Title: THE INSTITUTIONAL OFFICIAL’S AUTHORITY AND RESPONSIBILITIES

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to describe the authority and responsibilities of Syracuse University’s Institutional Official.

2.0 Policy:
It is the policy of Syracuse University that the Institutional Official (IO) is the University point of contact with DHHS Office for Human Research Protections (OHRP), is the signatory for the Federal-wide Assurance (FWA), and bears ultimate responsibility for ensuring University compliance with the federal requirements. By the authority of the Chancellor and President, Syracuse University’s Institutional Official is the Vice President for Research.

3.0 References and Reference Documents:
45 CFR 46.107, IRB Membership

4.0 Procedure
4.1 Specific Responsibilities of the Institutional Official include:
4.1.1 The oversight of all research activities at Syracuse University;
4.1.2 Designating one or more IRBs that will review research covered by the institution’s FWA;
4.1.3 Appointing IRB members in consultation with the IRB Chair and ORIP Director in order to ensure that the composition of the IRB meets the requirements set out in 45 CFR 46.107;
4.1.4 Providing sufficient resources, space, and staff to support the IRBs review and record keeping duties;
4.1.5 Providing training and educational opportunities for the IRB and investigators;
4.1.6 Playing a leadership role in establishing and implementing the Human Research Protections Program, reviewing and approving IRB policies and procedures, and maintaining authority over these policies and procedures;
4.1.7 Setting the “tone” for an institutional culture of respect for human participants;
4.1.8 Ensuring effective institution-wide communication and guidance on human participants research;
4.1.9 Ensuring that investigators fulfill their responsibilities for ethical conduct of research involving human participants;
4.1.10 Encouraging all staff engaged in the conduct or oversight of human participant research to participate in education activities; and
4.1.11 Delegating an appropriate individual to serve as a knowledgeable point of contact for OHRP.
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Date: 12 July 2007