Title: ROLES AND RESPONSIBILITIES OF HUMAN RESEARCH PROTECTION PROGRAM STAFF

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline who is responsible for administering the various aspects of the Human Research Protection Program (HRPP) at Syracuse University (SU).

2.0 Policy:

It is the policy of the SU Office of Research Integrity and Protections (ORIP) and the Institutional Review Board (IRB) that the responsibilities of individuals involved in the administration of the HRPP at SU be provided clear direction regarding their job responsibilities to ensure the highest quality service to the SU community.

The ORIP and the IRB operate in complementary roles with the ORIP serving as an administrative body to provide support to the IRB in carrying out its obligations under the federal regulations and other applicable policies and guidelines. The IRB recognizes that its primary responsibility is to protect the rights and welfare of human research participants recruited to participate in research activities conducted by SU investigators through ethically responsible and scientifically valid research, continuous education of the research community, monitoring of research activities, and compliance with the federal regulations and institutional policies and procedures.

3.0 References and Reference Documents:

45 CFR 46.107
45 CFR 46.108
SOP 001, Development, Approval, and Maintenance of Human Research Protection Program Policies and Procedures
SOP 027, Reporting of Unanticipated Problems Involving Risk to Participants or Others
SOP 028, Investigating and Managing Potential Issues of Non-compliance
SOP 034, Institutional Official Responsible for the Human Research Protections Program

4.0 Procedure:

4.1 The **Vice President for Research** is responsible for:

4.1.1 See SOP 034;

4.2 The **ORIP Director** is responsible for:

4.2.1 The preparation and revision of the SOP's. The Director may ask other staff in ORIP to assist in the development of SOP's; (See *SOP 001* for format and instructions).

4.2.2 Assuring that SU is in compliance with federal, state and local regulations through the timely development and implementation of institutional policies and procedures in collaboration with the IRB and other key stakeholders;

4.2.3 The timely dissemination and education of the University community on regulatory requirements and institutional procedures;

4.2.4 All correspondence and communications with parties external to the University;

4.2.5 Developing Memorandum of Understanding with regional partner institutions to foster multi-university collaborative research projects involving human participants;

4.2.6 Acting as the primary contact for questions pertaining to the administrative and regulatory compliance activities of the HRPP;
4.2.7 Making determinations that projects are exempt from review;
4.2.8 Approving non-technical revisions to provisionally approved expedited or full board applications, which the IRB or IRB Chair has designated authorization to the ORIP Director to approve;
4.2.9 Assisting investigators and key study personnel in the appropriate reporting of conflicts of interest and unexpected harms or unanticipated problems;
4.2.10 Providing recommendations to the Vice President for Research regarding the appointment of IRB members;
4.2.11 Reviewing and certifying congruence between Grant Applications & IRB Protocols;
4.2.12 Assisting the IRB Chair in designating primary and secondary reviewers for all applications submitted for full board review;
4.2.13 The selection, appointment, and training of ORIP/IRB Administrator and Office Assistant.

4.3 Under the supervision of the ORIP Director, the **ORIP/IRB Administrator** is responsible for:
4.3.1 Creating and maintaining the IRB calendar;
4.3.2 Meeting preparation including drafting the agenda, assembly of meeting packets, and ensuring a quorum will be in attendance;
4.3.3 Compiling and disseminating IRB meeting minutes (i.e., IRB deliberations, actions and votes);
4.3.4 Recording (in a memorandum) and maintaining all documentation pertaining to reporting noncompliance or unanticipated problems involving risks to participants or others in IRB application files, ORIP office file and *InfoEd* database (See *SOP 027* and *SOP 028*);
4.3.5 Compiling and mailing application materials for full IRB review to IRB members;
4.3.6 Delivering applications or amendments to the IRB Chair received for expedited or exempt review;
4.3.7 Mailing written letters to investigators regarding determinations made by the IRB;
4.3.8 Sending email and letter correspondence notifying investigators of protocol renewal dates;
4.3.9 Serving as a liaison between applicants and the IRB regarding the status of their application;
4.3.10 Assisting and verifying investigators and key study personnel have completed the required IRB training;
4.3.11 Front desk coverage when the Office Assistant is out of the office;
4.3.12 Training of the ORIP/IRB Office Assistant.

