Title: IRB MEMBER TRAINING

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the process for completing the human research protections educational requirements in order to become a member of the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:

It is the policy of the SU IRB that all IRB members complete initial and ongoing training in the review and conduct of human research protections.

2.1 All new IRB members are required to complete an initial orientation before being allowed to serve on the IRB, which includes the following:

- **2.1.1** Certification that the new IRB member has reviewed: the Syracuse University IRB policies and procedures, *The Belmont Report*, Federal regulations 45 CFR 46, and other applicable regulations and guidance.
- **2.1.2** Collaborative Institutional Training Initiative (CITI). This internet-based course in human research protection and bioethics is designed specifically for all personnel that have a significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. The course consists of training modules that are divided into two tracks: Biomedical Research and Social/Behavioral Research.
- **2.1.3** Committee Meeting Attendance and Observations. New IRB Committee members must attend and observe at least one IRB Committee meeting prior to functioning as a voting member.

2.2 Each new IRB Committee member receives the book entitled *Institutional Review Board Member Handbook* by Robert Amdur. Copies of revised or new policies and procedures as well as other pertinent documents will be forwarded to Committee members to facilitate the maintenance of a current reference manual.

2.3 Education is provided at the IRB meeting.

2.4 The IRB Chair and Associate Chair will be encouraged to attend a national or regional human research protections conference annually.

2.5 The IRB reference library is available in ORIP Office for all IRB Committee members to obtain additional information regarding the history and conduct of research activities.

2.6 IRB members have been provided and are expected to review the following documents: (1) *The Belmont Report*; (2) *SU HRPP Policies and Procedures, (3) Institutional Review Board Member Handbook* by Robert Amdur, 2007, *(4) DHHS Regulations*. In addition, IRB members are provided with copies of articles, reports, and policies by the IRB Chair and the ORIP Director. These articles and subsequent discussions are recorded in the minutes of convened IRB meetings.

3.0 References and Reference Documents:

45 CFR 46 (107)

Amdur, R. and Bankert, E. *Institutional Review Board Member Handbook*. Jones and Bartlett Publishers, Inc., 2007.

4.0 Procedure:

4.1 IRB Committee Member Responsibilities.

4.1.1 All new Committee members are required to certify review of the following before being allowed to serve on the IRB Committee. Materials include information on:

- **4.1.1.1** SU IRB Policies and Procedures;
- **4.1.1.2** DHHS Regulations 45 CFR 46;
- **4.1.1.3** *The Belmont Report*;
- **4.1.1.4** Committee Member Responsibilities;
- **4.1.1.5** Types of Review including Exempt, Expedited, and Full Board;
- **4.1.1.6** Assessment of Risks;
- **4.1.1.7** Informed Consent Process, Documentation, Required Elements, Waiver;
- **4.1.1.8** Vulnerable Populations and Supplemental Reviewer's Comment Forms;
- **4.1.1.9** Documentation and Discussion of Review Criteria;
- **4.1.1.10** Motions and Votes; and
- **4.1.1.11** Conflicts of Interest.

4.1.2 IRB Members must complete the modules in the Collaborative Training Initiative (CITI) designed for IRB Members.

- **4.1.2.1** All members are required to complete the Basic CITI course which is valid for a period of three years.
  - **4.1.2.1.1** New members have two months to fulfill training requirements.
  - **4.1.2.1.2** Members who have not completed the training cannot vote until training requirements are fulfilled.

4.1.3 New IRB Committee members must attend and observe at least one IRB committee meeting prior to functioning as a voting member, and must attend at least one meeting as a new voting member before serving as a primary or secondary reviewer on an IRB protocol.

4.1.4 Each new IRB Committee member receives the book entitled *Institutional Review Board Member Handbook* by Robert Amdur, 2007.

4.1.5 Education is provided at the IRB Committee meetings (articles from IRB newsletters, updates, review of policies and procedures, discussion of revisions to checklists and forms).

4.1.6 The IRB Chair and Associate Char will be encouraged to attend a national or regional human subject protection conference annually.

4.1.7 The IRB Committee members will review materials presented at IRB Committee meetings and may request additional educational resources.

4.2 Office of Research Integrity and Protections Responsibilities.

4.2.1 The ORIP/IRB Administrator and ORIP Director, in collaboration with the IRB Chair are responsible for planning and executing education at the IRB Committee meetings.

4.2.2 The ORIP/IRB Administrator and ORIP Director are responsible for maintaining Committee member education and training documentation.

4.2.2.1 ORIP/IRB Administrator will track member education and training using a checklist located in each member file.

4.2.2.1.1 If training requirements are not fulfilled members will be notified they have two months to complete the training.

4.2.2.1.2 Members who do not complete the training within the two month time frame will not be allowed to vote until training requirements are fulfilled.

4.2.2.1.3 ORIP/IRB Administrator will track member training to ensure quorum requirements.

4.3 IRB Member Training and Development.

4.3.1 The ORIP Director and the IRB Chair monitor current discussions and developments in research ethics, the protection of human subjects, and federal requirements through reviews of OHRP regulations and policies, and participation in workshops and conferences. The ORIP Director and IRB Chair report to the IRB at the meetings or through written materials on major new developments related to the IRB.

4.3.2 IRB Members are required to take the CITI refresher course every three years.

4.3.2.1 CITI training is tracked by CITI directly to the PI.

4.3.2.1.1 Members have two months to complete training.

4.3.2.1.2 Members who do not complete the training within the two month time frame will not be allowed to vote until training requirements are fulfilled.

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8/27/10
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