1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to describe the Syracuse University (SU) policy and procedure for the selection and appointment of Institutional Review Board (IRB) staff, requirements, training and evaluation of IRB staff.

2.0 Policy:
It is the policy of SU that the IRB office be knowledgeable of research in general, demonstrate an adequate level of knowledge in the protection of human research participants and have an understanding of their specific role and responsibility within the IRB office.

3.0 References and Reference Documents:
SOP 003, Roles and Responsibilities of Human Research Protections Staff

4.0 Procedure
4.1 General Qualifications: When a new IRB office administrator or staff position is to be filled the Director of the Office of Research Integrity and Protections (ORIP) will work with the Human Resources Department through the hiring process. The IRB staff should have the following general qualifications to be hired. Specific requirements will be listed with individual job descriptions depending on the need at the time of the hire.

4.1.1 Director of the Office of Research Integrity and Protections: A Bachelor’s degree plus experience or the equivalent experience in a regulatory research field; knowledge of federal, state and local laws and regulations; prior experience of working with institutional and agency officials; supervisory experience; excellent communications skills. A good understanding of the Syracuse University research regulatory system is preferred.

4.1.2 ORIP/IRB Administrator: A Bachelor’s degree or the equivalent experience in a regulatory research field; a general understanding of federal regulations; excellent communications skills.

4.1.3 ORIP/IRB Assistant: Experience in general office work; a willingness to gain a general understanding of federal regulations; excellent communication skills.

4.2 Selection of IRB Staff: The Vice President for Research is responsible for the selection and appointment of the Director of ORIP. The Director of ORIP is responsible for the selection and appointment of the IRB Administrator and Assistant.

4.3 Orientation and training of new office staff members: Once hired the new staff member will:

4.3.1 Receive an orientation by the Director of ORIP or designee. Orientation will include an overview of research at SU, the Office of Research Integrity and Protections, the general IRB policies and an introduction to other ORIP staff.

4.3.2 Be provided a copy of all policies, procedures and forms relating to human participants research. The new staff member will be required to read the documents and to ask questions on anything that is unclear.
4.3.3 Receive instruction from the Director of ORIP or designee on the specifics of the new staff member’s role and the responsibilities within the IRB office.

4.3.4 Each member of the IRB staff is required to complete CITI training which is valid for a period of three years.
   4.3.4.1 IRB staff is required to take the CITI refresher course every three years.

4.3.5 Each member of the IRB staff will attend a PRIM&R and IRB 101 training within the first year of employment.

4.4 Roles and Responsibilities of IRB Office Staff: See SOP 003.

4.5 Evaluation of IRB Roles and Responsibilities: The Director of ORIP will evaluate the ORIP/IRB office staff’s roles and responsibilities through a performance review no less than annually. Periodically, the Director of ORIP will evaluate IRB office staffing to determine if the office has adequate staffing levels to support the needs of the IRB.
SOP 035: REQUIREMENTS FOR IRB OFFICE STAFF EMPLOYMENT

Approved by:

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8/27/10
Date

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Date

27 August 10
Date