

DEPARTMENT: Research Compliance		Reference# IRB.008
Effective Date: 1/23/2006	Page 1 of 2	Replaces Policy Dated:
Description:	Functions of the IRB	

The Sunrise Health IRB (SHIRB) is responsible for the following:

- Determining exemptions from 45 CFR 46 in accordance with [45 CFR 46.101\(b\)\(1-6\)](#); Conducting initial and continuing review of research activities, including scientific review;
- Determining that risks to subjects are minimized;
- Determining that risks to subjects are reasonable in relation to anticipated benefits;
- Determining that selection of subjects is equitable;

Determining that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [45 CFR 46.116](#) and when applicable [21 CFR 50.25](#)

- Determining that informed consent will be appropriately documented, in accordance with, and to the extent required by [45 CFR 46.117](#) and when applicable [21 CFR 50.27](#);
- Determining that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- Determining that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- Determining that, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included to protect vulnerable subjects (i.e., pregnant women, human fetuses and neonates, prisoners and children) in accordance with 45 CFR 46 Subparts B, C, and D and when applicable 21 CFR 50 Subpart D.
- Determining which device studies pose significant vs. non-significant risk, in accordance with guidance provided by the FDA;
- Determining which device studies require review more often than annually;

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- Determining which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
- Reporting in writing the findings and actions of the IRB to the investigator and the institution;
- Ensuring prompt reporting to the IRB of changes in research activities;
- Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and
- Ensuring prompt reporting to the IRB, appropriate institutional official, OHRP and the FDA of (1) unanticipated problems involving risks to subjects or others, (2) serious or continuing noncompliance with regulations governing research involving human subjects or the requirements of the IRB; and (3) suspension or termination of IRB approval.