

**Memorandum of Understanding
JSC Institutional Review Board (IRB)
and
NASA Payload Safety Review Panel (PSRP)**

Version dated: March 19, 2014

Purpose

To define and clarify the joint responsibilities of the JSC Institutional Review Board (IRB) and the NASA Payload Safety Review Panel (PSRP) in reviewing NASA-sponsored experiments involving human research subjects. The IRB shall combine their biomedical expertise with the technical expertise and engineering capability of the PSRP in an effort to ensure that NASA-sponsored experiments involving human research subjects (i.e., human physiology experiments) are safe.

Roles and Responsibilities


1. The role of the physicians, human physiologists, and other professional support personnel of the IRB in ensuring the safety of human test subjects for in-flight and NASA-sponsored ground-based experiments is as follows:
 - a. The IRB shall review, from a biomedical perspective, all human research protocols for potential hazards and hazard controls with respect to all in-flight and NASA-sponsored ground-based experiments. The IRB will ensure that all credible hazards are identified and are adequately controlled. Potential hazards and their controls to be addressed by the IRB include excessive (intentional) electrical shock, ultrasound, personal fatigue, adverse effects of drugs or injectable solutions, excessive collection of blood, or other single or combined physiological stress factors.
 - b. The IRB or their appointed representative shall establish safe physiological limits for intentionally applied electrical, ultrasound, laser, and other types of electromagnetic impulses to the various parts of the body, as required for a given experiment system.
 - c. The IRB shall be responsible for ensuring that a planned sequence of human experiments does not create excessive risk or other adverse effects for the test subjects.
 - d. The IRB through the Safety and Mission Assurance Directorate (NA) representative shall verify that all ground-based human research (experiment) hardware is safe for use in human surroundings in accordance with JPG 1700.1 (JSC Safety and Health Handbook)..
2. The role of safety engineering support and other support persons of the PSRP in this joint responsibility to ensure crew safety are as follows:


- a. The PSRP shall review the design and operation of payload experiment hardware for compliance with the safety requirements in SSP 51700, "Payload Safety Policy and Requirements for the International Space Station." The PSRP will ensure that all identified hazards are adequately controlled, and that these controls have been adequately verified.
- b. The PSRP shall forward to the IRB for their resolution any potential hazard identified at a payload safety review that requires the biomedical expertise of the IRB to determine its risk potential. This will help the PSRP confirm that controls for this hazard are adequate.
- c. The PSRP shall send to the IRB requests for the establishment of physiological limits for ultrasound, electrical shock, and other physiological stresses that could result from either planned use or a malfunction during use of the equipment. These physiological limits will be used by the PSRP in determining whether the design and controls on the equipment items under review are adequate.

3. Joint roles and responsibilities between the IRB and PSRP:

- a. The IRB and PSRP shall be jointly responsible for ensuring the safety of all equipment used in human in-flight research. In this context, the IRB shall rely on the PSRP to review the design and operation of all custom-made equipment and modifications of off-the-shelf devices that could be hazardous to the in-flight test subjects or nearby participants in an experiment.

To facilitate the flow of information between the IRB and the PSRP, each group will be informed of the deliberations and actions of the other group regarding human research experiments of common interest to both groups via coordination/communication by the respective representative(s) from the Human Health and Performance Directorate (JSC/ISA).


 Michael R. Surber/OE Date
 ISS Safety Manager
 Safety & Mission Assurance /
 Program Risk Office


 Duane L. Pierson, Ph.D./SA Date
 Chairman
 JSC Institutional Review Board (IRB)

INFORMATIONAL NOTE:

The name of the JSC Institutional Review Board (IRB) was changed from the JSC Committee for the Protection of Human Subjects (CPHS). The name change was announced at the June 21, 2012 board meeting and recorded in the minutes (see excerpt below.)

1.	IRB Website "What's New" Update http://irb.nasa.gov/?c=what'sNew
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- Retire "Committee for the Protection of Human Subjects"
 - In order to promote our core capabilities and position us for the future, it is important that we use the same terminology as the Code of Federal Regulations, other NASA Centers, and universities. For this reason, we will resume use of the term Institutional Review Board (IRB), and retire the reference to the Committee for the Protection of Human Subjects (CPHS).