

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.005
<b>Effective Date:</b> 07/19/2007	<b>Page</b> 1 of 4	<b>Replaces Policy Dated:</b> 6/23/2006
<b>Description:</b>	Management of the IRB	

**A. Management and Support Staff**

Human research activities are overseen by the Vice President of Quality who reports to the Institutional Official. Specifically, the Vice President of Quality is responsible for overseeing the Sunrise Health IRB and the Office of Research Compliance.

The IRB is supported by the following administrative staff:

- Manager, Office of Research Compliance
- Research Compliance Analyst(s).

**B. IRB Chairperson**

The IRB Chair is selected and appointed by the Institutional Official and/or The Board of Trustees. The Chair is generally selected from among experienced members of the Sunrise Health IRB and as such is familiar with regulatory requirements and ethical considerations. There is no term limit placed on length of service. The Chairperson is provided with orientation and training and is highly encouraged to attend at least one IRB-related regional or national conference every two years.

**C. IRB Chairperson Responsibilities**

The IRB Chairperson is responsible for:

- Presiding at IRB meetings during which initial and continuing review of research activities involving human subjects is conducted;
- Conducting initial and continuing review of research activities involving human subjects that may be approved through the expedited review procedure;
- Reviewing (and approving) modifications required by the IRB at convened meetings to secure approval;
- Determining exempt status of research involving human subjects;
- Participating in the development of human subjects research policies and procedures;

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.005
<b>Effective Date:</b> 07/19/2007	<b>Page 2 of 4</b>	<b>Replaces Policy Dated:</b> 6/23/2006
<b>Description:</b>	Management of the IRB	

- Fulfilling biennial human subjects protection continuing education recommendations, including attendance at conferences, workshops, seminars, or lectures pertaining to human subjects research; and
- Performing other activities, as needed, to fulfill institutional responsibilities set forth in the FWA or at the request of the Institutional Official.

**D. Comments and Suggestions from the Research Community**

Open communication between the research community and the Sunrise Health IRB is encouraged and welcome. Investigators and members of the research community may suggest improvements in any aspect of the human subject protection program by submitting suggestions in writing, by email or by telephone to the Chair of the IRB. Suggestions will be considered by the appropriate IRB administrative staff and responded to by one of the above or his/her designee.

**E. Complaints from the Research Community**

Investigators and members of the research community may submit in writing or by email complaints about any aspect of the human subject protection program to the IRB Chair. Complaints will be reviewed by the Chair, and when relevant, by the Vice President of Quality. Serious complaints may be referred to the Institutional Official, who may at his/her discretion appoint an ad hoc committee to review the complaint and report findings and recommendations, if any, to the IO and Vice President of Quality for further consideration and/or implementation.

**F. Complaints from Research Participants**

Every IRB-approved consent form provides research participants with the telephone number of the IRB office if s/he wishes to speak to someone not directly involved in the research. Written or telephone complaints from subjects are handled by the Manager of the Office of Research Compliance or the IRB Chairperson.

The IRB staff provides the subject or his/her representative with a safe and confidential means to discuss research-related concerns with someone unaffiliated with the research protocol. The IRB staff makes reasonable efforts to protect the identity of the subject and not release his/her name in any communication with the investigator or others unless permission to do so has been given or there is a safety issue requiring disclosure. The IRB staff may involve others, as necessary, in the resolution of the concern or complaint,

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.005
<b>Effective Date:</b> 07/19/2007	<b>Page</b> 3 of 4	<b>Replaces Policy Dated:</b> 6/23/2006
<b>Description:</b>	Management of the IRB	

including, but not limited to the Principal Investigator (or his/her representative), Patient Accounts, Accounts Payable, the Chair of the IRB, and the Vice President of Quality. The Vice President of Quality may involve the Principal Investigator's Clinical Department Head, Risk Management, legal counsel and the Institutional Official if the concern or complaint involves serious allegations about the manner in which the research is being conducted.

**G. Allegations of Regulatory Noncompliance or Scientific Misconduct**

Allegations of regulatory noncompliance are managed by the Sunrise Health IRB as described elsewhere in this policy. Allegations of scientific misconduct are referred to the investigator's department chair/chief and Medical Staff Office for fact finding, further actions as required, and decisions regarding professional privileges.

**H. Signatory Authority**

The Chair and Vice-Chair are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects, which have been reviewed and approved pursuant to Sunrise Health IRB policies and procedures. This policy applies to all staff of the IRB. In all cases individuals must sign their own name and no other and indicate their title under their signature.

Specific Policies

- Authorization for Signatory Authority

Authorization to sign documents not described in this policy may be made in writing by the Chief Executive Officer.

- Results of Reviews, Actions and Decisions

The results of reviews and actions taken by the IRB, either by the full IRB or by expedited review, that grant or may appear to grant investigators with initial or continuing approval of research, training or educational projects involving human subjects, may be signed by designated IRB staff members. Designated staff member to perform this function is the Manager, Office of Research Compliance.

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.005
<b>Effective Date:</b> 07/19/2007	<b>Page 4 of 4</b>	<b>Replaces Policy Dated:</b> 6/23/2006
<b>Description:</b>	Management of the IRB	

- Routine Internal Correspondence

Any action, letters, memos or emails between the IRB, and/or members of the staff of Sunrise Health that provides information concerning the review of research protocols by the IRB or staff which do not imply or appear to imply approval of this activity, may be signed by designated IRB staff members. Designated staff members to perform this function are Manager, Office of Research Compliance and Research Compliance Analyst.

- Routine External Correspondence

Any letters, memos or emails between the IRB, and/or members of the research community that provide information concerning the review of research protocols by the IRB staff which do not imply or appear to imply approval of this activity, may be signed by designated IRB staff members. Designated staff members to perform this function are Manager, Office of Research Compliance and Research Compliance Analyst.

- Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the Chief Executive Officer or the IRB Chair.

- Decisions Made by Chairperson

Any letters, memos or emails sent representing the decision or opinions of the Chairperson of the IRB or his/her respective designees, as long as such correspondence does not imply review and approval of research projects, may be signed by designated IRB staff. Designated staff members to perform this function are Manager, Office of Research Compliance and Research Compliance Analyst.