

| SYRACUSE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM STANDARD OPERATING PROCEDURES | | | |
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| TITLE: DEVELOPMENT, APPROVAL, AND MAINTENANCE OF HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES | | | DOCUMENT NUMBER: 001 |
| REVISION NUMBER | REVISION DATE (SUPERSEDES PRIOR VERSION) | DATE FIRST EFFECTIVE | PAGE NUMBER |
| 01 | 08/01/07 | 01/01/2006 | 1 OF 4 |

Title: DEVELOPMENT, APPROVAL, AND MAINTENANCE OF HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline a standardized framework necessary for the consistent development of SOP's including the format for writing SOP's, assigning the SOP number, and tracking SOP's from inception through retention of previous versions.

2.0 Policy:

It is the policy of the Syracuse University (SU) Office of Research Integrity and Protections (ORIP) and the Institutional Review Board (IRB) that all policies and procedures for conducting research activities under its jurisdiction be written and maintained in congruence with Federal regulations, State and local laws, other SU policies and procedures, and standards of regulatory, accrediting, and funding agencies. The written procedures are to be used to guide personnel through various procedural steps and to standardize practices to ensure the protection of human participants in research and promote the responsible conduct of research.

3.0 References and Reference Documents:

None.

4.0 Procedure:

4.1 The ORIP Director is responsible for the preparation and revision of the SOP's. The Director may ask other staff in ORIP to assist in the development of SOP's. The following format must be used when writing SOPs.

4.2 SOP Format.

4.2.1 The SOP will contain a header like the one pasted below with the following information.

| SYRACUSE UNVIERSITY HUMAN RESEARCH PROTECTION PROGRAM STANDARD OPERATING PROCEDURE | | | |
|--|--|----------------------|------------------|
| TITLE: STANDARD OPERATING PROCEDURE FOR SOP'S | | | DOCUMENT NUMBER: |
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4.2.1.1 Title: Title of the SOP.

4.2.1.2 Document Number: Unique number assigned to an SOP. This is a sequential numeric designation. Example: 000

4.2.1.3 Revision Number: Each version of the SOP will have a version number, with

initial version designated as 00 and subsequent versions 01. 02 etc.

- 4.2.1.4 **Revision Date (Supersedes prior versions):** Effective date of the current document.
- 4.2.1.5 **Date First Effective:** The date the SOP initially went into effect.
- 4.2.1.6 **Page x of y:** Where x is the current page of the SOP and y is the total number of pages.
- 4.2.1.7 The last page of the SOP contains the printed name, signature and date of the Vice President for Research, IRB Chair, ORIP Director or other appropriate department head(s). The signatures represent approval of the SOP.
- 4.2.1.8 **Font:** The text of each SOP will be Times New Roman, 11-point font and unjustified. The header box of each SOP will be in Times New Roman, 9-point font.
- 4.2.1.9 **Margins:** The left margin will be 1 inch. The right, top, and bottom margins will all be .5 inch.

4.2.2 **SOP Content.**

- 4.2.2.1 Each SOP will be written with the following section headings. If a heading does not apply to a particular SOP then the heading will be included with the words not applicable or none printed below the section header.
 - 4.2.2.1.1 **Purpose:** Defines the reason for establishing the SOP.
 - 4.2.2.1.2 **Policy:** Describes the associated institutional, legal or safety policy that affects the activities of the SOP.
 - 4.2.2.1.3 **References and Reference Documents**
 - 4.2.2.1.4 **Procedure:** A description of all activities to be performed in following the SOP directions. A short narrative may be included in this section to further explain, provide background or clarify the procedures.

