

National Aeronautics and
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July 30, 2008

Reply to Attn of SA4-08-01

TO: Distribution

FROM: SA4/ Chair, Committee for the Protection of Human Subjects

SUBJECT: Committee for the Protection of Human Subjects (CPHS) Guidelines on
Subject Protections Requirements for Human-in-the-Loop Hardware Tests
and Evaluations

During the past few years, and especially during the past 3-6 months, the Johnson Space Center (JSC) CPHS has received numerous questions from personnel within and external to the Space Life Sciences Directorate about CPHS requirements for review and approval of hardware tests and evaluations where human test subjects are required to interface in some manner with the hardware being tested. These tests do not involve human research of the type normally reviewed by the CPHS but have the potential of exposing test subjects to some amount of risk to their safety and well-being.

The attached guidelines were developed by a sub-committee of the CPHS for application to human-in-the-loop hardware tests and evaluations at JSC. The guidelines are intended to ensure the safety and well-being of the test subjects, and to ensure that subjects are informed about all of their rights as defined by Federal and NASA regulations that govern human subject protections in such data collection activities. These guidelines are in addition to requirements that must be met for Test Readiness Reviews.

The guidelines address test subject medical qualification, informed consent, and medical monitoring. A new informed consent form approved by the JSC Legal Office representative to the CPHS and an outline for preparing a Layman's Summary description of the test are included with the guidelines.

It is important for users of these guidelines to recognize that hardware tests and evaluations may expose test subjects to risks that range from those that are very minimal to those that are potentially severe. In cases where it has been determined that the hardware test involves minimal risk, the test protocol can be reviewed and approved in an expedited manner by the CPHS Chair provided that the enclosed CPHS guidelines have been met. In cases where greater than minimal risk is involved (i.e., "reasonable risk") the test protocol may be reviewed and approved in an expedited manner by a sub-committee of the CPHS. In cases where the hardware test requires that test subjects be exposed to a high level of physiological stress to achieve the objectives of the test, a review by the full committee will be required. The CPHS will make every reasonable

effort to review and approve hardware test protocols in a timely manner in order to accommodate hardware test schedules. However, principal investigators and project managers of hardware tests must likewise submit review materials, including documentation regarding test subject medical qualification, to the CPHS in a timely manner.

These guidelines are effective upon the date of their distribution. General questions about these guidelines may be addressed to the CPHS Chair or Deputy Chair. Questions concerning test subject medical qualification should be addressed to the NASA Manager of the JSC Human Test Subject Facility. Documentation required by the guidelines should be sent to the CPHS Executive Secretary to process for CPHS review.

Original signed by,

Jerry. L. Homick, Ph.D.
Chair, JSC CPHS

Enclosure

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CPHS Guidelines on Subject Protections Requirements for Human-in-the Loop Hardware Tests and Evaluations

The following material represents a summary of JSC Committee for the Protection of Human Subjects (CPHS) requirements for the conduct of tests and evaluations where the primary focus of the project is to gather data on the performance of the hardware and not the human subject. These are tests where human subjects are required because the hardware cannot be evaluated without a human using or donning the hardware.

The primary intent of CPHS involvement in tests and evaluations of this type is to ensure that appropriate measures have been taken to properly medically qualify the human subjects involved, that the subject's informed consent to participate has been obtained, and that appropriate medical monitoring of the activity is implemented.

CPHS requirements are in three primary areas:

Test Subject Medical Qualification

The basic position of the CPHS is that all test subjects are required to annually complete an Air Force Class III physical examination or equivalent, preferably at the Building 37 Human Test Subject Facility (HTSF). Test subjects who have received a physical examination clearance from the Building 8 Occupational Health Clinic must provide a copy of the exam findings and lab reports to the HTSF for HSTF physician review prior to the subject being cleared for participation in a hardware test. For any exam completed in the Building 8 clinic, the HTSF will require that an updated medical history and other forms be filled out by the test subject. Any subsequent changes in the test subject's medical history must be reported to the HTSF prior to participation in a hardware test. The HTSF physician may require additional medical evaluations based on his or her review of the Building 8 records. Although test subjects must keep their HTSF physical exam clearances current on an annual basis, clearances to participate in any given hardware test must also be obtained on an individual case-by-case basis.

