Title: IRB FULL BOARD 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 Full Board Application for the review of human subjects research.

2.0 Policy:

The Syracuse University IRB has the implicit authority to approve, require modifications in, or disapprove all research involving human subjects. All human subjects research at Syracuse University, whether 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 IRB office.

The ORIP Director and IRB Chair confirm that at least one person on the IRB with appropriate scientific and scholarly expertise will conduct an in depth review of the protocol. If it is determined there is not at least one person with appropriate scientific and scholarly expertise, the ORIP Director and IRB Chair will obtain guidance or additional information to conduct an adequate study evaluation. This may include the request of an additional reviewer or consultant with expertise in the area of research under review. Consultants and ad hoc reviewers are held to the same standards as IRB members. A consultant may serve as an ad hoc reviewer when expertise in a specific area is needed. Consultants are determined by their area of expertise using the Infoed data base to verify their department and area of research.

The consultant may not be able to attend the meeting, but is expected to provide a written review of the research. This could be a narrative or could be captured on the reviewer's comment form. The consultant may attend the meeting to participate in the review and discussion, however; the consultant may not count toward a quorum or vote. An IRB member may request a written review from an expert consultant and may also request they attend the meeting for participation in the discussion.

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.

2.1 Full Board Eligibility.

2.1.1 IRB Full Board review applies to research that cannot be approved using the expedited review of human subjects research or cannot be determined to fall within one or more of the categories exempt from review under 45 CFR 46.101(b).

2.1.2 An Investigator may request a particular type of review, but the final determination is made by the IRB.

2.1.3 The IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

3.0 References and Reference Documents:

45 CFR 46.109
SOP 007, IRB Member Conflict of Interest
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 IRB Quorum Required for Full Board Review.

4.1.1 The IRB may only review proposed research at a convened meeting at which a quorum is present.

4.1.1.1 A quorum is present when a majority of the voting members of the IRB are present, including at least one member whose primary interests represent the general public, e.g. non-scientific members and/or when applicable a vulnerable population representative. All IRB members, including the unaffiliated member, are required to attend 8 out of 11 meetings. The alternate unaffiliated member will be contacted in the instance the unaffiliated member is not available.

4.1.1.1.1 IRB meetings are not convened if a non-scientist is not present.

4.1.1.2 No official actions take place at a meeting where a majority of the voting members are not present.

4.1.1.3 Should the IRB meeting lose quorum (e.g., those with conflicts being excused, early departures, loss of all non-scientists), the meeting is terminated from further votes until the quorum is restored.

4.1.2 Wherever possible, IRB meetings take place with all participating IRB members being physically present. However, circumstances sometimes warrant conducting IRB meetings via telephone conference call. IRB meetings conducted via telephone conference call will be recognized as "convened" provided that each participating IRB member:

4.1.2.1 Has received all pertinent material prior to the meeting to allow adequate time for review and the request of additional information, if needed; and

4.1.2.2 Can actively and equally participate in the discussion of all protocols (i.e., each member can hear and be heard by all other participating members).

4.1.2.2.1 The minutes of IRB meetings where an IRB member participated by conference call will clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance; initial and continued presence of a majority of members, including at least one non-scientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

4.1.3 No IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflict of interest. If a conflict exists, the IRB member can provide information requested by the IRB but cannot be present for the discussion and the vote. (See *SOP 007*).

4.1.4 Consultants and ad hoc reviewers will evaluate the research proposal for scientific, scholarly merit, and other issues as requested by the IRB. This includes consideration of research design, statistical power, equitable subject selection process, risk/benefit ratio, etc.

4.1.4.1 The consultant or ad hoc reviewer will agree not to review research in which he/she has or may be perceived as having a conflict of interest (see *SOP 007*).

4.1.4.2 The consultant or ad hoc reviewer will sign a confidentiality agreement each time he/she is asked to provide a review.

4.1.4.3 The consultant or ad hoc reviewer will provide a written report to the IRB. He/she may be requested to attend the Committee meeting for questions and clarifications of issues.

