

# THE **IRB** NEWSLETTER

A Publication of the Southern Connecticut State University Human Research Protection Program

## The SCSU Institutional Review Board Vol. 1, No. 2, Spring 2003

### Welcome

Welcome back to the Spring 2003 semester.

In an effort to maintain continued positive response to IRB requirements for human participant research during the Spring 2003 term, the following procedural issues are brought to your attention:

### Institutional Review Board Authority

The IRB does not have the authority to grant research privileges to investigators. The privilege to do research under the auspices of SCSU comes from the institution itself (administrators, deans, chairpersons). The privilege to do research is always subject to revocation by the administration, IRB approval not withstanding.

The IRB's authority extends only to the approval, disapproval or exemption of human participant research with respect to the level and probability of the participant harm it presents.

### Constructing the Informed Consent Document (ICD)

The heading of the first page of the ICD should contain the title of the research project. All of the elements of the scripted ICD presented in Appendix B of the IRB proposal application should be included if appropriate.

The document must be written in the second person (e.g. "you" should be used instead of "the subjects" or "they").

Principal investigators must carefully proofread their ICD document. Spelling, punctuation and syntax must be correct.

### When to Submit an IRB Proposal

Because many of the proposals the IRB receives are exempt from review or may receive an expedited review, proposals can be submitted to the IRB at any time.

The graduate office must login your proposal. Once

Submitted proposals will be subject to an initial review as they are received in the IRB office. Those proposals determined to be eligible for exemption or expedited review will be processed when received. Full reviews will be referred to the full board.

If your IRB proposal is to be reviewed by the full board it must be in the School of Graduate Studies office on or before the first Monday of the month in order to be reviewed in that month. The full IRB meets on the third Friday of each month.

It would, therefore, be to your advantage to submit your proposals when they are ready rather than waiting for the first Monday of the month.

### Where to Submit Your Proposal

Please send proposals to:

The School of Graduate Studies Office, EN 118,  
501 Crescent Street  
New Haven, CT 06515

logged-in, proposals will be delivered to the IRB office. Proposals sent directly to the

IRB office will be sent to the Graduate Office for log-in prior to review, thus delaying IRB response time.

## Signatures

A student must have the following signatures on the first page of the proposal:

1. Principal investigator
2. Co-investigators
3. Faculty sponsor
4. Chairperson

Faculty must have these signatures as well, with the exception of the sponsor. If the principal investigator is the chair, the school dean must sign the proposal.

Proposals that do not contain the appropriate signatures will be returned.

## Copies

Two copies of the entire IRB proposal and twelve additional copies of the research abstract are required. One of the proposal copies will be used for initial review purposes.

Please do not send disks or CDs containing the proposal.

### Information Regarding Outside Agencies

The IRB proposal application forms request four separate pieces of information regarding outside agencies:

1. Has this project been submitted to other IRBs?

If yes, please submit copies of all IRB approvals/disapprovals, [exemptions], and copies of all approved consent forms if applicable;

2. Location of data collection;
3. Where will participant recruitment take place?
4. If your research is being conducted at an agency external to SCSU, and this agency does not have an IRB, please submit a letter from the administration of the agency attesting to their agreement for you to conduct your research.

Principal investigators must respond to each of these queries as appropriate.

If you will ask persons from agencies other than SCSU to serve as participants in your research, you must have a written and signed indicator (IRB disposition or a CEO letter) that the agencies are aware of and support your project. The IRB will not complete reviews of proposals that do not provide this information.

## Response to Modification Memos

When responding to modification memos, please answer each numbered query in the memo with a corresponding numbered response. Please do not embed your responses in the pages of your proposal or develop a new proposal unless specifically asked to do so.

When requested to revise your consent form please return the form prepared exactly as it will be presented to your participants. The IRB will date stamp this form and send it back to you for use.

Many programs ask students to complete human participant research in partial fulfillment of course requirements. If this research is below the level of Special Project, and will not be considered for publication, an IRB certified instructor may serve as an AIRB of one and thus preempt IRB review for all of these research activities.

This process can reduce concerns about turn around time for IRB proposal review when class deadlines must be met.

Instructors interested in obtaining certification may interact with and print online forms as follows:

1. Go to: <http://www.southernct.edu/departments/graduatestudies/irbhrppforms.php>
2. Find "Application for Course Instructor Certification";
3. Read "Introduction";
4. Download (or interact with) and print "Course Instructor Certification Form". Completion of an on-line tutorial is required;
5. Download and print "Approved Course Research Form";
6. Send completed course instructor form to the IRB;
7. Have students complete course research forms and send them to the IRB.

## Information

For information regarding any aspect of the IRB process, presentations or education please contact:

Dr. Frank E. Sansone, IRB Chair

Voice: 203 392-5958  
Email: [sansonef1@southernct.edu](mailto:sansonef1@southernct.edu)  
FAX: 203 392-5968  
CMD: Davis Hall, 012B

## Classroom Instructor Certification