Title: IRB REVIEW OF HUMAN SUBJECTS RESEARCH EXEMPT FROM REVIEW

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the Institutional Review Board's (IRB) operating policies and procedures for an application for exemption from the review of human subjects research.

2.0 Policy:

The Syracuse University (SU) IRB has the implicit authority to approve, require modifications in, or disapprove all research involving human subjects. All human subjects research at SU, whether conducted 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 (or in the case amendments, memoranda) and submitted to the IRB office.

It is the policy of SU, 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.

The IRB determinations are sent via campus mail or email 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 or emailed to the address listed on the application.

The IRB may not create new categories of exempt research. Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research. The federal regulations permit research to be exempt from review if the only involvement with human subjects research is in one of the following categories. They are:

2.1 **45 CFR 46.101(b)(1):** Research conducted in established or commonly accepted educational settings, involving <u>normal</u> educational practices, such as:

- **2.1.1** Research on regular and special education instructional strategies; or
- **2.1.2** Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- **2.1.3** The research must not involve prisoners as participants.

2.2 **45 CFR 46.101(b)(2):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, <u>unless</u>:

2.2.1 Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

2.2.2 Any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

2.2.3 If the research involves children, the procedures must be limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. 45 CFR 46.401(b)

2.2.4 The research must not involve prisoners as participants.

2.3 **45 CFR 46.101(b)(3):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if:

2.3.1 The human subjects are elected or appointed public officials or candidates for public office; or

2.3.2 Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

2.3.3 The research must not involve prisoners as participants.

2.4 **45 CFR 46.101(b)(4):** Research involving the collection or study of <u>existing</u> data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects <u>cannot be identified</u>, directly or through identifiers linked to the subjects.

2.4.1 The reviewed materials must exist at the time the research is proposed.

2.4.2 The research must not involve prisoners as participants.

2.5 **45 CFR 46.101(b)(5):** Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

2.5.1 Public benefit or service programs;

2.5.2 Procedures for obtaining benefits or services under those programs;

2.5.3 Possible changes in or alternatives to those programs or procedures; or

2.5.4 Possible changes in methods or levels of payment for benefits or services under those programs.

2.5.5 The protocol must:

2.5.5.1 Be conducted pursuant to specific federal statutory authority;

2.5.5.2 Have no statutory requirements for IRB review;

2.5.5.3 Not involve significant physical invasions or intrusions upon the privacy interests of participants;

2.5.5.4 Have authorization or concurrence by the funding agency.

2.5.6 The research must not involve prisoners as participants.

2.6 **45 CFR 46.101(b)(6):** Taste and food quality evaluation and consumer acceptance studies;

2.6.1 If wholesome foods without additives are consumed; or

2.6.2 If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2.6.2.1 Note: *Although, contained as a category of exemption in the regulations, the IRB at Syracuse University as of June 21, 2004 voted to no longer recognize this category of research as qualifying for exemption from review.*

3.0 References and Reference Documents:

45 CFR 46.101(b)
45 CFR 46.109(a)
45 CFR 46.109(d)
45 CFR 46.110
45 CFR 46.301(a)
45 CFR 46.401(b)

4.0 Procedure:

4.1 Investigators must submit a completed "IRB Exempt from Review Application Form."

4.2 Once the application is received in ORIP, the application is date stamped and recorded as received in the Log Book located in the reception area of the ORIP and processed by the ORIP Office Assistant/ Administrator.

4.3 The application is assigned an IRB protocol number based on the current year (ex: 10-001). In addition, the protocol's title, principal investigator/faculty member listed on the protocol and if applicable, student name, academic department, and type of review requested are recorded next to the number in the IRB Log.

4.4 The protocol is then entered into *InfoEd* and an Exemption Checklist is generated and attached to the protocol. The protocol is given to the ORIP Director or designee for the review. Only the ORIP Director or designee may determine which activities qualify for an exempt review.

4.5 The reviewer must complete the Exemption Checklist to document the category allowing the exemption.

4.6 The reviewer will use the Exemption Checklist to determine whether research is ethically justified. Exemption determinations will not be granted to research that is not ethically justified.

4.7 After review, the exempt application is returned to the ORIP/IRB Administrator or designee for processing. The Exemption Checklist contains the determination and signature of the ORIP Director or designee.

4.8 The ORIP Office Assistant/Administrator or designee generates a Determination Letter within one week, which is then sent to the Principal Investigator/Faculty Member designated on the application, or in the case of a Student Investigator, to the Faculty Advisor via campus mail to the address included on the application. When requested, an email is sent in addition to the hard copy.

4.8.1 The Determination Letter details whether the application was authorized as exempt, modifications required, determined to require expedited or full board review, and in the case of modifications required, what changes are required.

4.8.1.1 If not given approval, the Investigator must submit a memorandum to ORIP addressing each of the changes required by ORIP Director or designee.

4.8.1.1.1 The ORIP Director or designee will review the changes, then authorize the study as exempt or request additional information. This process continues until the application receives authorization as exempt.

4.8.1.1.2 If the ORIP Director or designee determines the study requires expedited review, the Investigator will be notified that an application for expedited review must be submitted. The SOP for expedited review will then be followed.

4.8.1.1.3 If the ORIP Director or designee determines the study requires full board review, the Investigator will be notified that an application for full board review must be submitted. The SOP for full board review will then be followed.

Approved by: _____ 6-14-2010

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

_____ 11 June 2010

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

_____ 6-11-2010

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