4.1.5 The ORIP/IRB Administrator will maintain attendance logs ensuring members meet attendance requirements. The ORIP/IRB Administrator will monitor attendance in order to assure that quorum is maintained, despite absences and conflicts of interest, for scheduled IRB meetings.

4.1.5.1 The ORIP/IRB Administrator is responsible for recording accurate quorum notes and assuring that quorum is maintained throughout the meeting.

4.1.5.2 When the IRB reviews research that involves a vulnerable population, the IRB Administrator will assure that the IRB members present include someone who is knowledgeable and meets the requirements to review the proposed research.

4.1.5.3 ORIP/IRB Administrator will bring all continuing review of research protocol files to the meeting.

4.1.6 The ORIP/IRB Administrator will maintain a copy of the IRB meeting minutes in a paper file in ORIP and send a copy of the IRB meeting minutes to the Vice President for Research.

4.2 Required Review.

4.2.1 Substantive review of all applications takes place at convened meetings. Applications undergoing review are individually presented and discussed at a convened meeting of the IRB.

4.2.2 Prior to the monthly IRB meetings:

4.2.2.1 The ORIP/IRB Administrator will prepare IRB materials, including a tentative agenda and reviewer assignment list for the IRB Chair and ORIP Director one day following the IRB protocol submission deadline.

4.2.2.2 The IRB chair and ORIP Director will meet one/two days following the protocol submission deadline for the monthly IRB meeting and assign primary and secondary reviewers for new protocol applications and reviewers for any continuing renewal applications and/or amendments.

4.2.2.3 The IRB Chair and ORIP Director will determine if any of the protocols on the agenda require the expertise of a special consultant and will contact the consultant prior to the meeting date.

4.2.2.4 When review by a special consultant is required, the ORIP Office Assistant/ Administrator will provide the consultant with the appropriate review materials at least one week prior to the IRB meeting.

4.2.2.5 The ORIP/IRB administrator will prepare a final agenda and reviewer assignment list to include with IRB meeting materials for members.

4.2.2.6 The ORIP/IRB administrator will contact all reviewers via email with their protocol review assignment and attach an electronic copy of the reviewers checklist. A hard copy of the reviewers checklist will also be included in with the assigned reviewer's IRB packet.

4.2.2.7 If any conflicts arise, the ORIP/IRB Administrator will immediately contact the IRB Chair and ORIP Director so that a new reviewer can be assigned prior to the meeting.

4.2.3 IRB members receive a review packet of the research applications at least one week prior to the scheduled IRB meeting. Review packets also include a transmittial memorandum, the minutes from the previous meeting, the meeting agenda, a reviewer assignment list,

and a list of IRB actions (expedited approvals, exempt authorizations, and closings) that have taken place since the previous meeting.

4.2.3.1 The Full IRB meeting schedule is determined at the last meeting of the previous academic year for the following academic year.

4.2.3.1.1 Typically, meetings are scheduled once a month on Mondays, August-June. The IRB meeting schedule is posted on ORIP's website once it is finalized. Meetings in July are convened if necessary.

4.2.3.1.2 New applications for review must be submitted by the submission deadline posted on the ORIP website, two weeks prior to the scheduled meeting date.

4.2.4 For the Initial review of research by a convened IRB, the IRB Chair and all IRB members are provided:

4.2.4.1 The application from the Initial Review of Research;

4.2.4.2 Proposed informed consent documents;

4.2.4.3 Recruitment materials;

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

4.2.4.5 Review packets for the IRB Chair and assigned reviewers also include hard copies of the appropriate reviewer checklists, e.g. protocol review checklist and when appropriate, checklists for vulnerable populations. Review packet for the ORIP Director also includes ORIP checklists.

4.2.5 For the initial review of research all IRB members are expected to review all materials provided. The IRB Chair and assigned primary and secondary reviewers are expected to review all materials in depth and submit a signed copy of all checklists appropriate to the review to the ORIP/IRB Administrator at the meeting (e.g. vulnerable populations checklist may be required in addition to the protocol review checklist)

4.2.6 For the initial review of research IRB members may ask the ORIP Director to obtain information provided to any individual reviewer before or during the meeting.

