

National Aeronautics and Space Administration

**Headquarters**

Washington, DC 20546-0001



July 8, 2014

Reply to Attn of:

Chief Health and Medical Office

TO: Distribution

FROM: Chief Health and Medical Officer

SUBJECT: Institutional Review Boards (IRB) Policy Clarification

REF: NPD7180.8E of 31, May; 2012 , updated 12/18/12 and  
NPR7100.1 updated 6, June, 2014

Ref. (1) establishes and sets policy for IRB review for the protection of Human Research subjects volunteering to participate in NASA-sponsored Human Research protocols.

Occasionally, confusion arises over the IRB's responsibility with respect to operational test and verification. The IRB could find that the IRB is reviewing operational test protocols which fall outside the realm of Human Research. Once the Agency has decided to pursue a development program to support Human Space, it has determined that the risk/development supports the Agency's goals. Programmatic development is ordinarily outside the purview of the IRB unless it collects data on human subjects for research or development. Any tests involving Human subjects are required to follow standard test readiness reviews with appropriate system reviews.

IRB chairs should consider the following guidelines before reviewing operational test protocols. The IRB only needs to review engineering human-in-the-loop proposals that are clearly research, i.e., fit the definition of human subject and research. The definitions are listed below:

**Research**

A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d)

**Human Subject**

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. 45 CFR 46.102(f)

**Intervention**

Physical procedures and manipulations of the subject's environment performed for research purposes.

**Interaction**

Interaction includes communication or interpersonal contact between investigator and subject.

**Private Information**

Private Information is information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

**Definition of Human Research**

Data from living individuals

Biological material from living individuals

Interaction or intervention with a living individual

There are clearly engineering tests that do not fall within the above definition of research in which the health and safety of the human-in-the-loop will be either approved or monitored by non-IRB officials. In general, safety monitoring of humans-in-the-loop is not research. Areas of activity may include: 1) Training either with no monitoring of the individual or monitoring for safety reasons in accepted situations. An example: NBL training. (Although crew are monitored for heart rate, etc., this is clearly for safety purposes). 2) Testing of equipment in which the equipment is being tested, not the operator even if the operator is monitored for safety. Examples: an astronaut participating in an Egress test on an operational vehicle; an employee turning on a new machine, preparing and trying out procedures for operations, etc.; and a test pilot obtaining a data point about a research aircraft.

There are also times when the engineering test will fall under the above definitions and an IRB review is required. Examples include: Employees and/or others are asked/required to try on a space suit and describe its mobility while their physiologic parameters are being measured; the test pilot noted above is also instrumented and physiologic data is being obtained for non-safety issues.

There is a large "grey" area where such R&D could/should be considered research and when a person should be considered a research subject. It is recommended that the IRB discuss with appropriate NASA officials (e.g., engineering) and agree in advance which types of "human-in-the-loop" work should not be considered research, which should be, and how to handle those activities that may be considered in the "grey" area.

In those areas that are not defined as research, normal test readiness reviews should consider the risk and safety of all proposed operational tests and verification. NASA medical personnel and Human System Integrators should normally be a part of that review.

While the memo does not cover all situations, I am emphasizing that: 1) not all “human-in-the-loop” engineering activity should automatically be considered research requiring IRB review and approval; 2) the activity must fulfill the requirements of the definitions above for it to undergo IRB review and approval; and 3) a general or specific agreement between the IRB and concerned entities performing “human-in-the-loop” work would be appropriate and helpful. This should allow for appropriate initial screening of applications to the IRB. Unresolved questions should be addressed to the appropriate NASA Center local lead or the Office of the Chief Health and Medical Officer for review and determination.

A handwritten signature in black ink, appearing to read "R. Williams", followed by a horizontal line.

Richard S. Williams, MD, FACS

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