended is preferable to less information;

2. Please do not leave any questions blank. If you believe that the particular question does not apply to your project, please indicate Not Applicable (NA) and, if necessary, why it is NA;

3. Please clearly describe how the data will be collected. To do this, the level of detail should be such that a reader would be able to duplicate your **procedures exactly**. Often, this section presents great detail about the materials, but not the process;

4. If you have indicated that an IRB other than the SCSU IRB has reviewed, or will review, your project, please be sure to give complete details. Include a copy of the IRB approval if available;

5. Please be sure each required signature appears in the proposal cover page on its appropriate line. This is an important step, as the IRB relies on the expertise of the faculty sponsor or department chair to indicate that the project is scientifically valid and consistent with the discipline's research and ethical standards;

6. Please be sure to complete the on-line tutorial and include a copy of the completion certificate;

7. If there will be recruitment advertisement of any sort, the IRB must approve the copy. This includes scripted statements made by regular mail, email, telephone, or by any print or electronic media;

8. Please be sure to include written indicators from external research sites on site letterhead, showing site administrator awareness of your study and granting permission to conduct your study at the site.

"Applications received in 'good order' are often processed within two weeks. 'Good order' means that the application is complete with all supporting documents and signatures…"

Dr. W. Jerome Hauselt, IRB Chair

Psychology

203 392-5243/6874

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SCSU Research Protection Program General Policy Statement

The SCSU Research Protection Program (RPP) divisions include: The Office of Research Integrity; The Institutional Review Board; The Animal Care and Use Committee; and The Educational Resources Division. Collectively, the program, through its four divisions, encourages those engaged in research and in research education to adopt established moral, ethical, and legal principles of responsible research conduct, and to apply those principles in research activities and in research teaching according to accepted institutional policies and procedures in the following ways:

1. Promote and monitor responsible conduct in all human and non-human research, and to act on substantive allegations of research misconduct;

2 Safeguard the rights and welfare of human research participants in accordance with ethical principles delineated in The Belmont Report, and in federal, state, and institutional requirements;

3. Assure humane and sensitive care and use of vertebrate research animals through compliance with federal, state, and institutional requirements;

4. Disseminate information regarding research protection;

5. Provide and oversee training and educational requirements of investigators and research protection personnel.

Dr. Frank Sansone
Research Protection Program
Administrator
EN A 110 A-B
203 392-5958
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SCSU Office of Research Integrity Definition of Research

The SCSU Office of Research Integrity has established an operational definition of research it will use to decide if matters brought before it involve research misconduct or academic misconduct.

The Department of Health and Human Services, Office of Research Integrity Public Health Service Policies on Research Misconduct [42 CFR 93], defines research as a "... systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge [basic research] or specific knowledge [applied research] relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied."

The federal regulations at 42 CFR 93.319 suggest that institutions may develop "... internal standards of conduct different from the HHS standards for research misconduct...." Considering this allowance, it has been established that the SCSU ORI purview extends to all activities undertaken by faculty, staff and students that meet the federal definition of research and the following three SCSU ORI elaborations:

1. The SCSU ORI expands the HHS federal definition of research to include all SCSU research activities, not just those related to public health;

2. The SCSU ORI does not limit the recognition of research to "...biological causes, functions or effects, diseases, [or] treatments...," but rather encompasses all research activities undertaken on the SCSU campus;

3. The SCSU ORI excludes from consideration activities which collate or synthesize existing information, reports, reviews, opinion pieces, news articles, and any literary presentation not designed to create new information or insight through systematic investigation. This listing does not include all possible exclusions but rather suggests the form exclusions may take.

The SCSU ORI recognizes that disciplines may hold differing definitions of research. The ORI will therefore use the federal definition and the above listed variances as guidelines during the "Initial Assessment" phase of a research misconduct inquiry. The Initial Assessment will determine if the project, against which an allegation of misconduct has been made, meets the federal and SCSU ORI research definitions. If the SCSU ORI determines that the project does not fall within the federal and SCSU ORI definitions of research, the complainant will be referred to SCSU Academic Affairs.

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The SCSU Research Protection Program Personnel

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" - upper right on horizontal menu

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

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

New Pain Scale to be Used in Revised IACUC Protocols for Fall '08

Beginning with the Fall '08 term, accompanying the introduction of revised protocol forms, the SCSU IACUC will be using the new USDA scale for determination of pain levels and stress in research animals as follows (note: there is no USDA Level A):

"**Level B:** Breeding or Holding Colony Protocols;

Level C: No more than momentary or slight pain or distress. For example: euthanatized for tissues, just observed under normal conditions, positive reward projects;

Level D: Pain or distress relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress. For example: survival surgery, non survival surgery, induced infections or antibody production with appropriate anesthesia and post-op/post procedure analgesia when necessary;

Level E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress." *

Definitions associated with the pain scale:

"**Euthanasia**: **...** is derived from the Greek terms eu meaning 'good' and thanatos meaning 'death.' A "good death" would be one that occurs without pain and distress. Euthanasia ... should result in rapid unconsciousness followed by cardiac or respiratory arrest and ultimate loss of brain function....

Humane: is defined as 'Characterized by kindness, mercy, or compassion, marked by an emphasis on humanistic values and concerns. The central meaning... is... motivated by concern with the alleviation of suffering.'

Non-Survival Surgery: ... surgical procedure[s] where there is the potential for more than momentary or slight pain prior to death, including those due to procedures requiring extended time periods. Protocols which include surgery not directly associated with euthanasia, prior to euthanasia, should be categorized as non-survival surgery."*

*http://compliance.vpr.okstate.edu/acuc/USDA%20Pain%20Levels.doc (referenced April 2008)

Please see Dr. Edgington for further information on definitions and USDA guidelines regarding tissue collection.

Dr. Nicolas Edgington,
IACUC Chair
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203 392-6219