4.2.7 For continuing review of research by a convened IRB, all IRB members are provided:

4.2.7.1 A current copy of the initial IRB protocol application updated with all changes since the initial approval. Access to the full file will be available at the Committee meeting;

4.2.7.2 The current informed consent document;

4.2.7.3 Any proposed consent document;

4.2.7.4 Application for Renewal of Approval of Research Protocol.

4.2.7.5 Review packets for the IRB Chair and assigned reviewers also include hard copies of the appropriate reviewer checklists, e.g. checklist for continuing renewal application.

4.2.8 For the continuing review of research all IRB members are expected to review all provided materials. The IRB Chair and assigned reviewer are expected to review all provided materials in depth and submit a signed copy of the checklists appropriate to review to the ORIP/IRB Administrator at the meeting.(e.g. continuing renewal checklist, amendment/modification checklist-when appropriate).

4.2.9 The convened IRB is responsible for the evaluation of proposed research for scientific and scholarly validity.

4.2.10 For the continuing review of research IRB members may ask the ORIP Director to obtain information provided to any individual reviewer before or during the meeting.

4.2.11 For the review of modifications to previously approved research by a convened IRB, all IRB members are provided all modified documents. The IRB Chair and assigned reviewer are also provided with Amendment/Modifications Checklists

4.2.12 For the review of modifications to previously approved research all IRB members are expected to review all provided materials. The IRB Chair and assigned reviewer are

expected to review all provided materials in depth and submit a signed copy of the amendment/modifications checklist to the ORIP/IRB Administrator at the meeting.

4.2.13 In conducting the Full IRB review (including initial review, continuing review, and the review of modifications to previously approved research), the majority of the IRB members present at the meeting must agree that materials are in sufficient detail to determine the study meets criteria in 45 CFR 46.111 by completing the Review of Research Checklist.

4.2.15 All designated reviewers present comments and concerns for their assigned protocols, then additional comments or concerns are raised by any of the members. The IRB Chair facilitates the discussion.

4.2.16 The Full IRB determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval. The IRB will obtain review more often than annually when any of the criteria for more frequent review on the Review of Research Checklist are met.

4.3 After the IRB Board has had a chance to discuss the proposed protocol, the IRB Chair recommends a determination (i.e. Approval, Modifications required, or Disapproval (i.e. Withheld)) based on the discussion.

4.4 The IRB Members then vote on the recommendation regarding the determination of the protocol's status.

4.5 The IRB determination outlining the details of the status of the protocol, are conveyed to the Investigator, within five business days following approval of the minutes. If the protocol requires modifications, the determination letter clearly outlines the revisions required by the Investigator for approval. The IRB determines whether modifications can be reviewed by the expedited review process or if they require full board review. If the modifications can be reviewed by the expedited process, either the IRB Chair or the ORIP Director is authorized for review and approval, dependent upon the nature of the modifications. If the IRB determines the revisions require full board review, the PI will be notified that the required modifications require a revised application for resubmission and review at a future convened meeting of the IRB.

4.5.1 If the application is disapproved, the determination letter outlines the IRB's rationale for disapproval and includes an invitation for reply by the Investigator(s), either in person or in writing.

4.5.2 The Investigator(s) may appeal the decision in person at the next IRB meeting or in writing.

4.5.3 If the Investigator(s) responds in writing, the appeal will be discussed at the next convened meeting of the IRB. The IRB determines whether to change the disapproval determination after the appeal. The range of actions may include: disapproval, approval, or request changes. The determination will be communicated in writing to the investigator.

4.5.4 Investigators also have the opportunity to resubmit their study and appear before a convened meeting of the IRB to answer questions or discuss any concerns the Board has with the study.

4.5.5 The IRB determination letters are sent via campus mail to the address included on the application, with the IRB Chair's signature, to the Investigator, or in the case of a Student Researcher, to the Student's Faculty Advisor. When requested an email is sent in addition to the hard copy.

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

SOP 013: IRB FULL BOARD REVIEW OF HUMAN SUBJECTS RESEARCH

Approved by:

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

8/27/10
Date

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

27 August 10
Date

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

8-27-10
Date