4.2.3 **Creation of New SOPs.**

- 4.2.3.1 The ORIP Director or designee assigns a number and title to the SOP.
- 4.2.3.2 The ORIP Director or designee drafts the SOP and distributes the draft to the designated reviewers to review.
- 4.2.3.3 The ORIP Director revises the draft SOP and if necessary convenes a meeting of the reviewers to discuss the requested revisions.
- 4.2.3.4 The ORIP Director or designee ensures all terms and definitions are listed in the glossary.
- 4.2.3.5 The ORIP Director or designee prints the final version on bond paper for signature.
- 4.2.3.6 The ORIP Director or designee distributes the original of the final SOP to each signatory.
 - 4.2.3.6.1 The signature of the Vice President for Research, IRB Chair, ORIP Director or other appropriate department heads indicate review and agreement with the content of the SOP.
- 4.2.3.7 Once signed and approved, the SOP is added to the IRB Standard Operating Procedure Master Binder under the control of the ORIP Director.
- 4.2.3.8 The ORIP Director files the original signed SOP in the master file and distributes controlled copies to the staff of ORIP and the IRB Chair.
- 4.2.3.9 An electronic uncontrolled copy of the SOP is stored on the shared drive in a folder labeled IRB SOPs to access when revisions or reviews of the SOP are needed, and electronic copies are uploaded onto the ORIP website for investigators to reference.

4.2.4 **Revisions of SOPs.**

- 4.2.4.1 Revisions of an SOP are warranted in two situations, when the ORIP Director or the IRB Chair determines that a change in the procedures is necessary to

minimize deviations to the stated procedure or when federal regulations and guidance, state or local laws are amended that necessitate a revision in the procedures.

4.2.4.2 The ORIP Director or designee revises the SOP, assigns a revision number, and distributes the draft to the other signatories to review.

4.2.4.3 The ORIP Director or designee then follows the procedures in 4.2.3.3-4.2.3.9.

4.2.5 Review of SOPs.

4.2.5.1 Each SOP will be reviewed annually in July.

4.2.5.2 The ORIP Director or designee mails or delivers a copy of the SOP to the signatory officials with a Scheduled Review Notice that states that the SOP is up for annual review and failure to respond to the notice within 30 days of the review date will result in the SOP being automatically renewed without revisions for one year.

4.2.5.3 If one of the signatory officials returns the letter stating that either the SOP is obsolete or revisions are needed, then the ORIP Director or designee will make the requested revisions and proceed with steps 4.2.3.3-4.2.3.9.

4.2.6 Distribution and Control of SOPs.

4.2.6.1 ORIP is responsible for the distribution and control of all SOPs.

4.2.6.2 ORIP maintains an IRB Standard Operating Procedure Master Binder that is kept in a designated secure place with access limited to ORIP personnel. The Master file contains:

4.2.6.2.1 The original of all current, previous and obsolete SOP versions.

4.2.6.2.2 Records regarding the distribution of controlled copies (who and when).

4.2.6.2.3 Records of retrievals and disposals.

4.2.6.3 ORIP Director or designee disseminates controlled copies of the SOPs to all ORIP staff members, the IRB Chair, Associate Chair, or members if the SOP involves their activities as listed in the procedure.

4.2.6.4 ORIP Director or designee is responsible for ensuring that previous and obsolete copies are retrieved and destroyed.

4.2.7 Training on SOPs.

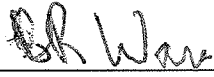
4.2.7.1 ORIP is responsible for training the applicable individuals on the SOPs.

4.2.7.1.1 Applicable individuals include the IRB Chair, staff of ORIP and any other individuals or offices if the SOP involves their activities.

4.2.7.2 ORIP will document the training of all applicable individuals in the IRB Standard Operating Procedure Master Binder.

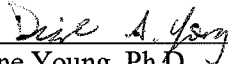
SOP 001: DEVELOPMENT, APPROVAL, AND MAINTENANCE OF HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES

Approved by:




Ben Ware, Ph.D.
Institutional Official
Vice President for Research and Dean of the Graduate School
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7-19-07
Date



Diane Young, Ph.D.
Chair of the Institutional Review Board
Syracuse University

7-25-07
Date



Tracy Crompton, M.S.W.
Director of Office of Research Integrity and Protections
Syracuse University

7-29-07
Date