THE IRB NEWSLETTER

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

The SCSU Institutional Review Board Vol. 1, No. 1, Fall 2002

Welcome

Welcome to the Fall 2002 semester. The SCSU HRPP will publish "**The IRB Newsletter** *"* at the start of each regular semester and more frequently as needed.

The past year of IRB proposal reviews and questions from principal investigators have raised several issues concerning the IRB process. These issues will be addressed in this initial newsletter.

The IRB Forms

The IRB has developed forms for submitting research proposals. There is information in the forms that explains the SCSU IRB process, investigators' responsibilities, informed consent, and IRB on-campus resources.

The IRB forms may be downloaded from the School of Graduate Studies web site, http://www.southernct.edu/departments/graduatestudies/irbhrppform.php. An interactive floppy disk containing the forms in MSWord, may be obtained from the School of Graduate Studies office. Proposals will be accepted for review, only if these forms are used. The IRB requires that all of the information in the forms be completed. The IRB uses this information to determine review level and if approval criteria have been met.

Please be sure to take advantage of the checklist at the end of the forms to assure that forms have been appropriately completed.

Completed forms should be sent to the Graduate School office, EN 118, so that they may be logged in.

Exempt/Expedited Review

All research that involves human subjects must be submitted to the IRB for review. Investigators may believe that their research is exempt from IRB review, or may be expedited (full board review not required), but an evaluation by the IRB is needed to confirm the appropriate review level.

What is Research?

The SCSU IRB is bound by the definition of research offered by the federal government as follows: "A systematic investigation designed to develop or contribute to generalizable knowledge". *(45 CFR 46.102 (d))*

Who is a Human Subject?

The IRB is again bound by the federal government definition of human subjects as follows: " A living individual about whom an investigator . . . conducting research obtains; (1) data through intervention or interaction with the individual, or (2) identifiable private information." *(45 CFR 46.102 (f))*

Who Must Submit an IRB Proposal?

If your project falls within the research and human subject definitions above, you are expected to submit an IRB proposal.

All human participant research planned by faculty, staff, or students at the special project level or above must be submitted to IRB review. Independent studies involving human participants that are used as a program's capstone experience must be submitted to IRB review.
Classroom research involving human participants that will not be published may be able to be reviewed by the course instructor providing the instructor has completed IRB

course instructor certification and follows the IRB course instructor's guidelines.

Information and forms regarding course instructor certification may be found on the Graduate School web site.

Informed Consent and Assent

Instructions, an outline, and scrips for completing an appropriate informed consent document may be found within the IRB forms. It is strongly suggested that you use the outline, and when appropriate, the scrips, to develop your informed consent.

A series of informed consent examples that cover acceptable variations in informed consent may be found on reserve in Buley library under The Human Research Protection Program (along with other IRB items).

Your written consent document must be able to be understood by your research participants. It must be written in their language of understanding and at a level consistent with their reading ability.

If your participant is a child and the child is old enough to understand the project, you must, in addition to obtaining consent from the parent or care giver, obtain assent by signature, from the child. If constructed properly with respect to language, the consent document may also serve as an assent document. The child signs under the parents' signature.

Continuing Review

The IRB may approve research for a maximum of 365 days. Your approval letter will indicate an expiration date. If your project is to continue beyond the expiration date assigned, you must apply for a continuation prior to the expiration date using the "Continuing Review Form". If you have not received continuing approval, you must stop obtaining data from your human participants on the expiration date.

Request for Revision

If you wish to revise your research and this revision will in any way change your IRB proposal as originally submitted, you must submit a "Request for Revision Form". The revision must be approved prior to initiating the changes.

Research Completed

When you have completed collecting data from your research participants, you must inform the IRB by submitting a "Research Completed Form". When received, the IRB will close your file.

Modification Memo

If the IRB requires further information to make approval decisions regarding your proposal, you will receive a "Modification Memorandum". The memo will present what the IRB requires in order to continue the review process. Once returned, the IRB will reevaluate your proposal in light of your responses. This re-review may result in a disposition decision or follow-up memoranda.

Investigator Responsibilities

These responsibilities have been excerpted from "OHRP-Investigator 101":

1) Design and implement ethical research consistent with the Belmont Report (reviewed in SCSU mandatory investigator IRB education);
2) Comply with all human subject federal regulations;
3) Submit all human research to the IRB for approval.
4) Comply with all local IRB policies and procedures;
5) Implement research as approved, obtain prior approval for changes and continuance;
6) Obtain informed consent in accordance with federal and local IRB regulations;
7) Report all adverse events;
8) Retain all data and research documents for three years.

Information

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

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