Title: INSTITUTIONAL COMMITMENT TO HUMAN RESEARCH PROTECTIONS PROGRAM

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline Syracuse University's institutional commitment to the Human Research Protections Program (HRPP).

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) to uphold and keep current its Assurance as filed with the Office for Human Research Protections (OHRP) in order to ensure its institutional commitment to the protection of human participants.

The IRB is committed to two key principles. The first is that research undertaken by faculty, students, and staff at SU must meet the highest standards of ethical conduct. The IRB recognizes that the conduct of ethical research and the protection of participants in research studies represent a shared responsibility among faculty and student investigators, department chairs, deans, university officials, and research support staff as well as the IRB. Accordingly, the IRB seeks to foster among members of the university community an atmosphere in which the design and implementation of research studies are based on internalized values regarding ethical conduct.

Although the IRB supports the research mission of SU and believes that research can benefit society, it also is aware that the pursuit of knowledge, the extrinsic and intrinsic rewards that accompany research productivity, and the influence of external funding have caused some investigators and some institutions to ignore or downplay risks to research participants. The IRB's primary responsibility is to protect the rights and welfare of those who participate in research.

The second principle is that the IRB should establish safeguards and implement policies and procedures to ensure, to the extent possible, that all research conducted at SU is in compliance with applicable federal regulations and policies, in accord with the University's Federal-wide Project Assurance of Compliance with the U.S. Department of Health and Human Services' Regulations for Protection of Human Research Subjects (FWA). The FWA is signed by the Vice President for Research who is the University's authorized institutional representative. The FWA acts as an assurance that SU will comply with all federal regulations and provide the necessary authority to the IRB to make determinations regarding protections of human participants in research.

It is important that all members of the SU community understand that unethical research conduct and a failure to follow established policies and procedures are not only wrong, but also threaten the ability of all investigators at SU to conduct research.

Lastly, the IRB is guided by proportionality. Within the discretionary decision-making permitted by the regulations, the IRB attempts to carefully weigh protections against risks. The greater the potential risks to participants, the greater the oversight exercised by the IRB and the greater the protections it will impose on investigators, whether or not these are required by the regulations.

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3.0 References and Reference Documents:

The Belmont Report
45 CFR 46, Subpart A
SOP 014, Amendments to Previously Approved Applications or Claims for Exemption
SOP 030, Reporting to the Appropriate Institutional Officials, and the Department or Agency Heads
OHRP Guidance Document: IRB Knowledge of Research Context, August 27, 1998
OHRP Guidance Document: Institutional Review Board's Reliance on Another Institution's IRB, July 9, 1991

4.0 Procedure:

4.1 FWA Responsibilities and Maintenance.

4.1.1 A full copy of SU's Assurance, with all amendments, will be maintained in ORIP. A copy will be available via the ORIP website. SU's Assurance is based on the following principles:

4.1.1.1 Safeguarding the rights and welfare of human participants in research and other research activities is a general Institutional policy delegated by the Chancellor through the Vice President for Research. It is the responsibility of the Vice President for Research to exercise appropriate administrative oversight to assure that SU's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance.

4.1.2 SU faculty, staff, and students, which comprise its schools, departments and divisions, are subject to the Assurance and this policy. This includes any research for which an Assurance or another formal agreement (e.g., MOU) identifies the SU Institutional Review Board (IRB) as the IRB of record.

4.1.3 The ORIP Director is responsible for submitting a memorandum to OHRP within one month of any changes to the FWA. The memorandum is drafted by the ORIP Director and signed by the Vice President for Research.

4.1.3.1 A copy of all correspondence regarding the FWA is maintained in a paper file in ORIP under the control of the ORIP Director.

4.2 Application of Applicable Regulations.

4.2.1 SU agrees to uphold the ethical principles of *The Belmont Report* and apply DHHS regulations (45 CFR 46, Subpart A) to all proposed research involving human participants regardless of sponsorship. The ethical principles set forth in *The Belmont Report* are:

4.2.1.1 Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;

4.2.1.2 Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and

4.2.1.3 Justice: Fairness in the distribution of research benefits and burdens.

4.2.2 SU further agrees to apply additional regulations such as, the U.S. Food and Drug Administration Human Subject Regulations (21 CFR 50, 56, 312 and 812), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under review.

4.2.3 In the event that an unanticipated issue arises involving human participants research at the University, the ORIP Director and IRB Chair have the authority to report directly to the Chancellor, and if necessary, may contact outside legal counsel for SU. (*See SOP 030).*

4.3 Structure of the Institutional Review Board.

4.3.1 The IRB members are appointed to the IRB as members of University Committees. As such, the IRB serves SU as a whole, rather than a particular school or department, and any institution for which the SU IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding MOU.

4.3.2 SU's Assurance presently has one OHRP-registered IRB. Designation of additional IRB Committees under the Assurance requires prior notification of and approval by OHRP.

4.3.3 The VP for Research, IRB Chair and ORIP Director evaluates no less than annually, the composition and number of IRBs to ensure they are appropriate to the volume and types of research reviewed, so that reviews are accomplished in a thorough and timely manner.

4.4 Reliance of the Syracuse University IRB on Another Institutions IRB

4.4.1 The State University of New York Upstate Medical University (SUNY UMU) provides SU with initial and continuing review of biomedical protocols being conducted by its investigators as outlined in the MOU.

4.4.2 Both Upstate and SU have Office for Human Research Protections (OHRP) approved Federal Wide Assurances (FWA) of protection for human participants, which allow institutions to designate an Institutional Review Board (IRB) under their assurances. SUNY UMU must maintain an OHRP approved Assurance for human participant research to assure SUNY UMU continues to follow and meet federal standards.

4.4.3 SUNY UMU provides SU with review of protocols (including exemption requests, initial review, continuing review, and review of modifications) being conducted by SU investigators and that are FDA-regulated (i.e., involve the use of drugs or medical devices, or data that is being accumulated for support of a marketing permit).

4.4.3.1 Typically, SU does not conduct research involving investigational drugs or devices, including unapproved non-significant risk devices; however, in such cases SUNY UMU would provide SU with protocol review.

4.5 Determination of Budget for ORIP and the IRB (fiscal and space determinations).

4.5.1 Annually, the IRB budget will be reviewed by the ORIP Director and modified as necessary to accommodate the volume and type of research reviewed, space, facilities and staff. The budget then undergoes a thorough review process by the Vice President for Research.

4.6 Responsibilities of the IRB to Provide Oversight for its Assurance Agreement.

4.6.1 Approval of the IRB is required prior to the initiation of any research involving human participants.

4.6.2 Through the review process, the IRB has the authority to approve, require modifications, suspend, disapprove (withhold), or terminate all research activities that fall within its jurisdiction. (*See SOP 014).*

4.6.3 Research reviewed and approved by the IRB may be subject to review and disapproval by officials of SU, or any institution for which the SU IRB is designated as the IRB of record in accordance with an Assurance or a signed MOU with the SU IRB. However, officials may not approve research previously disapproved by the SU IRB; in addition, officials may not approve research that has not been approved by the SU IRB.

Approved by: BR Ware 7-19-08

Ben Ware, Ph.D. Date
Institutional Official
Vice President for Research and Dean of the Graduate School
Syracuse University

Diane A Young 7-25-08

Diane Young, Ph.D. Date
Chair of the Institutional Review Board
Syracuse University

Tracy Cromp 7-25-08

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