

**SYRACUSE UNIVERSITY  
HUMAN RESEARCH PROTECTION PROGRAM  
STANDARD OPERATING PROCEDURES**

<b>TITLE: IRB OF RECORD</b>		<b>DOCUMENT NUMBER: 039</b>	
<b>REVISION NUMBER</b>	<b>REVISION DATE (SUPERSEDES PRIOR VERSION)</b>	<b>EFFECTIVE DATE</b>	<b>PAGE NUMBER</b>
00		06/30/10	1 OF 2

**Title: IRB OF RECORD**

**1.0 Purpose:**

The purpose of this Standard Operating Procedure (SOP) is to describe the Syracuse University (SU) policy and procedure for establishing the provisions under which the SU IRB will serve as the IRB of Record for an external site engaged in research.

**2.0 Policy:**

When SU serves as the IRB record, it is accepting the responsibility of oversight of the conduct of the research for a particular site. The details of such an agreement are outlined in the Memo of Understanding (MOU) Template.

**2.1 Basis for SU to serve as the IRB of Record**

- 2.1.1 The performance site engaged in research will rely solely on SU IRB for review of human subjects research activities; or
- 2.1.2 The performance site engaged in research may or may not have an IRB of Record, but will rely on the SU IRB for a specific research project

**3.0 References and Reference Documents:**

45 CFR 46

Memo of Understanding Template

**4.0 Procedure:**

**4.1 Memorandum of Understanding (MOU).**

- 4.1.1 A MOU between the relevant parties will outline specific provisions and responsibilities for each party entering into the agreement.
- 4.1.2 The MOU must be reviewed, approved and signed by the Institutional Official and the appropriate official of the external performance site.

**4.2 The performance site.**

- 4.2.1 The performance engaged in research requesting SU IRB to serve as the IRB of Record must:
  - 4.2.1.1 File a Federalwide Assurance (FWA): and
  - 4.2.1.2 Conduct the research in accordance with the terms and conditions specified in the MOU

**4.3 The Investigator.**

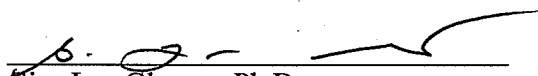
- 4.2.1 The Investigator and external sites will abide by all SU policies and procedures (completing the IRB forms, training, reporting).
- 4.2.2 The Investigator must provide all necessary information pertaining to local research activities conducted at external sites in accordance with SU IRB policies and procedures.
- 4.2.3 Investigators will comply with all oversight activities seemed appropriate by the IRB, Federal oversight agencies and federal funding agencies at all sites (e.g. monitoring).
- 4.2.4 The Investigator or representatives from the external site must provide to the IRB phone numbers of local contact persons who can make decisions regarding IRB issues.

**4.3 Federalwide Assurance (FWA).**

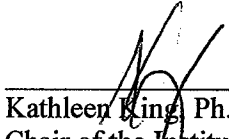
- 4.3.1 SU and the external performance site will maintain an approved FWA.

**SOP 039: IRB OF RECORD**

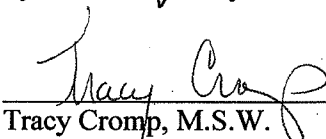
Approved by:

  
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Gina Lee-Glauser, Ph.D.  
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Syracuse University

6-14-10  
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Date

  
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Kathleen King, Ph.D.  
Chair of the Institutional Review Board  
Syracuse University

11 June 2010  
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Date

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

6-11-10  
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Date