Title: OFFICE OF SPONSORED PROGRAMS/IRB/ORIP COORDINATION

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for coordinating the internal review of human subjects' protocols and sponsored research agreements involving human participants between the Office of Sponsored Programs (OSP), and the Office of Research Integrity and Protections (ORIP) in administering sponsored research agreements at Syracuse University.

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) and OSP to ensure the protection of human participants involved in sponsored research. OSP and ORIP coordinate activities in significant areas of sponsored research including: proposal submission, when applicable; negotiation of award agreements; negotiation of clinical trial agreements; subaward agreements for off-site research; and suspensions, terminations, and lapses of approval.

3.0 References and Reference Documents:

Syracuse University's Policy on Conflict of Interest for Research Investigators (http://supolicies.syr.edu/fac_teach/conflict_int_pi.htm)

4.0 Procedure:

4.1 Proposal Submission.

4.1.1 Before OSP submits a grant application or contract proposal to an extramural sponsor, the PI completes the OSP Proposal Checklist, clearly indicating the involvement of human subjects, if applicable, and submits it to OSP.

4.1.1.1 The Proposal Checklist includes questions designed to verify whether the project involves human subjects and whether the PI has obtained IRB approval.

4.1.2 The OSP Research Administrator (RA) and Executive Director of Sponsored Programs screens each application/proposal and the associated Proposal Checklist. When OSP review indicates human participants appear to be involved in the project and this is not indicated on the OSP checklist, the PI is contacted and advised to contact ORIP for their determination as to whether the project involves human subjects research. ORIP is copied on this communication. In addition, when appropriate, the RA advises the PI of sponsor requirements for submission of the certification of IRB approval, or mandatory educational requirements, as required by the sponsor. The RA refers the PI to ORIP in cases where the PI requires additional clarification or assistance with human research protections.

4.1.3 When the RA receives the IRB protocol number, OSP staff enters it into the OSP electronic database. OSP codes all proposals involving human subjects in the electronic database, so that OSP or ORIP may generate reports of all research involving human subjects.

4.1.4 The RA submits certifications of IRB approval or mandatory education requirements to the agency in accordance with agency requirements.

4.1.5 The PI indicates on the IRB application whether the project will be /or has been submitted for external funding through OSP. Initial IRB review applications require the PI to provide information on the sponsor.

4.1.6 The OSP RA ensures that PIs and research personnel responsible for the design, conduct, or reporting of sponsored research complete financial disclosure statements and certify that they have read and understand the Conflict of Interest Policy prior to proposal submission.

4.1.7 If OSP review indicates that the PI (or other senior/key personnel) has a financial conflict of interest as indicated by an affirmative "Part II" in the Conflict of Interest (COI) data base, and the proposal checklist indicates human subjects research in a proposed sponsored research project involving human subjects, OSP RA will notify ORIP. In such cases, the Vice President for Research, PI and Director of ORIP assess if a conflict pertains to human subjects research, if so the conflict is noted in the (COI) data base by the Vice President for Research and a plan is developed to manage, reduce, or eliminate the conflict.

4.1.8 OSP facilitates the notification of financial conflicts of interests to sponsors, according to their policy or regulations, by the VP for Research.

4.2 Negotiation of Award Agreements.

4.2.1 OSP provides investigators with up-to-date information on institutional policy in negotiating the terms of sponsored research agreements to ensure compliance with applicable law, university policy, and good business practice. OSP publishes information resources on the OSP web site, including regulatory resources.

4.2.2 Once SU receives an extramural award, the RA reviews the proposed research agreement and negotiates acceptable terms between the sponsor and the institution. The agreement includes provisions for human research protections in compliance with all applicable laws, institutional policies for ethical conduct of research, and the written research protocol. The PI receives a copy of the completed agreement from OSP.

4.2.3 The RA will not accept a research agreement without the administrative approvals, including human subjects protections when applicable, contained in the OSP Proposal Checklist.

4.2.4 The OSP RA includes provisions in the research agreement outlining the plans for disseminating research findings in alignment with SU policies and the roles of the PI and the sponsor in publication or disclosure of research results.

4.3 Establishing Accounts.

4.3.1 Before establishing a new account, the RA reviews all relevant award documentation received from the sponsor and SU internal compliance documentation for accuracy and completeness.

4.3.2 The RA requests a comparison of protocol to proposal. ORIP verifies that the proposal and protocol are congruent using the Protocol v. Proposal Checklist, and verifies that the PI has obtained IRB approval.

4.3.3 Most sponsors will not issue an award for sponsored research involving human subjects or allow expenditure of funds without IRB approval. If, however, all other documents are complete except the certification of IRB approval, and there are project components that clearly and unambiguously do not involve human subjects, with ORIP approval OSP will establish an account for an amount restricted to the costs of the non-human subjects research. OSP communicates with the PI that no expenditures for activities involving human subjects are allowed until the PI obtains IRB approval.

4.3.4 If OSP establishes an account prior to IRB approval, the OSP staff will add a statement to the OSP electronic database: "This account has been established in advance of approval by the IRB. You may not enroll subjects or initiate contact with prospective subjects, prior to obtaining IRB approval."

4.3.5 Once the RA receives the IRB approval letter from the ORIP or the PI, the Grants & Contracts Assistant enters the IRB protocol number in the OSP electronic database. Any award amounts restricted, pending IRB approval, are subsequently released by OSP upon notification by ORIP. Release of restrictions is communicated to Office of Sponsored Accounting, with copies to the PI, and departmental administrators.

