



DEPARTMENT: Research Compliance		Reference# IRB.001
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AUTHORITY

The Institutional Review Board of Sunrise Health derives its authority from the Board of Trustees. The responsibility for the protection of the rights and welfare of human subjects is shared both by the Institution and the Investigators conducting the research.

A. SCOPE OF AUTHORITY

The IRB is responsible for the review and approval of all human-subjects research that is conducted under the auspices of Sunrise Hospital and Medical Center, Sunrise Children's Hospital, MountainView Hospital, and Southern Hills Hospital and Medical Center.

Review by the Sunrise Health IRB or another IRB authorized by Sunrise Health is required when:

- The research is sponsored by Sunrise Health;
- The research is conducted by or under the direction of employees or agents of Sunrise Health in connection with their institutional responsibilities;
- The research is conducted by or under the direction of any employee or agent of Sunrise Health using any property or services of Sunrise Health; or
- The research involves the use of Sunrise Health's private information to identify or contact subjects.

The Sunrise Health IRB (SHIRB) is also responsible for the review of innovative diagnostic and therapeutic activities that involve human subjects, research involving non-living individuals that would otherwise meet the definition for human subjects research, and research activities that qualify for exemption from the Common Rule as outlined in [45CFR46.101\(b\)\(1-6\)](#).

The Sunrise Health IRB has the authority to:

- Determine exemptions from [45CFR46](#);

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- Approve, require modifications in (to secure approval of), or disapprove research activities involving human subjects;
- Require progress reports from investigators;
- Oversee the conduct of research;
- Require a third party to observe the consent process;
- Suspend or terminate approval of a study;
- Place restrictions on a study;
- Conduct reviews and inquiries regarding research activities as needed to obtain information necessary for the fulfillment of the institutional responsibilities outlined in the OHRP-approved FWA.

The Sunrise Health IRB and relevant ancillary committees or departments must approve all human research activities prior to initiation of the research. The decision of the IRB to disapprove human research cannot be overruled by any other institutional body or individual(s); however an investigator may appeal the decision of the IRB in writing directly to the IRB Chair. The Chair reviews the appeal and schedules the appeal for review at a convened meeting of the IRB.

B. Relationship of Other Institutions to the Sunrise Health IRB

Institutions outside Sunrise Health may rely on the Sunrise IRB if there is an executed IRB Authorization Agreement (or Inter-Institutional Agreement) in effect between the outside institution and the Sunrise IRB. The decision of whether to rely on the Sunrise IRB for review of a particular protocol is made jointly by the Chairperson of the Sunrise IRB and the Chairperson of the collaborating institution's IRB. Both must agree that it is acceptable to rely upon the Sunrise IRB for initial and continuing review of the research in accordance with the terms and conditions of the Agreement. When acting as the IRB of record, the Sunrise IRB sends the site responsible principal investigator and designated institutional representative copies of IRB correspondence. Copies of relevant IRB Minutes are provided to the designated institutional representative, upon written request.

D. Dual IRB Oversight

Under authority granted by the Board of Trustees of Sunrise Hospital and Medical Center, the IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding

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duplication of effort as allowed and upon modification of the institutional Federal –Wide Assurance agreement (FWA). Any such arrangement must be documented mutually by both IRB's utilizing the written agreement for dual IRB oversight.