Title: IRB OFFICE RECORDS

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to outline the necessary maintenance of IRB office records associated with research activities under the jurisdiction of the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:
It is the policy of the SU IRB to maintain IRB office records for research activities under its jurisdiction. The IRB office files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, and reports of violations, unexpected harms or unanticipated problems.

2.1 **Document Retention.** The Office of Research and Integrity Protections (ORIP) must retain all IRB records regarding an application (regardless of whether it is approved) for at least two (2) years. For all applications that are approved and the research initiated, ORIP must retain all records regarding that research for at least two (2) years after completion of the research on file in the ORIP office. After two (2) years, protocol files are sent to Syracuse University's Archives and Records Management Records Center where they are retained for five (5) years after which time they are automatically destroyed. All other records not related to a research protocol (e.g., minutes) are retained for at least 3 years.

2.2 **Access to Documents.** The ORIP must make all records accessible for inspection and copying by authorized representatives of any regulatory oversight agency at reasonable times and in a reasonable manner.

2.3 The ORIP must prepare and maintain all of the following documents:

2.3.1 **IRB Applications.** Copies of all research applications reviewed, including scientific and scholarly evaluations, if any, approved sample informed consent documents, data safety monitoring board/committee reports, progress reports submitted by the Investigators, and reports of any unexpected harms and unanticipated problems to participants or other reports;

2.3.2 **IRB Minutes.** The minutes of all IRB meetings document:

2.3.2.1 Actions taken by the IRB;

2.3.2.2 Separate deliberations for each action;

2.3.2.3 Votes for each protocol as numbers for, against and abstaining;

2.3.2.4 Attendance at the meeting for each action;

2.3.2.5 The basis for requiring changes in research;

2.3.2.6 The basis for disapproving research;

2.3.2.7 A written summary of the discussion of controverted issues and their resolution;

2.3.2.8 Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document;

2.3.2.9 For initial and continuing review, the approval period;

2.3.2.10 The names of IRB members who absented themselves from the meeting due

to a conflicting interest;

2.3.2.11 When an alternate member replaces a primary member;

2.3.2.12 Documentation of key information provided by consultants shall be summarized in the IRB minutes.

2.3.2.13 Determinations required by the regulations and protocol specific findings justifying those determination for:

2.3.2.13.1 Waiver or alteration of informed consent;

2.3.2.13.2 Research involving prisoners;

2.3.2.13.3 Research involving children.

2.3.3 Continuing Reviews. Records of continuing review activities;

2.3.4 Correspondence with Investigators. Copies of all correspondence between the IRB and the Investigators;

2.3.5 List of IRB Committee Members. Changes in membership which must be reported promptly to the Office of Human Research Protections (OHRP);

2.3.6 IRB Policies and Procedures. The IRB will maintain written standard policies and procedures (SOPs) that will be reviewed at least every three years by the IRB; and

2.3.7 New Findings. Statements of significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation that will be provided to the participants;

2.3.8 Consultant Review. Documentation of key information provided by consultants shall be summarized in the IRB minutes and if available, the written report shall be filed in the IRB file.

3.0 References and Reference Documents:

45 CFR 46.115

4.0 Procedure:

4.1 ORIP Responsibilities.

4.1.1 The ORIP must prepare and maintain the following documents:

4.1.1.1 Copies of all materials contained in the research applications (e.g., IRB application, protocol, recruitment materials, , etc.) that have been reviewed, including scientific evaluations, any approved informed consent documents, data and safety monitoring reports, progress reports submitted by Investigators, protocol deviation reports, modifications, and reports of injuries and unanticipated problems to participants and others;

4.1.1.2 Statements of significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation;

4.1.1.3 Records of continuing review activities;

4.1.1.4 IRB records for initial and continuing review by the expedited procedure include:

4.1.1.4.1 The specific permissible category;

4.1.1.4.2 Description of action taken by the reviewer;

4.1.1.4.3 Any findings required under the regulations.

4.1.1.5 IRB records for exempt determinations cite the specific category of exemption;

4.1.1.6 IRB records document determinations required by the regulations and protocol-specific findings supporting those determinations;

4.1.1.7 IRB records for each study's initial and continuing review note the frequency for the next continuing review;

4.1.1.8 Amendments or changes to IRB approved documents;

4.1.1.9 Copies of all correspondence between the IRB, the Investigators and key study personnel; and

4.1.1.10 The minutes of all IRB meetings.

4.1.2 ORIP must keep on file in ORIP the following information regarding IRB members and alternate IRB members identified by:

4.1.2.1 Name;
4.1.2.2 Earned degrees;
4.1.2.3 Representative capacity;
4.1.2.4 Curriculum Vitae (CV) or biosketch;
4.1.2.5 Indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations;
4.1.2.6 A current conflict of interest disclosure;
4.1.2.7 A current privacy statement (e.g., confidentiality agreement);
4.1.2.8 Indication of the required human participants protection training, and continuing education;
4.1.2.9 Any employment or other relationships between each member and the institution (e.g., full-time employee, part-time employee, member of a governing panel or board, stockholder, paid or unpaid consultant);
4.1.2.10 Representative capacities (whether the member has knowledge or experience in working with specific vulnerable populations, such as children, prisoners, or cognitively impaired adults);
4.1.2.11 Affiliation status (whether the member or an immediate family member of the member was affiliated with the organization); and
4.1.2.12 The IRB staff is required to poll unaffiliated IRB members on appointment and annually to determine whether any of their family members have any relationship to the organization.

4.1.3 The IRB staff must promptly report changes in IRB membership to the Office for Human Research Protections (OHRP).

4.1.4 The Records are kept in the file cabinet with each IRB member having their own file and all supporting documentation including appointment letters.

4.1.5 The IRB must keep written policies and procedures on file and available on the ORIP website as a reference for members of the SU community including Investigators and IRB members, which will address the following:
4.1.5.1 Initial and continuing review of research and for reporting its findings and actions to the Investigator and the institution;
4.1.5.2 Determining which projects require review more often than annually and which projects need verifications from sources other than the Investigators that material changes have not occurred since previous IRB review;
4.1.5.3 Assuring prompt reporting to the IRB of proposed changes in a research activity, and for assuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to the participants;
4.1.5.4 Assuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any:
4.1.5.4.1 Unanticipated problems involving risks to participants or others;
4.1.5.4.2 Serious or continuing noncompliance with the Federal regulations and IRB policies and procedures or the requirements or determinations of the IRB; and
4.1.5.4.3 Suspensions or terminations of IRB approval.

4.1.6 All research approved by the SU IRB which is currently approved and active will remain in the file cabinets maintained in ORIP. Once a study is closed or terminated, the ORIP/IRB Administrator will move the protocol documents from the active protocol file cabinets and the protocol will be filed according to the retention date established in 2.1.

4.2 ORIP/IRB Administrator Responsibilities.

4.2.1 The ORIP/IRB Administrator is responsible for the retention of all research documents and required documentation in the IRB file.

4.2.2 The ORIP/IRB Administrator and Office Assistant will maintain the collation of all IRB documents into the appropriate sections of the study file.

4.2.3 ORIP will be responsible for retaining the final approved copy of all IRB meeting minutes and agendas in electronic and paper formats.

Approved by: _____ 6-14-10

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

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
Syracuse University

Date