Exceptions to the requirement for an annual Air Force Class III equivalent medical clearance may be made for tests or evaluations where very minimal risk to the test subject is involved and the activity would be defined by the CPHS as requiring only Level 4 medical monitoring. In these cases, other types of physical examinations performed in the Building 8 Clinic may suffice as long as copies of the medical records are provided to the HTSF physicians for review. However, investigators must realize that such exams will typically not be sufficient for any of their other hardware tests involving higher levels of risk.

The HTSF does not need to recruit test subjects from the HTSF-qualified pool if the investigators already have their own qualified test subjects. However, in all cases, the investigators will need to submit a test subject request form, a copy of the CPHS approval letter, and a copy of the Layman's Summary to the HTSF.

Test Subject Informed Consent

The individual who is designated as the Principal Investigator for the hardware test or evaluation is required to give each subject an informed consent briefing that describes the procedures and conditions to which the subject will be exposed. This briefing must include a complete description of all potential hazards or discomforts associated with the test or evaluation and the measures that will be taken to mitigate the hazards and discomforts. In addition to a verbal briefing, the Principal Investigator must provide to the subject an informed consent form for his or her signature, and a Layman's Summary must accompany the informed consent form.

- **Informed Consent Form**

Because existing informed consent forms that are in the CPHS "Redbook" were designed to apply to ground-based or space flight human research, they are not suitable in their present form for use in studies where the primary purpose is to test or evaluate hardware performance and not collect data on the human. For this reason a new informed consent form has been developed by the CPHS with guidance from the JSC Legal Office. A copy of this new informed consent form is attached (Appendix A). The CPHS requires that after receiving an informed consent briefing, this consent form be read and signed by all human subjects who volunteer to participate in hardware test and evaluation projects. This consent form and the Layman's Summary (see following paragraph) that must accompany the consent form will ensure that the subjects are properly informed about all of the protections to which they are entitled as defined by Federal regulations.

- **Layman's Summary**

An outline of the information that must be included in the Layman's Summary is attached (Appendix B). The Layman's Summary may be limited to 2-3 pages of carefully worded text.

Medical Monitoring

The Principal Investigator shall propose the required level(s) of Medical Monitoring for the hardware evaluation protocol. The JSC CPHS will thereafter evaluate the proposed level(s) and guide any necessary changes.

The following levels of medical monitoring are recognized by the CPHS:

Level 1

- Typically for invasive or highly provocative procedures or for protocols that require maximal aerobic exertion
- Physician with current ACLS training is present at the time of the test and is actively monitoring the test subject.
- A crash cart is available in the immediate vicinity of the test
- Two personnel with current BLS-AED training are present during testing

- Quarterly emergency drills are conducted by the investigator team
- Protocol Compliance Officer is made aware of the test and emergency drill schedules

Level 2

- Typically for modestly provocative procedures carrying more than minimal risk such as those that require sub-maximal aerobic exertion of >85% of maximum predicted heart rate or oxygen consumption (VO₂)
- Physician with current ACLS training is able to reach the testing area within two minutes
- A crash cart is available in the immediate vicinity of the test.
- Two personnel with current BLS-AED training are present during testing
- Quarterly emergency drills are conducted by the investigator team
- Protocol Compliance Officer is made aware of the test and emergency drill schedules

Level 3

- Typically for procedures that carry less risk than Level 2 procedures, for example those that require sub-maximal aerobic exertion of <85% of maximum predicted heart rate or VO₂
- Physician with current ACLS training is available within 15 minutes of notification
- Two BLS-AED certified personnel can respond to the test site within two minutes
- An AED is located nearby and available for use within two minutes

Level 4

- Typically for minimal risk procedures
- Physician is aware of the specific testing and is available for telephone consultation

For certain protocols and other human-in-the-loop hardware evaluations, for example those that are conducted at remote terrestrial locations wherein an ACLS-certified physician may not always be readily available or wherein none of the above levels of Medical Monitoring readily apply, the CPHS will assign the required level(s) of Medical Monitoring on a case-by-case basis.

