Title: HUMAN RESEARCH PROTECTION PROGRAM QUALITY ASSESSMENT AND IMPROVEMENT

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to provide a description of the quality assurance/improvement focus of the Syracuse University (SU) Human Research Protection Program (HRPP).

2.0 Policy:
The SU HRPP implements procedures to ensure ongoing development, assessment, and improvement of the HRPP.

3.0 References and Reference Documents:
SOP 008, IRB Member Training
SOP 009, Community Outreach
SOP 015, IRB Continuing Review
SOP 035, Requirements for IRB Office Staff Employment

4.0 Procedure

4.1 Quality Assurance (QA) Activities:

The following are categorized as QA Activities:

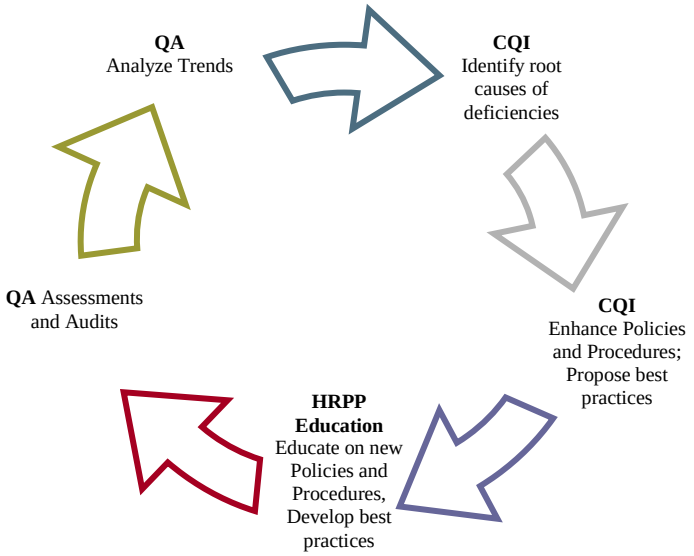
4.1.1 Not-for-cause, regularly scheduled activities (e.g., review of consent forms, review of minutes, review of protocol files, and review of protocols with and without external sponsors). Routine QA activities may be performed by ORIP Staff in the course of handling and processing files. Immediate follow-up steps are taken as necessary;

4.1.2 Assessments triggered by selected events (e.g., The ORIP Director comparison of grant proposals and progress reports to the approved IRB protocol and subsequent amendments); and

4.1.3 For-cause assessments that in the judgment of the IRB or ORIP Director is warranted by particular circumstances (e.g., repeated failure of the consent form to comply with the required elements, or lapse in reporting obligations).

The results of QA activities are reported to the IRB Chair, ORIP Director and the Institutional Official, as well as to other units as appropriate. Based on the results of assessment and reviews, the plan will establish a feedback mechanism between evaluation activities, best practices and refinement of the HRPP. This leads to continuous improvement of HRPP Education and Participant Outreach. (See *SOP 009*).

4.1.4 See diagram below:



4.2 Institutional Training and Education:

4.2.1 The foundation for the effective implementation of all facets of the HRPP and for efforts to promote compliance with HRPP requirements lies in a comprehensive mandatory education program for investigators/study personnel, IRB members, administrators, and research support staff. The ORIP administrator documents completion of training for all investigators conducting human research. (See *SOP 008* and *SOP 035*).

4.2.2 The IRB reference library is available in ORIP Office for the campus community to obtain additional information regarding the history and conduct of research activities.

4.2.3 ORIP frequently conducts IRB presentations to generate awareness of the SU HRPP and promote an understanding of the ethical principles upon which the regulations are based.

4.3 Post-Approval Monitoring:

4.3.1 Questions, concerns, and self-reporting by investigators and research staff are an avenue to evaluate knowledge and implementation of ethical and compliant research practice.

4.3.2 Continuing review and required reporting. (See *SOP 015*).

4.4 Invitation for Comments/Suggestions:

4.4.1 Any person (investigator, staff, research participant, etc.) may contact ORIP to make comments or recommend changes to the procedures followed by the SU IRB. It is helpful to receive feedback on SOPs, the website and other IRB related forms and documents. Specific suggestions for improvement often result in constructive additions or changes to procedures, forms and website information.

4.4.2 Investigators may also contact the Vice President for Research with complaints or suggestions regarding the IRB or ORIP.

4.5 Assessment of IRB Function:

4.5.1 The function and performance of the SU IRB is continually monitored and evaluated by the ORIP Director and IRB Chair. The ORIP Director monitors the conduct of IRB meetings as well as provides resources and guidance for full-board, expedited, exempt reviews, and determinations of non-human subject research.

4.6 Assessment of the SU HRPP:

4.6.1 The ORIP Director and ORIP Administrator are responsible for tracking the above components to monitor the major elements of quality control and quality improvement which allow the institution to:

4.6.1.1 Monitor and measure the effectiveness of the human research protection program

4.6.1.1.1 New Full Board protocols:

4.6.1.1.1.1 Mean number of days from submission to:

4.6.1.1.1.1.1 Review at meeting

4.6.1.1.1.1.2 Approval.

4.6.1.1.2 New Expedited Protocols:

4.6.1.1.2.1 Mean number of days from submission to:

4.6.1.1.2.1.1 Review by IRB member.

4.6.1.1.2.1.2 Approval.

4.6.1.1.3 New Exempt protocols:

4.6.1.1.3.1 Mean number of days from protocol submission to exempt determination:

4.6.1.2 (review turnaround time on an annual basis for protocol review and approval);

4.6.1.3 Plan improvements based on those measures;

4.6.1.4 Implement planned improvement; and,

4.6.1.5 Monitor and measure the effectiveness of those improvements**.**

4.7 SU HRPP Assessment Improvement Goals:

4.7.1 Conduct at least one random audit per month on an active IRB protocol.

4.7.2 To maintain metrics on HRPP performance below the mean number of days to review and approval as reported in AAHRPP's Metrics on HRPP Performance.

SOP 024: HUMAN RESEARCH PROTECTION PROGRAM
QUALITY ASSESSMENT AND IMPROVEMENT

Approved by:

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8/27/10
Date

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27 August 10
Date

Tracy Cromp, M.S.W.
Director of Office of Research and Integrity Protections
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8-27-10
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