

**SYRACUSE UNIVERSITY  
HUMAN RESEARCH PROTECTION PROGRAM  
STANDARD OPERATING PROCEDURES**

<b>TITLE: IRB CONTINUING REVIEW</b>			<b>DOCUMENT NUMBER: 015</b>
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**Title: IRB CONTINUING REVIEW**

**1.0 Purpose:**

The purpose of this Standard Operating Procedure (SOP) is to outline the requirements for continuing review of Full Board and Expedited Review applications by the Syracuse University (SU) Institutional Review Board (IRB) for the review of human subjects research.

**2.0 Policy:**

It is the policy of the SU IRB that research activities be periodically reviewed at intervals appropriate to degree of risk, but not less than once per year as required by Federal regulations.

In addition, research activities exempt from review do not require an annual review; however, any changes to the research proposal are submitted to the IRB for approval before implementation.

Syracuse University, ORIP, and the IRB require that all policies and procedures for conducting continuous review of research that has received either full board or expedited status under its jurisdiction, be written or 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 in order to ensure the protection of human participants in research and promote the responsible conduct of research.

Amendments to exempt protocols are reviewed and approved by the ORIP Director. However, if the amendment reflects a change in status of the protocol review level, the ORIP Director forwards to the IRB Chair or the designated IRB Member for review and determination at the appropriate review level (i.e. Expedited or Full Board review).

**3.0 References and Reference Documents:**

- 45 CFR 46
- 45 CFR 46.109(e)
- 45 CFR 46.110
- 45 CFR 46.111

*SOP 012, IRB Review of Human Subjects Research – Expedited*

*SOP 013, IRB Review of Human Subjects Research-Full Board*

*SOP 016, Legally Effective and Prospectively Obtained Informed Consent*

OHRP Guidance on Continuing Review, July 11, 2002

**4.0 Procedure:**

**4.1 Continuing Review Criteria.**

- 4.1.1** The SU IRB uses the Review of Research for Continuing Review Checklist to determine that the criteria for approval are met.
- 4.1.2** The IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:
  - 4.1.2.1** Complex protocols involving high levels or types of risks to participants;

- 4.1.2.3 Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
- 4.1.3 **Informed Consent Documents (ICDs).** Review of the currently approved ICD must ensure that the information is still accurate and complete. Any significant new findings that may relate to the participant's willingness to continue participation should be included and submitted with the Continuing Review Application. Review of currently approved or proposed ICDs occur during the scheduled continuing review of research by the IRB, but may be done more frequently if new information becomes available.
- 4.1.4 **New Amendments to Protocol Submitted at Time of Continuing Review.** Amendments or revisions to a research protocol may be submitted at the time of continuing review. An "IRB Amendment Form" and all appropriate documentation accompany the "Full/Expedited Continuing Renewal Application." The amendment or revision is not implemented by an Investigator prior to the review and approval by the IRB.
- 4.2 **Submission of Applications for Continuing Review.**
- 4.2.1 **Investigator Responsibilities.**
- 4.2.1.1 The Investigator must submit a copy of the "Full/Expedited Continuing Renewal Application" with a current copy of the initial IRB protocol application updated with all changes since the initial approval.
- 4.2.1.1.1 The Investigator's signature must appear on the completed continuing review application, indicating that he or she is in agreement with all the information being presented for continuing review as the most current and accurate information regarding the status of the study.
- 4.2.1.1.2 The Investigator submits a copy of the current IRB date-stamped informed consent documents as well as a clean copy for stamping of the new approval and expiration dates once granted by the IRB. (See *SOP 016*).
- 4.2.1.1.3 The Investigator submits the continuing review application, a current copy of the initial IRB protocol application (including all changes since the initial approval) and all continuing review documents to the IRB at a minimum of four weeks prior to the expiration date in order to allow adequate time for IRB review and to avoid any unnecessary delays.
- 4.2.1.2 If a study is not reviewed prior to the expiration date, IRB staff will immediately notify the Investigator to cease all research activities. The Investigator must immediately submit a continuing review application with all required materials or the study will remain closed.
- 4.2.2 **IRB Responsibilities.**
- 4.2.2.1 All continuing review determinations are completed using the criteria found in 45 CFR 46.111 for approval of research. The Primary Reviewer documents the review of criteria using the review of research checklist. (See *SOP 013* and *SOP 012*).
- 4.2.2.1.1 The primary reviewer receives a copy of the *Full/Expedited Continuing Renewal Application*, the current IRB protocol application, and all continuing review documents.
- 4.2.2.1.2 For protocols that meet the criteria of full board review, the primary reviewer and all IRB members receive a copy of the *Full/Expedited Continuing Renewal Application*, the current IRB protocol application, and all continuing review documents.
- 4.2.2.1.3 Upon request any member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the meeting.

- 4.2.2.2 Research activities initially reviewed by the IRB are reviewed using the procedure for full IRB review of applications unless:
  - 4.2.2.1.1 The study was initially reviewed by expedited review procedure at the initial submission of the application; or
  - 4.2.2.1.2 The study has been modified and is now eligible for expedited review as defined in the regulations; or
  - 4.2.2.1.3 The study meets one of the following expedited review criteria:
    - 4.2.2.2.3.1 The research is permanently closed to the enrollment of new participants;
    - 4.2.2.2.3.2 All participants have completed all research-related interventions; and
    - 4.2.2.2.3.3 The research remains active only for long-term follow-up of participants; or
    - 4.2.2.2.3.4 No participants have ever been enrolled at any site and no additional risks have been identified; or
    - 4.2.2.2.3.5 The remaining research activities are limited to data analysis.
- 4.2.2.3 When conducting research under an expedited review procedure, the IRB Chair or designated IRB member conducts the review on behalf of the full IRB.
- 4.2.2.4 Research protocols that were originally reviewed using expedited review procedures may receive continuing review on an expedited basis, unless previously met criteria have changed the previous IRB review and approval.
- 4.2.2.5 The reviewer is responsible for the evaluation of proposed research for scientific or scholarly validity.