4.3.6 SU will not disburse sponsored research funds in the event of an unresolved financial conflict of interest on the part of a PI or other research personnel on a project. (See *Section 4.1.7* above)

4.4 Negotiations of Subaward Agreements for Off-Site Sponsored Research.

4.4.1 OSP staff contact ORIP for advice whenever questions arise in subaward agreements for off-site human research.

4.4.2 Before submitting a grant/contract proposal to an extramural sponsor, the PI completes the OSP Proposal Checklist, checking *yes* if the project uses subcontractors.

4.4.3 OSP makes available to the PI specific forms and standard content/clauses of subaward agreements in the form of templates to facilitate communication and exchange of required information between subrecipients, their non-SU IRBs, and the SU IRB when subcontracted research involves human subjects.

4.4.4 OSP pre-award set up review includes confirmation of receipt of authorized materials from subrecipients or letters of collaboration from outside consultants.

4.4.5 The RA directs the PI to complete the "Request to Issue a Subcontract or Consultant Agreement" form, available from the OSP web site.

4.4.6 The PI completes the "Request to Issue" Form, checks *yes* if the subcontracted portion of the project includes human subjects, attaches a detailed scope of the work to be completed by the subrecipient, and describes the plan for monitoring the subrecipient's performance and reporting. The subrecipient shares responsibility for detailing the scope of work.

4.4.7 OSP uses current versions of the Federal Demonstration Project (FDP) subrecipient for applicable agencies (www.thefdp.org) and also maintains boilerplate templates for other agencies or sponsors not covered by the FDP templates. The PI may obtain the template upon request from the OSP RA.

4.4.8 The RA ensures that the subaward agreement includes clauses which require the subrecipient to abide by all applicable human research regulations and which specify that the subrecipient bears full responsibility for the proper and safe performance of its work and services involving human subjects.

4.4.9 In the subaward agreement, the RA identifies the subrecipient's work under the subaward as involving human subjects by checking *yes* in the blank for that statement.

4.4.10 If the RA checks *yes* indicating that the subrecipient's scope of work involves human subjects, the subrecipient provides documentation to the RA that an IRB has reviewed and approved the work.

4.5 Negotiations of Subaward Agreements for Off-Site Research Sponsored by the Department of Health and Human Services.

4.5.1 If research is federally funded by the Department of Health and Human Services (DHHS), each performance site must independently assure DHHS of its intent to comply with federal regulations for the protection of human subjects. To do so, each site negotiates approval of its own written assurance with the Office for Human Research Protections (OHRP).

4.5.2 The subrecipient templates referenced in 5.4 also include versions applicable to DHHS agencies. The subaward agreement for DHHS-sponsored research involving human subjects includes clauses which require the subrecipient to abide by all applicable human research regulations and which specify that the subrecipient bears full responsibility for the proper and safe performance of its work and services involving human subjects.

4.5.3 If the subrecipient's work involves human subjects, the PI checks *yes* for that statement on the Request to Issue a Subcontract or Consultant Agreement Form. The subaward agreement contains provisions requiring the subrecipient to provide the institution's federally assigned assurance number to the RA along with documentation that an IRB has reviewed and approved the research described in the subagreement scope of work.

4.5.4 For DHHS-sponsored projects, the subrecipient also provides a letter from an IRB representative indicating the date of review/approval and the IRB's federally assigned assurance number to the PI.

4.5.5 The PI is responsible for maintaining current documentation for the entire project throughout the course of the research in accordance with federal requirements.

4.5.6 In the subaward agreement for DHHS-sponsored projects, the subrecipient certifies that his/her institution has a human subjects education program that complies with federal requirements.

4.5.7 The subaward agreement and any subsequent amendments for continued funding also contain a certification statement that the project is under a currently active approval.

4.5.8 The RA confirms that no invoices are processed without an active IRB approval in place; if documentation is not current, the RA obtains from the subrecipient.

4.5.9 If approval has lapsed, the RA informs the PI and the subrecipient that no expenditures are allowed on the subaward during the unapproved period.

4.6 Terminations or Lapses in IRB Approval.

4.6.1 If the IRB terminates IRB approval of a sponsored project due to noncompliance, the ORIP Director provides the OSP Executive Director with a copy of the resulting termination letter.

4.6.2 OSP takes the appropriate action in accordance with the sponsor requirements.

4.6.3 If an IRB approval lapses due to failure of the PI to submit a continuation review application, ORIP staff sends the PI a lapse of approval letter and notifies OSP.

4.6.4 OSP then notifies Office of Sponsored Accounting, the PI, the departmental administrator and any subrecipients or consultants that the award has been frozen and that no expenditures will be allowable during the period between IRB approval termination and reinstatement.

4.6.5 Once OSP is informed by ORIP of IRB approval, OSP informs the Office of Sponsored Accounting, the PI, Departmental administrators and any subrecipeints or consultants that work on the project can again begin. The allowabilty date for expenditures is clearly communicated.

4.7 Continuation of Awards

4.7.1 When IRB protocol is renewed ORIP provides a copy of the IRB approval letter to OSP to forward to the sponsor to assure continuous approval.

4.7.2 When there is a submission of a progress report by OSP or the Investigator, ORIP completes a protocol comparison to assure congruence between the grant and protocol.

4.7.3 In instances of changes, ORIP requests an amendment to the protocol.

Approved by: BR Ware 7-26-07

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