Title: REPORTING TO THE APPROPRIATE INSTITUTIONAL OFFICIALS, AND THE DEPARTMENT OR AGENCY HEAD(S)

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure for reporting to the appropriate institutional officials, and the Department or Agency head(s).

2.0 Policy:

The Syracuse University (SU) Institutional Review Board (IRB) has the implicit authority to approve, require modifications in, or disapprove research involving human subjects. All human subject research at Syracuse University or by university faculty, staff, or students must be prospectively reviewed and approved by the IRB unless determined to be exempt from review. 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 (or in the case amendments, memoranda) and submitted to the ORIP office. All IRB determinations are sent via campus mail with the IRB Chair'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 mailed to the address listed on the application.

It is the policy of Syracuse University, ORIP and the IRB 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.

It is the responsibility of the SU IRB and ORIP to assure that reporting occurs according to the Federal regulations, and SU policy.

- **2.1** The IRB and ORIP will maintain written procedures for assuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of:
  - **2.1.1** Any unanticipated problems involving risk to participants or others;
  - **2.1.2** Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
  - **2.1.3** Any suspension or termination of IRB approval.
- **2.2** This reporting will take place within 30 days of the completion of an investigation and determination.

3.0 References and Reference Documents:

45 CFR 103(b)(5)

4.0 Procedure:

4.1 IRB Chair Responsibilities.

4.1.1 The IRB Chair will report to the ORIP Director:

4.1.1.1 Any event determined by the IRB to represent any unanticipated problems involving risks to subjects or others;

4.1.1.2 Any non-compliance determined by the IRB to be serious or continuing non-compliance; and

4.1.1.3 Any action of the IRB to suspend or terminate its approval.

4.2 ORIP Responsibilities.

4.2.1 The ORIP Director or designee will draft letters describing:

4.2.1.1 The nature of the event;

4.2.1.2 The findings of the organization and IRB;

4.2.1.3 Actions taken by the organization or IRB;

4.2.1.4 Reasons for the organization's or IRB's actions; and

4.2.1.5 Plans for continued investigation or action.

4.2.2 The letter is sent to the following people for review and approval:

4.2.2.1 The Vice President for Research; and

4.2.2.2 The IRB Chair, and any edits are then incorporated.

4.2.3 The letter is signed by the VP for Research.

4.2.4 The ORIP Director sends a copy of the letter to:

4.2.4.1 IRB Members (as an item in the agenda packet);

4.2.4.2 The Dean for the appropriate school;

4.2.4.3 OHRP;

4.2.4.4 Study sponsor, if the research was sponsored (this includes NIH, NSF, and industry sponsors);

4.2.4.5 The Office of Sponsored Programs (OSP), if the research involves a grant or contract for all determinations involving faculty, staff, or students whose primary affiliation is with Syracuse University;

4.2.4.6 The Principle Investigator, or in the case of student research, the Faculty Sponsor;

4.2.4.7 Legal Counsel, if appropriate; and

4.2.4.8 Risk Management, if appropriate; and

4.2.4.9 To any federal agency that is a signatory of the Common Rule when the research is conducted or funded by the agency.

SOP 030: REPORTING TO THE APPROPRIATE INSTITUTIONAL OFFICIALS, AND THE DEPARTMENT OR AGENCY HEAD(S)

Approved by: BR Ware 7-20-07

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

Diane S. Young 7-29-07

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

Mary Cromp 7.29.07

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