4.4 Under the supervision of the ORIP Director, the **ORIP/IRB Office Assistant** is responsible for:
4.4.1 Delivering applications or amendments to the IRB Chair and the IRB Associate Chair received for expedited review;
4.4.2 Mailing written letters to investigators regarding determinations made by the IRB;
4.4.3 Sending email and letter correspondence notifying investigators of protocol renewal dates;
4.4.4 Serving as a liaison between applicants and the IRB regarding the status of their application;
4.4.5 Front desk coverage;
4.4.6 Assisting the ORIP/IRB Administrator and Director as necessary.

4.5 The **IRB Chair** is responsible for:
4.5.1 Providing recommendations to the Vice President for Research regarding the appointment of IRB members;
4.5.2 Reviewing and approving new applications and continuing review applications for expedited review;

4.5.3 Designating primary and secondary reviewers for all applications submitted for full board review;

4.5.4 Sharing in primary and secondary reviews for applications submitted for full board review;

4.5.5 Communicating to all IRB members and ORIP any decisions that need to be made regarding corrective actions or sanctions as a result of noncompliance or an unanticipated problem involving risks to participants or others;

4.5.6 Acting as the primary contact regarding ethical questions or scenarios pertaining to human participants research by investigators;

4.5.7 Serving in an advisory capacity to University officials and faculty with regard to research conducted by investigators from other institutions that does not fall under IRB jurisdiction (e.g., the IRB Chair can provide advice on such matters as the risks and benefits of the proposed research, informed consent, etc.);

4.5.8 Participating in annual training and assisting in the development of IRB Member training.

4.6 The **IRB Associate Chair** is responsible for:

4.6.1 Assisting the IRB Chair in meeting the responsibilities described under IRB Chair.

4.7 The **IRB Members** are responsible for:

4.7.1 Having an understanding of basic ethical principles, the regulatory requirements, and the mechanics of serving on the IRB;

4.7.2 Conducting new and continuing review of research activities according to 45 CFR 46 and when applicable, federal, state and local laws, and institutional policies and procedures;

4.7.3 Conducting primary and secondary reviews of full board applications as designated;

4.7.4 Evaluating the research proposal for both scientific and scholarly merit, including consideration of research design, equitable subject selection process, etc.;

4.7.5 Identifying any conflicts of interest prior to the review of research activities and bringing this to the attention of the IRB Chair;

4.7.6 Obtaining guidance or additional information in order to conduct an adequate review of the application. This may include the request of an additional reviewer or consultant with expertise in the area of research under review;

4.7.7 Requesting additional information, qualification documentation, or licensure to assure the investigator's competence in performing proposed research activities;

4.7.8 Reviewing and making determinations (e.g., approve, provisionally approve, withhold) on applications that contain more than minimal risk;

4.7.9 Determining when more than annual review is required;

4.7.10 Determining when external validation of protocols (including informed consent) is required;

4.7.11 Determining if an unanticipated problem is deemed to be serious and the appropriate actions required by the investigator to protect human participants;

4.7.12 Participate in training and educational opportunities.

4.8 The **Investigator/Faculty Sponsor** is responsible for:

4.8.1 Assuring that human participants research, including research that is conducted by students under the faculty sponsor's supervision, is implemented according to the information presented in the approved application;

4.8.2 Acting as the primary contact for all IRB-related correspondence;

4.8.3 Submitting amendments to the IRB for review and approval prior to initiating any changes in the research protocol;

4.8.4 Submitting continuing review applications prior to the approved application's expiration date;

4.8.5 Immediately reporting any unexpected harms or unanticipated problems to the IRB Chair or ORIP by telephone and following up with a detailed memorandum to the IRB and ORIP;

4.8.6 Prior to submitting applications for review by the SU IRB the investigator will:

4.8.6.1 Meet the required IRB training requirements for human research protections including:

4.8.6.1.1 Completion of the Basic CITI course (valid for three years).

4.8.6.1.1.1 Completion of the CITI refresher course that is required every three years;

4.8.6.1.2 Ensure all research staff listed in the protocol who will have direct contact with the participants and/or identifiable human participant data, have completed the required IRB training appropriate to their role in the research.

4.8.6.1.3 Research cannot be conducted until CITI training requirements have been fulfilled.

4.8.6.2 Disclose any conflicts of interest of the investigator or key study personnel;

4.8.6.3 Assure other investigators and key study personnel are competent and licensed, if applicable, relevant to the scope and complexity of the research conducted;

SOP 003: ROLES AND RESPONSIBILITIES OF HUMAN RESEARCH PROTECTION PROGRAM

Approved by:

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