THE IRB NEWSLETTER

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

The SCSU Institutional Review Board Volume 1, Number 3, Spring 2003

Greetings

We hope that your spring semester is progressing nicely and that preparations for term's end are well underway.

As students and faculty formulate research proposals to meet grant and course deadlines, the IRB wishes to up-date investigators regarding a few issues which we hope will make the IRB application mandates more comprehensible and less effortful.

Federal Definition of Research

Fundamental to the IRB process is the ability to distinguish human research from non-research activity. The IRB must follow the federal definition of research.

Federal regulations define research as:

> " . . . a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to ***generalizable*** knowledge."
> *(CFR Title 45, Part 46)*

Generalizable knowledge is in evidence when a fundamental goal of the research activity is to learn something that may benefit people other than the research participants, and can, therefore, be applied to populations outside the population studied.

Federal Definition of a Human Research Participant

The federal regulations offer the following definition of a human participant as a guide to determine if research actually involves humans as participants:

> "A living individual about whom an investigator . . . conducting research obtains data (1) through intervention or interaction with the individual, or (2) [through] identifiable private information."
> *(CFR Title 45, Part 46)*

When collecting information from the records of living or deceased persons you must consider the possibility of risk to "Secondary" or "Third party" participants. These are individuals who are not principal participants but about whom private, identifiable information is collected either deliberately or inadvertently. For example: information about family (substance abuse, cancer, disabilities, etc.); Information about a partner's sexual history; and, information about financial or economic status.

The Investigator as Moral Fiduciary

The investigator must hold in trust participant's rights, welfare and safety above all other personal and scientific concerns. Self interest must be blunted by the obligation to protect the participant. Scientific knowledge, remuneration and prestige must be side effects of being a participant's moral fiduciary.

Social Science and Behavioral Research

Risks to participants are often not as apparent in Social Science and Behavioral Research.

Risks of research may not only be physical. Risks could also be: psychological; social; dignitary; or economic.

Investigators are responsible for indicating the degree of risk human participants face by engaging in the research study. Risks must be balanced by the benefits of conducting the research.

Federal Definition of Research Risk and Minimal Risk

Research risk is defined as ". . . the probability of harm occurring as a result of participation in research." *(CFR Title 45, Part 46)*

Minimal research risk is defined as ". . . the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." *(CFR Title 45, Part 46)*

It is the IRB's and investigator's responsibility to minimize risk.

It is the IRB's responsibility to assess risk in assigning protocol review level and approval.

Exempt Research

Exempt does not mean there is no IRB review at all. The principal Investigator may not make an exemption determination (conflict of interest). The IRB must conduct a review to determine if a study satisfies one of the exempt categories.

The Belmont Principles and Derived IRB Policies

The SCSU IRB operates under Title 45 part 46 of the Federal Register known as ***The Federal Policy for the Protection of Human Subjects***. These regulations are based on the three underlying principles of the Belmont Report: respect for persons; beneficence; and justice.

Below are listed the Belmont principles and a few IRB policies derived from those principles:

Respect for Persons:

Principles:
- Treat individuals as autonomous agents;
- Do not use people as a means to an end;
- Allow people to choose for themselves;
- Give extra protections to those with limited autonomy.

Derived Policies:
- Initial and continuing informed consent;
- Allow withdrawal from research;
- Maintain the welfare of the participant;
- Respect for privacy.

Beneficence:

Principles:
- Acts of kindness or charity that go beyond duty;
- Obligations derived from beneficence:
    - do no harm;
    - prevent harm;
    - prevent evil;
    - promote good.

Derived Policies:
- Good research design;
- Competent investigators;
- Favorable risk/benefit analysis;
- Scientific validity;
- Social and/or scientific value.

Justice:

Principles:
- Treat people fairly;
- Fair sharing of the benefits and burdens of research;
- Distinguish procedural justice *(justice of the courts which may not be fair to all)* from distributive justice *(justice that can be distributed equally to all)*.

Derived Policies:
- Equitable selection of subjects.
- Inclusion and exclusion criteria.
- Recruitment requirements.

Procedural Matters

The following is a list of a few procedural issues which may speed the IRB process:

- Students should include exemption letters when submitting thesis proposals;
- Please do not staple IRB proposal documents;
- All correspondence and email must be accompanied by the proposal IRB number;
- In the proposal, indicate whether or not the investigator or assistants will be completing the intervention or just measuring an intervention outcome;
- If measuring the outcome of an intervention at an agency, the IRB must know if the intervention is part of the regular activities of the agency;
- There must be some evidence in the IRB proposal that the intended study has scientific merit.

Information

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

Dr. Frank Sansone, IRB Chair

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