Definitions:

Advanced Cardiac Life Support (ACLS) refers to a set of clinical interventions for the urgent treatment of cardiac arrest and other life threatening medical emergencies, as well as the knowledge and skills to deploy those interventions. The physician must possess a valid and current ACLS certification issued by the American Heart Association in order to be considered ACLS certified.

Automated External Defibrillator (AED) refers to a portable electronic device that automatically diagnoses the potentially life threatening cardiac arrhythmias of ventricular fibrillation and ventricular tachycardia, and is able to treat them through defibrillation, the application of electrical therapy which stops the arrhythmia, allowing the heart to re-establish an effective rhythm.

Basic Life Support (BLS) is a basic level of pre-hospital medical care provided by trained responders, including in the absence of advanced medical care. The American Heart Association (AHA) BLS program requires individuals to take a refresher or renewal course every two years in order to be considered currently certified.

Crash Cart refers to a collection of medical equipment, medications, and supplies used to provide resuscitation to an individual. While traditionally a "crash cart" is a wheeled storage chest, the more important feature is that all material necessary to perform resuscitation are readily available to the advanced clinician. Onsite at JSC, responsibility for maintaining JSC crash carts and training all medical personnel in the use of equipment lies with the Occupational Medicine and Test Support Group.

APPENDIX A – INFORMED CONSENT FORM

NASA/JSC INFORMED CONSENT
FOR EQUIPMENT TESTING INVOLVING HUMANS

1. I, the undersigned, to voluntarily give my informed consent for my participation as a test subject in the following study, test, investigation, or other evaluation procedure:

NAME OF INVESTIGATION _____

PRINCIPAL INVESTIGATOR _____

RESPONSIBLE NASA PROJECT SCIENTIST _____

I understand or acknowledge that:

- (a) This procedure is part of an investigation approved by NASA.
- (b) I am performing these duties as part of my employment with _____
- (c) This equipment test has been reviewed and approved by the JSC Committee for the Protection of Human Subjects (CPHS) which has also determined that the investigation involves _____ risk to the subject.
(minimal or reasonable)

(d) Definitions:

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the equipment test are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Reasonable risk" means that the probability and magnitude of harm or discomfort anticipated in the equipment test are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the equipment test.

"Equipment Testing Involving Humans" means that new or modified equipment or hardware that is to be worn or used by humans is being tested and/or evaluated under this protocol. Human subjects are required for the testing and evaluation of this equipment because the human interaction with the equipment is an integral part of the system being tested and/or evaluated.

- (e) The equipment test procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my satisfaction. A layman's description was provided to me.**
- (f) I am medically qualified to participate in the testing of this equipment.
- (g) I know that I can refuse to participate in the equipment tests at any stage of their performance, and my refusal will be honored, except in those cases when, in the opinion of the responsible physician, termination of the tests could have detrimental consequences for my health and/or the health of other subjects. I further understand that my withdrawal or refusal to participate in the testing of this equipment will not result in any penalty or loss of benefits to which I am otherwise entitled.

- (h) In the event of physical injury resulting from the testing of this equipment which calls for immediate action or attention, NASA will provide or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedure.
- (i) Except as provided for any Agency-approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result of my participation as a test subject for the testing of equipment shall be maintained so that no data may be linked with me as an individual.

I understand, however, that if a "life-threatening" abnormality is detected, the investigator will notify me and the JSC Occupational Medicine Clinic. Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my professional (flight) status.

Signature

Signature:

Test Subject

Date

Witness

Date

2. I, the test subject designated above, do further understand that the responsible Principal Investigator designated above for the equipment test in which I am participating, must meet the following elements as a condition for valid authorization for disclosure of my protected data:
 - (a) Provide specific and meaningful description of the types of information to be used or disclosed.
 - (b) Identify the person(s) or class of persons who will be allowed the use of my protected data.
 - (c) Identify the person(s) or class of persons to whom the institution may release my protected data.
 - (d) A description of the purpose of the requested use or disclosure of my protected data.
 - (e) Provide an explanation indicating that the use or disclosure of my protected data will be used until the end of the testing of this equipment.

