Title: ACTIVITIES SUBJECT TO IRB JURISDICTION

1.0 Purpose:

The purpose for this Standard Operating Procedure (SOP) is to provide guidance on the type of activities that are subject to review and approval by the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:

The SU IRB has jurisdiction over all human participants research subject to its Assurance. All human participants research conducted by faculty, staff, and students in conjunction with their official roles at SU is subject to IRB review. In addition, human participants research by students used to fulfill any requirements for their degree programs, including but not limited to thesis and dissertation research, must be approved by the IRB. Faculty and staff research must be approved by the IRB, whether or not the research is externally funded.

Specifically, the SU IRB makes determinations regarding: (1) exemptions from IRB review; (2) expedited IRB approval; (3) full IRB approval; (4) modifications or amendments to protocols approved by the IRB; (5) continuing reviews of approved protocols; and (6) actions regarding unanticipated problems, noncompliance and untoward incidents.

Although the Vice President for Research, deans, department chairs, and other university officials or bodies have the authority to disapprove research activities approved by the IRB or to set more stringent requirements on research protocols, research disapproved by the IRB cannot be conducted.

Approval from the IRB must be obtained prior to the formal recruitment of participants, obtaining informed consent, or initiation of research activities. The IRB is guided by a policy of proportionality. Within the discretionary decision-making permitted by the federal regulations, the IRB attempts to carefully weigh protections against risks. The greater the potential risks to participants, the greater the oversight that will be exercised by the IRB and the greater the protections that it will impose on investigators whether or not required by the federal regulations. All applications to the IRB must be in writing and on approved forms available on the ORIP website and submitted to the ORIP office. All IRB determinations are sent via email or campus mail (based on the investigator's preference marked on the application) with the IRB designee's signature to the investigator, or in the case of a Student/Researcher, to the Student's Faculty Sponsor. If the investigator doesn't have a campus address, the letter is emailed or mailed to the address listed on the application.

SU, ORIP and the IRB require that all policies and procedures for conducting initial review of research under its jurisdiction be written and maintained in congruence with Federal regulations, State and local laws, other SU policies and procedures, and standards of regulatory, accrediting, and funding agencies. The written procedures are to be used to guide personnel through various procedural steps and to standardize practices to ensure the protection of human participants in research and promote the responsible conduct of research.

The State University of New York Upstate Medical University (SUNY UMU) provides SU with review of protocols (including exemption requests, initial review, continuing review, and review modifications) being conducted by SU investigators and that are FDA-regulated (i.e., involve the use of drugs or medical devices or data being sent to or held for inspection by FDA).

3.0 References and Reference Documents:

45 CFR 46 102(d)
21 CFR 50 and 56
Memorandum of Understanding with State University of New York Upstate Medical University

4.0 Procedure:

4.1 **Research Versus Non-Research.** The IRB recognizes that researchers and non-researchers might use the same procedures and techniques in pursuit of their goals. For example, both may rely on written responses to questions, interviews, observations, videotaping, and document analysis. Research is characterized by an intent to share knowledge with others in professional, scholarly, or scientific publications or forums.

4.1.1 The normal practice of journalism, art, literature, and music do not fit the definition of research subject to IRB review. Practitioners in these fields engaged in normal professional practice are not expected to submit their planned work to the IRB.

4.1.2 Journalists and others who use the methods of social and behavioral science to contribute knowledge to members of their professions are expected to undergo IRB review.

4.1.3 If an individual is uncertain whether their activity is considered research involving human participants they should submit a summary of the research project to the ORIP office. The IRB designee will make a determination about whether the activity is either:

- "Research" as defined by DHHS regulations, that involves "human subjects" as defined by DHHS regulations; or
- "A clinical investigation" as defined by FDA regulations that involves "human subjects" as defined by FDA regulations.

The IRB designee will notify the individual in writing of his/her determination.

4.2 **Covered Research.** The IRB has no jurisdiction over research conducted by members of the University community independently of their official roles and responsibilities. Faculty, in particular, may undertake research projects on their own as private contractors. Such research will be deemed independent of their official roles and responsibilities and not subject to IRB review if: (1) the research is conducted on their own time and not reimbursed by the University or through University accounts; (2) the research is conducted without the use of University space, materials and supplies, and secretarial or staff support; and (3) any research publications, reports, or presentations will not list the faculty member's position and affiliation with SU.

4.2.1 IRB approval is not required for University members to act as consultants on research, if there are no living individuals about whom they obtain, receive, or possess identifiable private information or obtain information through interaction or intervention with those individuals.

4.4 **Research Conducted at Syracuse University by Investigators from Other Institutions.** SU officials and faculty sometimes are approached by investigators at other institutions for cooperation in their research. For example, department heads or deans might be asked to assist in the distribution of surveys to faculty or students. This research does not fall under the jurisdiction of the IRB unless: (1) university facilities, including physical space, and resources will be used; (2) data are being gathered from living individuals and university officials, faculty, staff, or students are involved with obtaining (a) data through intervention or interaction with those individuals or (b) identifiable private information about those individuals.

4.3.1 The Chair of the IRB serves in an advisory capacity to university officials and faculty with regard to research conducted by investigators from other institutions at SU that does not fall under IRB jurisdiction (e.g., the Chair can provide advice on such matters as the risks and benefits of the proposed research, informed consent, etc.).