#### **4.3 IRB Approval of Continuing Review.**

- 4.3.1 The IRB conducts continuing review of all research proposals, with the exception of research that meets the criteria as being exempt from review, at intervals appropriate to the degree of risk, but not less than once per year.
- 4.3.2 Research that meets the criteria for full board review is reviewed within one year of the date of the full, convened IRB meeting at which the research was approved (with or without specific revisions) even though the research activity may not begin until after final IRB approval is granted.
- 4.3.3 Research may be restricted, modified, or halted altogether based on continuing review by the IRB. A provisional approval or withheld status is given to all studies in which the IRB requests changes to the application or ICDs during Continuing Review. IRB approval is not granted until all requested changes to previously approved documents are completed by the Investigator, and reviewed and approved by the IRB. This does not extend the expiration period.
- 4.3.4 Based on IRB continuing review, previously imposed restrictions may be relaxed or additional restrictions may be imposed.

#### **4.4 Notification to SU Investigators of Impending Need for Continuing Review.**

- 4.4.1 **ORIP/IRB Administrator Responsibilities.**
  - 4.4.1.1 Two months prior to expiration, the ORIP/IRB Administrator, or designee will electronically send continuing renewal email reminders to PI's and student researchers (if applicable). The reminders include an attached electronic copy of the renewal application and the link to the continuing renewal application on the ORIP website. ORIP/IRB Administrator, or designee will forward a second email renewal reminder from the original renewal reminder email to the Investigators that did not respond to the earlier notice.

**4.4.2** Continuing review must occur as long as the research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions? Continuing review must occur as long as data analysis continues and data have not been de-identified. Continuing review of research must occur even when the remaining research activities are limited to collection of private identifiable information.

**4.5 Expiration of IRB Approval.**

**4.5.1** There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Therefore, the study expires and extensions beyond the expiration date are not granted. The expiration date is the last date that the protocol can be conducted.

**4.5.2** If the IRB does not re-approve the research by the specified expiration date, all research activities including advertisement, recruitment, enrollment, data collection, data analysis, and interventions and interactions on current participants must cease, pending re-approval of the research by the IRB as previously described in Section 4.2.1.2. Such actions are not considered suspensions or terminations of IRB approval since the loss of approval is automatic and requires no action by the IRB.

**4.6 Notification to SU Investigators that Study Approval has Expired.**

**4.6.1 ORIP/IRB Administrator Responsibilities.**

**4.6.1.1** The ORIP/IRB Administrator sends the Investigator and student researcher (when applicable) electronic email notification of expiration. An electronic copy of the IRB letter of expiration is attached to the email along with an electronic copy of the continuing renewal application. The researchers are notified that all research activities must cease immediately including advertisement, recruitment, enrollment, data collection, data analysis, and interventions and interactions on current participants until the protocol receives renewal approval.

**4.6.1.2** Studies that were given formal notification of expiration on the basis of receipt of a completed continuing review application when received within 60 days of the date of expiration must be reviewed and approved by the convened IRB, unless the research meets the criteria for review using the expedited procedure.

**4.6.1.3** Investigators who believe their participants might be harmed by stopping research procedures must submit a list of those participants, the procedures that should continue, and their reasons to the IRB chair. The IRB chair will determine whether there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions. Under no circumstances will the IRB allow new enrollment of participants to occur after the expiration of IRB approval.

**4.7 Procedures used by the IRB to determine which projects require review more often than annually.**

**4.7.1** During the course of either initial or continuing review, the IRB reviews the level of risk to which human participants are subject, the nature of the research protocol (e.g., novel vs. routine), and the investigator's experience and professional history.

**4.7.2** The IRB may determine that research should be reviewed more frequently than annually when:

**4.7.2.1** It involves a high level of risk to subjects;

**4.7.2.2** It involves an intervention or procedure that is highly experimental in nature;

**4.7.2.3** The investigator has violated IRB policies and procedures in the past (i.e., nontrivial technical breaches or other ethical violations); or

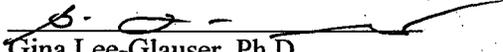
**4.7.2.4** The investigator's initial application required substantial revisions and changes prior to receiving IRB approval such that the IRB believes that the investigator requires ongoing guidance to protect subjects.

**4.7.3** If the IRB determines that the project requires more frequent review than annually, this will be communicated to the investigator with the approval letter mailed from the IRB

office to the investigator (see Full IRB review procedure) and recorded in *InfoEd* and the application's file.

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Approved by:

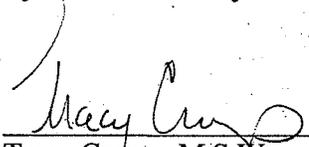
  
Gina Lee-Glauser, Ph.D.  
Institutional Official  
Vice President for Research  
Syracuse University

6-14-2010

Date

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

11 June 2010  
Date

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

6-11-2010  
Date