

NASA/JSC HUMAN RESEARCH INFORMED CONSENT

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

NAME OF INVESTIGATION _____

FLIGHT TO WHICH ASSIGNED _____

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 research study 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 research 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 research 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 research.

“Protected Research Data” means that the individually identifiable research data maintained or shared will be protected.

- (e) The research 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 investigation.
- (g) I know that I can refuse to participate in the 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 this investigation 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 this study and calling 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 research subject in this study 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 Flight 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 research investigation for which I am participating, must meet the following elements as a condition for valid authorization for disclosure of my protected research 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 research data.
- (c) Identify the person(s) or class of persons to whom the research institution may release my protected research data.
- (d) A description of the purpose of the requested use or disclosure of my protected research data.
- (e) Provide an explanation indicating that the use or disclosure of my protected research data will be used till the end of the research study.

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 research investigation 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 study 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:

* This form is valid for the period including preflight, in-flight, and postflight data collection sessions for the mission. Before the first baseline data collection, the Principal Investigator will repeat the briefing concerning risks involved in the investigation. 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 SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

** A detailed description of the investigation 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 research must, at a minimum, include the following:

- (1) An explanation of the purposes of the research 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 research;
- (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 research protocol (e.g., exercises, diet, medications, etc.); and
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

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 research;

- (11) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (12) A statement that significant new findings developed during the course of the research 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 study.