Signature

Signature

Test Subject

Date

Principal Investigator

Date

3. I, the Principal Investigator of the investigation certify that:
 - (a) I have thoroughly and accurately described the equipment test and procedures to the test subject and have provided him/her with a layman's description of the same.

- (b) The test setup involves _____ risk to the test subject. All equipment
(minimal or reasonable)
be used has been inspected and certified for safe and proper operation.
- (c) The test subject is medically qualified to participate.
- (d) Except as provided for by Agency-approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result of the test subject's participation in this equipment test shall be maintained so that no data may be linked to him/her as an individual.
- (e) The test protocol has not been changed from that originally approved by the JSC CPHS .

Signature

Signature:

Principal Investigator

Date

NASA Project Scientist

Date

Notes:

* A signed, dated copy of this form with attachments must be forwarded to Chairperson, Johnson Space Center Committee for the Protection of Human Subjects , Mail Code SA4, Lyndon B. Johnson Space Center, Houston, Texas 77058.

**A detailed description of the equipment test will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required of him/her and the risks associated therewith.

The detailed description of the test must, at a minimum, include the following:

- (1) An explanation of the purposes of the test and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject, including, but not limited to, possible adverse reactions of all medications to be administered and any risks/hazards resulting from exposure to ionizing radiation;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the test;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) Clarification of all forms of behavior, if any, interdicted by the test protocol (e.g., exercises, diet, medications, etc.); and
- (7) An explanation of whom to contact for answers to pertinent questions about the equipment testing, test subjects' rights, and whom to contact in the event of an injury related injury to this test.

When appropriate, the following information shall also be provided in the detailed description:

- (8) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

- (9) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (10) Any additional costs to the subject that may result from participation in the equipment testing;
- (11) The consequences of a subject's decision to withdraw from the test, and procedures for orderly termination of participation by the subject;
- (12) A statement that significant new findings developed during the course of the test which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (13) The approximate number of subjects involved in the equipment testing.

APPENDIX B – LAYMAN’S SUMMARY OUTLINE

Must be submitted in a narrative format. Consistent grammar tense (first or second person) is required.

Purpose:

Include a brief explanation of the purpose of the test /evaluation, the procedures to be followed, and the number and source of the test subjects to be used.

Risks and Discomforts:

Include a description of any reasonably foreseeable risks or discomforts to the test subjects.

Benefits:

Include a description of any benefits to the subject or to others which may reasonably be expected from the test activity.

Alternative Procedures:

Disclose appropriate alternative procedures, if any, that might be used in lieu of the proposed test procedures.

Constraints/Restrictions:

Identify any constraints or restrictions imposed on the test subject by the test protocol (e.g., exercises, diet, medications, etc.)

Confidentiality/Privacy of Records:

Use the following statement:

"Except as provided for Agency approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result of my participation as a test subject in this test shall be maintained such that no data may be linked with me as an individual. In the event of any publications resulting from this test, no personally identifiable information will be disclosed without my prior consent unless required by law. I understand, however, that if a life threatening abnormality is detected, I will be counseled by the investigator and medical monitor appropriately."

Compensation in the Event of Injury:

Use the following statement:

"I understand that in the event of physical injury resulting from my participation in this test and calling for immediate action or attention, NASA will provide or cause to be provided, the necessary treatment. I understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA, or any third party, from any future liability, which may arise from, or connected with, the above procedures."

C-9 Aircraft Airworthiness Statement:

If applicable, include the following statement:

"Since the C-9 is considered to be a public aircraft within the meaning of the Federal Aviation Act of 1958, as amended, and as such does not hold a current airworthiness certificate issued by the Federal Aviation Administration, any individual manifested to board the C-9 should determine before boarding the whether their personal life or accident insurance provides coverage under such conditions."

Point of Contact:

Provide an explanation of who to contact for answers to pertinent questions about the test subjects' rights, and who to contact in the event of injury to the test subject.

Voluntary Participation:

Use the following statement:

"I understand that my participation in this test is completely voluntary and that I am free to withdraw my consent and terminate my participation at any time by notifying the investigator. I also understand that my withdrawal from this test will be entirely without penalty and will not affect my participation in future studies."

Date: _____

Subject's Signature: _____

Date: _____

Investigator's Signature: _____