Date: March 8, 2001

To: Al Lewis, Committee on Instruction, Chair

From: Brenda Nordenstam, Chair, AdHoc COI Committee on Use of Human Subjects

Re: Human Subjects Review Policy

Listed below are key points relevant to ESF researchers and instructors who survey or otherwise utilize human participants for teaching, research, or instructional purposes. Also attached is a two-page summary of the SU IRB policy on human subject review. More information may be found at the SU IRB website located at:

http://www.syracuse.edu/osp/human.html

1. The Institutional Review Board for research involving human subjects:
For purposes of fulfilling federal requirements, ESF jointly participates with SU's Institutional Review Board (IRB) – designated to review all research that employs human subjects through their Office of Sponsored Research. Larry Abrahamson is the representative for ESF.

2. Applicability to both funded and unfunded research:
Because ESF receives public funds, IRB reviews are mandated by the Office for Human Research Protections (OHRP) of the National Institutes of Health. *This applies to all researchers, not just those receiving federal funding.* If any researcher at ESF violates the tenets of this agreement, the OHRP can suspend all research and withdraw all federal funding from the university. Research may be qualitative or quantitative in nature, and may involve one human subject or many.

3. Types of review:
Expedited Review (available when there is minimal risk), and *Full Board Review*. Most research conducted by social scientists at ESF will meet the requirements for expedited review (see attached summary). Research conducted by graduate students for their thesis or dissertation must also be approved through this process, with notification of approval sent to their major advisor by mail.

4. Classroom research projects:
Some research is exempt from IRB review (see attached summary below). This includes *research conducted by students as a class requirement.* However, the Board does require that the instructor for the course submit a list of the titles of the projects being conducted in that class. If you believe your study is exempt, you MUST submit a short memo to the IRB Chair describing the nature of the research and why you believe it is exempt. Even participation projects carried out at zoos, elementary classes, or on field trips may require an exemption, especially if children are involved.

5. Application forms:
The SU IRB web site provides downloadable application forms with instructions and deadlines for submittal.

6. Faculty should be aware that NIH now requires all investigators submitting NIH proposals involving humans to receive training on the protection of human participants. It is possible that this NIH requirement may eventually be expanded to cover all proposals involving human

subjects. This requirement can currently be satisfied by completing the NIH computer based training located on the NIH web site.

Summary of Syracuse University Policy on Human Subjects

What is the IRB?

Syracuse University has an Institutional Review Board (IRB) designated to review research which employs human subjects. The purpose of the review is to ensure the safety and well-being of subjects and to ensure that subjects are fully informed of the risks and benefits of participating in research. Thus, the board tries to review research from the perspective of the subject.

Why is such review required?

Because Syracuse University receives public funds, this review is mandated by the Office for Human Research Protections (OHRP) of the National Institutes of Health. SU has signed an assurance stating that all research studies involving human subjects performed by the students and faculty of Syracuse University will be reviewed and approved by the IRB before research can begin. This applies to all researchers, not just those receiving federal funding. If any researcher at SU violates the tenets of this agreement, the OHRP can suspend all research and withdraw all federal funding from the university.

What constitutes research?

Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. Research may be qualitative or quantitative in nature, and may involve one human subject or many.

What kind of research is exempt from IRB review?

Some research may be exempt from IRB review. Exemption is determined by the IRB chair, not the investigator. If you believe your study is exempt, you MUST submit a short memo to the Chair describing the nature of the research and why you believe it is exempt. Examples of research that are exempt include:

* Analyses of previously collected data that has no identifiers (e.g. name, SS#, phone number.)
* Observations of everyday behavior in public places in which the researcher does not talk directly with those being observed.
* When students are conducting research as a class requirement when they have no intention of contributing to generalizable knowledge. This is likely to be the case, for example, when students are enrolled in research methods classes and are doing projects that are designed to teach them specific research tools or methods. The Board does require, however, that the faculty member for the course submit a list of the titles of the projects being conducted in that class to the IRB office before the research projects are initiated.

Types of review
There are two types of review: Expedited Review and Full Board Review.

1. Expedited Review is available only where there are minimal risks to subjects and where the research does not involve legally restricted (e.g. inmates) or mentally incompetent subjects or other groups who may not be able to freely consent to research. "Minimal risk means that 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." (IRB Guidebook, 1993.) The decision concerning minimal risk is made by the Chair of the IRB or an IRB committee member designated by the Chair. If researchers are in doubt about the eligibility of their project for an expedited review, they should call the IRB office.

   Application procedure for Expedited Review:
   Submit one copy of your IRB application and attachments to the IRB in the Office of Sponsored Programs. Expedited reviews are generally acted upon within one - two weeks of submission. Your advisor will be notified of the outcome of your review by letter.

   Until recently, expedited review was not available for studies involving children. However, recent changes in federal regulations permit expedited review for studies involving children where there is minimal risk involved.

2. Full Board Review is required for research that involves children, the elderly, legally restricted or mentally incompetent subjects or when risk is deemed more than minimal. Such research is read and discussed at a monthly meeting, and the members of the board provide feedback to the investigator regarding how the proposed research protects human subjects.

   Application procedure for Full Board Review:
   Full board review takes place at the monthly meetings listed below. In order for a proposal to be included on the agenda for that month, the original application plus 13 copies and attachments must be received at the IRB office before noon of the dates in parenthesis below. No protocols will be accepted after the deadline for each meeting. Your advisor will be notified of the outcome of your review by letter. The board does not meet during the month of July.

Please Note: All correspondence will be addressed to the investigator and advisor and mailed to the advisor's address.