



the IRB newsletter

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

The SCSU Institutional Review Board – Volume 4, Number 1, Fall 2005

Meet the SCSU IRB

Below are listed the current members and alternates of the SCSU IRB. They unselfishly volunteer their time to assure fair treatment of human research participants at SCSU.

Members

Vincent Avallone, Esq.–Attorney
Robert Axtell, Ph.D.–Exercise Science
David Denino, LPC, NPC–Counseling
Shirley Girouard, Ph.D.–Nursing
Marianne Kennedy, Ph.D.–CMD
James Mazur, Ph.D.–Psychology
Michael Perlin, Ph.D.–Public Health
Jaak Rakfeldt, Ph.D.–Social Work
Frank Sansone, Ph.D.–CMD

Alternates

Cynthia McDaniels, Ph.D.–EDF
Mary Purdy, Ph.D.–CMD
Karl Rinehardt, Ph.D.–Exercise Science

Prior Newsletters

The IRB encourages you to view prior IRB Newsletters. Information in these missives may assist you in reducing application construction and submission hassles. Newsletters may be found online at the School of Graduate Studies web site under **Research**> *IRB Newsletter Directory*.

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During the past year concerns have come to the board's attention regarding the level of IRB purview over qualitative, non-clinical, humanistic, social science research. The concern is timely. This matter is being argued across the nation in academic and research institutions and will be a topic of discussion at the 2005 national IRB conference. The concern, simply stated is this: Can the federal regulations governing IRB activity, appropriately consider the risks to, and protection of, participants in qualitative social science research? Until this matter is definitively settled and new regulations developed, institutions must set their own review procedures which *meet existing federal policies*.

Current SCSU procedures for review of qualitative social science research:

1. Establish that there is an intent to do research.
 - a. Research, as defined by the federal regulations is, "... a systematic investigation . . . designed to develop or contribute to generalizable knowledge." There is no differentiation made between qualitative and quantitative research.
 - b. Generalizable knowledge is described operationally as follows: When a fundamental goal of the activity is to learn something that may benefit people other than the research participants; i.e., obtaining knowledge that can be applied to populations outside the population studied.
2. Perform a risk/benefit analysis.
 - a. What are the knowable risks to participants? Investigators must predict risk levels based on information obtained from literature in the discipline and prior research.
 - b. How is the risk to participants balanced by benefits the research may produce?
 - c. Benefits must outweigh or be in balance with participant risks.
3. Consider a discipline's research ethical codes for guidance.
 - a. The discipline's approach to research and research design will be considered.
 - b. The discipline's ethics regarding research participant protection will be considered.
4. Arrange a dialogue with the investigator.

The IRB, using the definition above, must decide if there is an intent to do research. All studies involving human participants, once defined as research, must be subject to IRB review. It is understood by the SCSU IRB that a rendering of the federal codes specific to individual cases may be required.

Other IRB issues:

Quality improvement projects and IRB review:

Quality improvement research was addressed in the most recent *IRB Advisor*, Vol. 5, No. 10, 2005, pages 109-111. The summary information below, draws liberally from this presentation.

Education

The IRB can provide Human Research Protection educational information in the form of CD's, video tapes, and PowerPoint presentations. These materials may be borrowed for classroom use by instructors or may be presented by the IRB.

Information

For information regarding educational materials or any other aspect of the IRB please contact:

Dr. Frank Sansone, IRB Chair
voice: (203) 392-5958
fax: (203) 392-5968

e-mail
SansoneF1@SouthernCT.edu

campus address:
CMD, Davis Hall, 012B, SCSU

The boundary between quality improvement (QI) projects, which are generally designed to improve operations within an institution, and research designed to provide information to populations outside of the institution, is frequently blurred. As the need to provide more specific information and in greater quantities to internal entities increases, the data provided by human response to surveys and questionnaires, initially developed and used for internal QI, may be of interest to other populations and thus may find placement in conference presentations and in journal papers. As a result, there may be research activity at an institution performed innocently under the guise of QI which should be reviewed by the IRB. If the data has been collected by an institution solely for dissemination to internal staff for the purpose of improving institutional quality, and there will be no attempt to use the data for generalization to populations external to the institution, the activity may properly be called QI, and may not need IRB purview. However, if there is a chance that the data may prove to be valuable to other populations, and, as a result the investigator may consider dissemination to external agencies, the IRB should review the work, because it then might be considered human participant research.

At SCSU, the IRB would rather have investigators over report than under report. Please be aware, the IRB is not permitted to review research retrospectively. The IRB will assist in determining if a project is considered human subject research or QI.

Exit surveys: Requiring participation:

Professionals in human research protections, through the Applied Research Ethics National Association, maintain a member's only e-mail list called, "The IRB Forum." The forum provides a medium for on-line discussion of current concerns and issues in the field of human research protections. In a recent interaction, the practice of requiring student participation in program exit surveys was questioned.

It appears that some institutions are requiring exiting students to participate in an information gathering survey as one of the conditions for graduation. In some instances this is being done in order to show 100% student compliance in responding to the survey for accrediting agency purposes.

The federal Office of Human Research Protections (OHRP) was queried regarding this matter and the following was presented:

1. There may be the possibility of coercion if students are required to participate. The statement "Your response is voluntary and failure to provide some or all of the requested information will not in any way adversely affect you." should appear in a cover letter or on the first page of the survey. Completion of the survey should not be a condition for graduation.
2. There may be a violation of the Family Educational Rights and Privacy Act (FERPA) if information from the institution's student records is used in any way to transmit survey data.

The SCSU IRB position: If the survey data will in any way be transmitted to an outside agency the IRB must review the project. The IRB will not approve a project if there is any possibility of coercion. In this instance, students cannot be required to offer their opinions regarding a program or the institution as a graduation condition. In contrast, students may be required to offer their opinions in classroom discussions and may be graded for their responses. This activity however, is generally considered a course expectation not coercion.

Sponsoring research by external investigators:

SCSU IRB policy: "Investigators from external institutions who wish to aggressively recruit . . . and/or conduct research on the SCSU campus must obtain an SCSU . . . sponsor . . ."

It is expected that persons, as discipline representatives, will only agree to be a sponsor after careful consideration of the research with respect to its merit and any discipline related ethical codes and human research participant protections associated. If the project does not fulfill sponsor requirements, *it should not be sponsored*. The IRB relies heavily on the expert consideration of SCSU sponsors when reviewing external research.