

DEPARTMENT: Research Compliance		Reference# IRB.015
Effective Date: 6/23/2006	Page 1 of 4	Replaces Policy Dated: 1/24/2005
Description:	Cooperative Research	

A. NCI CIRB Protocols

The Sunrise Health Institutional Review Board (SHIRB) is a participating member of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) (FWA00002195). The CIRB's primary function is *initial and continuing review of protocols*. The Sunrise Health IRB's primary function is *consideration of local context and oversight of local performance* of these protocols.

The responsibilities of the CIRB are to:

1. Perform initial review of new research studies, discuss any issues with the lead organization and Study Chair, and make a final decision of approval or disapproval of the study;
2. Maintain and make accessible to a designated local IRB at the local institution the CIRB application, protocol reviews, letters to Study Chairs, approvals and disapprovals, and minutes of the CIRB meetings;
3. Carry out Continuing Reviews, reviews of submitted Serious Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the lead organization or Study Chair;
4. Notify each local institution that has accepted the CIRB review of any new materials that have been reviewed for an active study and any changes in the study approval status;
5. Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CFR 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each study;
6. Make available to the local institution the roster of CIRB membership and the CIRB Standard Operating Procedures and policies;
7. Provide CIRB members with proper initial and continuing education on topics relevant to human subjects protections;
8. Notify the local institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review studies; and

DEPARTMENT: Research Compliance		Reference# IRB.015
Effective Date: 6/23/2006	Page 2 of 4	Replaces Policy Dated: 1/24/2005
Description:	Cooperative Research	

9. Notify the local institution of any CIRB policy decisions or regulatory matters that might affect the institution's reliance on CIRB reviews or performance of the research at the local institution.

The Sunrise Health IRB will rely on the NCI CIRB to fulfill the above-stated responsibilities.

The Sunrise Health Institutional Review Board will:

1. Ensure the safe and appropriate performance of the research at its institutions. This includes, but is not limited to, monitoring study compliance, major protocol violations, and any serious adverse events occurring at Sunrise Health sites, and provide a mechanism by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas will be shared with the CIRB and reported as required by the procedures established by the protocol's lead organization.
2. Ensure that the investigators and other staff at Sunrise Health who are conducting the protocol are appropriately qualified and meet Sunrise Health's standards for eligibility to conduct research.
3. Notify the CIRB immediately if there is a suspension or restriction of a local investigator.
4. Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the SHIRB.
5. Establish a procedure by which the Sunrise Health IRB will receive and review the CIRB materials for protocols to be performed at Sunrise Health sites. For each CIRB reviewed protocol that is submitted to the SHIRB by a local investigator:
 - Review the CIRB's materials
 - Determine if there are any local context issues that must be addressed by the SHIRB.
 - Decide whether to accept the CIRB review or to conduct a separate local IRB review.

DEPARTMENT: Research Compliance		Reference# IRB.015
Effective Date: 6/23/2006	Page 3 of 4	Replaces Policy Dated: 1/24/2005
Description:	Cooperative Research	

- Report to the CIRB the decision about local acceptance/non-acceptance of the CIRB review.
 - Notify the CIRB if there is ever a change in the acceptance/non-acceptance of the CIRB.
6. As appropriate, add local restrictions, stipulations, or substitutions to CIRB approved informed consents. Deletion of CIRB approved requirements in the protocol and Informed Consent Form is not allowed, and substantive changes that affect the meaning of CIRB approved requirements are not allowed.
 7. If the Sunrise Health IRB accepts the CIRB approval of a protocol, the SHIRB will maintain, in the study binder, documentation of the decision and evidence that SHIRB has received and considered all CIRB material relevant to the protocol.
 8. Maintain an OHRP approved Assurance for human subjects research.
 9. Maintain the SHIRB membership to satisfy the requirements of 45 CFR 46.
 10. Maintain a human subjects protection program, as required by the DHHS OHRP.
 11. Ensure that SHIRB members and local investigators receive proper initial and continuing education on the requirements related to human subjects protections.
 12. Notify the CIRB immediately if there is ever a suspension or restriction of SHIRB's authorization to review studies; and
 13. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

DEPARTMENT: Research Compliance		Reference# IRB.015
Effective Date: 6/23/2006	Page 4 of 4	Replaces Policy Dated: 1/24/2005
Description:	Cooperative Research	

B. IN THE ABSENCE OF AN EXISTING IRB AUTHORIZATION AGREEMENT

In order for a patient being admitted to a Sunrise Health Facility to continue on an investigational study with current external IRB approval, prospective Sunrise Health IRB notification must occur.

The following documentation must be submitted to the Sunrise Health IRB office:

1. Investigational protocol or relevant pertinent information regarding patient safety (i.e., dosing, preparation, administration, expected adverse events, reversal agents);
2. Current signed patient informed consent, a copy of which is to be placed on the patient's medical record;
3. IRB approval letter on IRB letterhead demonstrating current approval of the study;
4. Brief patient history to include current diagnosis, if applicable.