4.4 Typical activities that may require SU IRB review and approval, prior to initiation of such activities are:

ACTIVITIES	DESCRIPTION	IRB REVIEW REQUIRED
Innovative Procedures, Treatment, or Instructional Methods	A systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.	**YES**
	The use of innovative interventions that are designed solely to enhance the well being of an individual patient or client and have a reasonable expectation of success. The intent of the medical or behavioral science practitioner is to provide diagnosis, preventive treatment, or therapy to the particular individual and no component of the activity is a systematic investigation designed to develop or contribute to generalizable knowledge	**NO**
Syracuse University functioning as the Coordinating Center for a Multi-center Research Project	SU is NOT an enrolling site and the SU PI has agreed to serve as the coordinating center for a multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	**YES**
	SU IS an enrolling site and the SU PI has agreed to serve as the coordinating center for the multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	**YES**

Research Practicums/Research Methods Classes	Activities designed for educational purposes only. The data will not contribute to generalizable knowledge or be published outside the classroom, will not result in an article, master's thesis, doctoral dissertation, poster session, abstraction or result in any other publication or presentation. Students may continue projects for a research methods course after the semester has ended if the research methods do not involve human participants.	**NO**
	Projects for research methods course after the semester has ended for a project involving human participants research.	**YES**
	Activities that will result in a thesis, publication, or article, but does NOT involve human participants.	**NO**
Student Research Projects	Student projects designed at least partially to provide data for research purposes. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate in research that will be submitted for publication.	**YES**
	Student is involved in research, results will not be submitted for publication. (Research is defined by generalizable knowledge, not by publication).	**YES**
	The student is involved with research that does NOT involve human participants; however, the results are submitted for publication.	**NO**
Case Studies	A single subject study with clear intent, before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of daily life. The intent is to report and publish the case study.	**YES**
	Retrospective review of a patient's medical records for use in an educational setting. The data will be de-identified.	**NO**

Ethnographic Research	The investigator or his/her staff will participate, overtly or covertly, in people's daily lives for an extended period of time. They will be watching what happens, listening to what is said, asking questions and collecting data to create a broader understanding of a particular environment, ethnic group, gender, etc.	**YES**
Autobiography or Auto-Ethnography	In sociology, anthropology, and related disciplines, postmodern ethnography, autobiography, or auto-ethnography is a narrative method in which the investigator and "participant" are one and the same. That is, the investigator reports on his or her own experiences and perspectives.	**NO**
Internet Research	Online websites are set up for the purposes of collecting data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.	**YES**
	Information gathered in internet/website data collection. The information is NOT about the individuals completing the survey.	**NO**
Third Party Information	The IRB considers on a case-by-case basis the circumstances under which third parties should be considered research participants. Third parties normally are not considered research participants from whom consent must be obtained unless information obtained about them pertains to their personal behavior unrelated to the interests and experiences of the originally designated research participants.	**MAYBE**
Quality Assurance and Quality Improvement Activities	Evaluations of a specific project, process, or resource utilization review, etc. where the primary intent (design) of the activity is solely for internal assessment or improvement. There are no plans for publication or presentation outside SU.	**NO**

	Evaluations that do not involve human participants.	**NO**
Pilot Activities	Activities including those involving only one individual may be subject to the same scrutiny as a full scale research project. Although the data derived from a pilot activity may not be included in the full scale research project, the activity would still need IRB review prior to conducting the activity.	**YES**
	Pilot activities that do not involve human participants.	**NO**
Expert Opinions	Faculty, staff, and students sometimes solicit the opinions of experts through phone or face-to-face interviews, surveys, and panel discussions. For IRB purposes, experts are not human participants when asked to provide information and opinions within their areas of expertise.	**NO**
	Surveys of experts when the surveyor is obtaining information about the expert.	**YES**
Evaluations	Evaluations are subject to IRB review if they fit the definition of research provided above (i.e., a faculty member or administrator evaluating a program or teaching strategy with a view towards reporting the results professionally).	**YES**
	Evaluations that do not involve human participants.	**NO**

Public Use Data Files	Research involving public data containing identifiable private information.	**YES**

4.5 The investigator may contact ORIP Staff or the IRB Chair for advice, or an authoritative decision, on the application of federal regulations and SU policy.

4.5.1 The IRB designee makes determinations about whether an activity is human research by determining whether the activity is either:

a. "Research" as defined by DHHS regulations that involves human subjects as defined by DHHS regulations or

b. "A clinical investigation" as defined by FDA regulations that involves "human subjects" as defined by FDA regulations.

4.5.2 In cases where it is not clear whether the study requires IRB review, ORIP or the IRB may ask the investigator to send a memorandum to the IRB by e-mail or hard copy detailing the proposed research. In complicated cases, ORIP or the IRB may ask the investigator to complete and submit an application to the IRB for a decision. ORIP communicates the decision of the IRB or ORIP to the investigator via phone, e-mail, or hard copy.

Approved by: _____ 6-14-2010

Gina Lee Glauser, Ph.D.
Institutional Official
Vice President for Research
Syracuse University

Date

_____ 11 June 2010

Kathleen King, Ph.D.
Chair of the Institutional Review Board
Syracuse University

Date

_____ 6-11-2010

Tracy Cromp, M.S.W.
Director of Office of Research and Integrity Protections
Syracuse University

Date