Title: EXPEDITED IRB REVIEW OF HUMAN SUBJECTS RESEARCH

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 a New Expedited Application for the review of human participant research.

2.0 Policy:

2.1 The Syracuse University (SU) IRB has the implicit authority to approve, require modifications in, or disapprove all research involving human participants. All human participant research at SU conducted by university faculty, staff, or students, must be prospectively reviewed and approved by the IRB unless determined to be exempt from review by application to the IRB. 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 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.

2.2 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.

2.3 The IRB Chair or one or more experienced reviewer designated by the Chair is required to review and approve research meeting expedited criteria. An experienced IRB member means a voting member or alternate voting member who has served on an IRB for at least one year, has received training relative to the expedited review categories, and possesses the scientific expertise needed to review the proposed research. However, the reviewer may request a second reviewer or refer the research to the full IRB Committee for further determination.

2.4 The IRB Chair or designee may provide one of three decisions on applications for expedited review:

- **2.3.1** Approval;
- **2.3.2** Modification required, pending required changes on basic modifications, additional information, or a rationale for the procedures; and
- **2.3.3** Hold for Full Committee.

The reviewer may not disapprove expedited applications for IRB approval without providing for an opportunity for full IRB review.

2.5 The Chair or designee must determine that:

2.5.1 Research submitted for initial or continuing review falls into one or more allowable categories and meets all four applicability criteria; and

2.5.2 Modifications of previously approved research are minor modifications.

2.6 The following is a brief description of categories eligible for expedited review and corresponding to research commonly conducted at SU:

2.6.1 Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week;

2.6.2 Category 3 - Prospective collection of biological specimens for research purposes by noninvasive means;

2.6.3 Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.);

2.6.4 Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis);

2.6.5 Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes;

2.6.6 Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies (*NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.*);

2.6.7 Category 8 - Continuing review of research previously approved by the convened IRB as follows: where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis;

2.6.8 Category 9 - Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

If it is determined that research qualifies under Category 1-Clinical studies of drugs and medical devices, the State University of New York Upstate Medical University will review the study under terms of the Memorandum of Understanding (See *SOP 004*)

2.7 To be eligible for initial or continuing review using the expedited procedure, research must:

2.7.1 Present no more than minimal risk to research participants (except for continuing review of research where no participants have been enrolled and no additional risks have been identified);

2.7.2 When identification of the participants or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal (except for continuing review of research where no participants have been enrolled and no additional risks have been identified);

2.7.3 Not be classified research involving research participants; and

2.7.4 Involve only procedures listed in one or more of the categories **2.6.1** to **2.6.8.**

3.0 References and Reference Documents:

45 CFR 46.109(a)
45 CFR 46.110
SOP 001, Amendments to Previously Approved Applications or Claims for Exemption
SOP 004, Activities Subject to IRB Jurisdiction
SOP 015, IRB Continuing Review
SOP 016, Legally Effective and Prospectively Obtained Informed Consent
SOP 017, Documentation of Informed Consent
SOP 018, Waiver of Informed Consent.
SOP 038, Individual Financial Conflict of Interest

4.0 Procedure:

4.1 For the initial review of research using the expedited procedure, the reviewer is provided and expected to review in depth:

4.1.1 Application for the Initial Review of Research;

4.1.2 Proposed informed consent documents;

4.1.3 Recruitment materials;

4.1.4 The full protocol;

4.2 For continuing review of research using the expedited procedure, the reviewer is provided and expected to review in depth:

4.2.1 A current copy of the initial IRB protocol application updated with all changes since the initial approval;

4.2.2 The current informed consent document;

4.2.3 Any proposed consent document;

4.2.4 Application for Renewal of Approval of Research Protocol;

4.2.5 The complete protocol including any protocol modifications previously approved by the IRB.

4.3 The application is stamped on the date of receipt by the ORIP Office Assistant/Administrator or designee.

4.4 The Investigator must submit a copy of the Application signed and dated by the Investigator or in the case of student research, the faculty sponsor and the student researcher.

4.5 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.

4.6 The protocol is then entered into InfoEd.

4.7 The ORIP/IRB Administrator then creates two checklists, an ORIP Office review checklist and a protocol review checklist.

4.8 The protocol is reviewed by the ORIP Administrator and ORIP Director using the ORIP reviewer checklist. The protocol is then returned to the ORIP Office Assistant.

4.9 Once all of the ORIP review checklists are completed for the new applications, a Protocol Transmittal Log is generated and all of the applications are delivered to the IRB Chair or designee.

The IRB Chair determines on a protocol by protocol basis if she/he has the expertise to review the protocol. If the Chair determines he/she does not have the appropriate expertise, the Chair will review the IRB Roster to determine a qualified IRB member, then will notify ORIP. ORIP will pick up the protocol, document the reviewer on the Transmittal Log and will deliver the protocol to the designated reviewer.

4.10 Two copies of the IRB Transmittal Log are generated. One copy of the report is attached to the applications being sent to the Chair or designee to review. The other copy is filed in the IRB office binder labeled Transmittal Logs.

4.11 For the review of modifications to previously approved research by the expedited procedure, the designated reviewer is provided all modified documents and is expected to review all provided materials in depth.

4.12 The IRB Chair or designated reviewer must complete the appropriate reviewer checklist for new reviews or for reviews requiring modifications using the expedited procedure.

4.13 The applications are picked up by the ORIP Office Assistant/Administrator or designee with the Review of Research Checklist attached containing the signed checklist including the IRB Chair's or designee's determination regarding the approval status of the application and the comments regarding the application. The ORIP/IRB Administrator generates a Determination Letter within one week, which is then sent to the Principal Investigator designated on the application or in the case of a Student Investigator, to the Faculty Sponsor via campus mail to the address included on the application. When requested an email is sent in addition to the hard copy

4.14 The Determination Letter details whether the application was approved, if modifications are required, if it is held for Full Board review, or determined to be exempt, and in the case of modifications required, what changes are required.

4.15 If modifications are required, the Investigator must submit a memorandum to ORIP addressing each of the changes required by the IRB Chair or designee, including highlighted changes in the application, consent/assent documents, and recruitment materials.

4.16 If the IRB Chair or designee reviews and approves the application upon receipt of the revisions, the ORIP Office Assistant/Administrator, or designee processes the IRB Determination/Approval Letter. If not approved, the memorandum is sent to the IRB Chair or designee and the steps required for approval in **4.10** through **4.15** are repeated. This process continues until the application receives approval, the Investigator decides to withdraw the protocol application, or the investigator requests for the protocol to be reviewed by the convened IRB.

4.17 If the Investigator does not address the requested changes, a reminder is sent within 4-5 weeks. If the investigator does not respond to the reminder within 10 working days the protocol is archived and the Investigator is notified.

4.18 **Financial Conflict of Interest**. If the investigator discloses a financial interest *SOP 038* will be followed.

4.19 **Communication of Actions for Expedited Review.** Projects approved using an expedited review procedure (new proposals, amendments, continuing reviews, unanticipated problems, closures, terminations) will be listed and included in the protocol review packet distributed to the full board. The projects do not require any action at the convened IRB meeting

SOP 012: EXPEDITED IRB REVIEW OF HUMAN SUBJECTS RESEARCH

Approved by: _____ 6-14-2010

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Date

_____ 11 June 2010

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

Date

_____ 6-11-10

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