

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.004
<b>Effective Date:</b> 6/23/06	<b>Page 1 of 3</b>	<b>Replaces Policy Dated:</b> 1/23/06
<b>Description:</b>	Responsibilities	

#### **A. The Institutional Official**

Sunrise Health has an approved [FederalWide Assurance \(FWA\)](#) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The FWA has been signed by an individual with the legal authority to represent the institution. This individual is referred to as the Institutional Official (IO).

The Institutional Official understands the institution's responsibilities under the FWA, assures the protection of human subjects of research, and assures that the IRB is knowledgeable about the local research context and will comply with the terms of the FWA. The FWA has been approved by OHRP and is updated as necessary when information changes.

The Institutional Official is responsible for:

- Setting the "tone" for the institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human subjects issues;
- Ensuring that investigators fulfill their responsibilities;
- Facilitating participation in human subject education activities; and
- Serving as a knowledgeable point of contact for OHRP.

Administratively, the Institutional Official is responsible for:

- Appointing IRB Chairpersons;
- Providing the IRB with necessary resources and staff; and
- Supporting the authority and decisions of the IRB.

#### **B. Department Chairs/Chiefs**

Department chairs/chiefs are responsible for ensuring that the PI is qualified by training and experience to conduct the proposed research, including applicable institutional credentialing and privileging requirements.

#### **C. Investigators**

Primary responsibility for protecting the rights and welfare of human subjects participating in research rests with the principal investigator (PI). The PI must have a medical staff appointment or be an employee of a Sunrise Health institution, and may not be a resident, fellow, or trainee. Authorized agents of an

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institution with which Sunrise Health has entered into an Affiliation Agreement may serve as PI for Social and Behavioral research under these policies and procedures. Agents wishing to conduct Biomedical research must go through the Medical Staff Office procedures to establish appropriate privileges. For each protocol submitted to the IRB for approval, the PI must certify that s/he accepts responsibility for assuring adherence to applicable federal and state research regulations and Hospital policies relative to the protection of the rights and welfare of subjects enrolled in the research.

Principal investigators must be qualified by training and experience to conduct the research and must be in compliance with the Sunrise Health IRB Conflicts of Interest Policy. The PI's department chair or chief or his/her designee must review and sign the submission to the IRB. The department chair/chief's signature on the IRB submission signifies that the PI has the necessary qualifications to be the PI for the study. When the research involves the administration of a drug or use of a device for research purposes, the PI must be a licensed physician. Exceptions to this requirement will be made only on a case-by-case basis where there are licensed physician co-investigators.

PI's may delegate responsibility to appropriately qualified co-investigators and research staff. Co-investigators and research staff must be qualified by training and experience to perform these responsibilities and must be in compliance with the Sunrise Health Conflicts of Interest Policy. It is the responsibility of the PI to complete the submission paperwork and obtain signatures, or to designate an authorized agent (i.e., a Research Coordinator) to complete the process. Research sponsors cannot be designated as authorized agents.

Effective January 1, 2007, all research staff must submit evidence of current Human Subjects Protections training with each new submission.

#### **D. Sunrise Health Office of Research Compliance**

The Sunrise Health Office of Research Compliance is responsible for assisting the institution and investigator in fulfilling their human-subjects research responsibilities through compliance with Federal and State regulations governing human research and for promoting an environment in which human subjects research will be conducted according to the highest standards. The Sunrise Health Office of Research Compliance accomplishes these goals through on-site assessments, review of self-assessments completed by investigators, and education.

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The Sunrise Health Office of Research Compliance is responsible for and has the authority to:

- Perform routine review of any study that has been approved by the Sunrise Health IRB; and
- Conduct directed (for-cause) audits at the request of the Sunrise Health IRB or the Institutional Official.