



NASA Procedural Requirements

COMPLIANCE IS MANDATORY

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Request Notification of Change (NASA Only)

Subject: Protection of Human Research Subjects (Revalidated 6/26/14)

Responsible Office: Office of the Chief Health & Medical Officer

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CHAPTER 4. Informed Consent

4.1 Principle Investigator

4.1.1 Except as provided in section 4.6 below, no PI may involve a human subject in research covered by this NPR unless the PI has obtained the informed consent of the subject or the subject's legally authorized representative, and done so under the following conditions:

- a. Such consent will be sought only under circumstances that provide the prospective subject, or the subject's representative, with sufficient latitude and opportunity to decide whether or not to participate, while minimizing the possibility of coercion or undue influence.
- b. All information that is provided will be in language understandable to the subject or the representative.
- c. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases, or appears to release the PI, the sponsor, the institution, or its agents from liability for negligence.

4.2 Elements of Informed Consent

4.2.1 The following basic elements of informed consent information shall be provided to each subject in nontechnical, easily understood language:

- a. A statement that explains that the study involves research; 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.
- b. A description of foreseeable risks or discomforts to the subject.
- c. A description of any benefits to the subject, or to others that may reasonably be expected from the research, or a statement that the research is of no benefit to the subject.
- d. A disclosure of appropriate alternative procedures or courses of action or treatment that could be advantageous to the subject.
- e. A statement describing the extent to which confidentiality of records identifying the subjects will be maintained. (Special attention should be given to explaining the problem of maintaining confidentiality with electronically stored databases.)
- f. For research involving more than minimal risk, an explanation as to whether any compensation and medical assistance are available if injury or illness occurs and, if so, of the specifics relating thereto and any other relevant information.

- g. Identification of contacts for answers to pertinent questions concerning specifics of the research and the research subject's rights. The contact in the event of a research-related injury or illness to the subject should also be identified.
- h. Except as provided in sections 4.4. b and 4.4.d below, a statement that participation is voluntary, and that subjects have the right to refuse to participate and to discontinue participation in the research at any time and that they may do so without penalty or loss of benefits to which they would be otherwise entitled. If the subject, in fact, cannot withdraw at any given time, because it would be unwise, dangerous, or impossible, the circumstances must be explained to the subject in writing as part of the informed consent document.
- i. Subjects concerned about protocol violations may request a meeting with the relevant IRB Chair or designated IRB member.

4.3 Withdrawal From Research

4.3.1 Consideration for withdrawal from non-space-based research shall be guided by the following:

- a. Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.
- b. In the event that a subject withdraws from non-space flight research involving human subjects, NASA reserves the right to replace that individual with another test subject.

4.4 Consideration for Withdrawal from Space-based Research

4.4.1 Consideration for withdrawal from space-based research shall be guided by the following:

- a. Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.
- b. In the event that the research subject is a crewmember, withdrawal from research may result in removal of that individual from that mission if all of the following conditions are met:
 - (1) The IRB-approved life science experiment is part of the central or core function of the mission.
 - (2) The crewmember was clearly and completely informed of the experiment prior to assignment to the mission.
 - (3) The crewmember formally consented to participate in the experiment.
 - (4) No substantial change has occurred in the protocol since the crewmember's consent.
 - (5) No new interim scientific information has surfaced indicating that the initial protocol presents a more than minimal increase in health or medical safety risk and no new, safer techniques have become available.
 - (6) This action will be based on the determination that it is in the best interest of the Government and to ensure mission success.
- c. The determination of whether all conditions in section 4.4.1 b have been met will rest with the IRB that approved the initial protocol. In the case of NASA or international astronauts, or payload specialists, a review will be conducted by the ANO to validate the findings of the IRB under section 4.4.1 b and formulate a recommendation. Approval of the recommendation and final disposition resides with the AA for Human Exploration Operations Mission Directorate in consultation with the mission-sponsoring organization.
- d. When a crewmember has withdrawn and all conditions in section 4.4.1 have been met, such withdrawal will not influence career opportunities; however, it could be used in the decision process regarding assignments to a future mission in which similar life science experiments are central or core to the mission.

4.5 Other elements of Informed Consent

4.5.1 Additional elements of informed consent may include one or more of the following elements of information:

- a. 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.
- b. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.
- c. Any additional monetary costs to the subject that may result from participation in the research.
- d. The consequences of a subject's decision to withdraw from the research and prescribed procedures for an orderly termination of participation by the subject.
- e. A statement that the subject will be informed of significant new findings developed during the course of the

research, including adverse reactions of other subjects participating in this research, which may affect the subject's willingness to continue participation.

- f. The approximate number of subjects in the study.
- g. Any collective impact of multiple protocols, if applicable.
- h. PI disclosure of financial interest in the research study, to include the benefits the PI will derive from the study, or drugs or devices being developed through the study.

4.6 Waiver

4.6.1 An IRB may consider waiver of elements of informed consent and may approve a consent procedure that either does not include or otherwise alters some or all of the elements of informed consent set forth in this NPR; or the IRB may waive the requirements to obtain informed consent, provided that the IRB shall find and document each of the following:

- a. The research involves no more than minimal risk to the subjects.
- b. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- c. The research could not practically be carried out without the waiver or alteration.
- d. The subjects will be provided with additional pertinent information after participation.
- e. Published or released astronaut data and other human experimental data derived from or associated with such approved research will not be attributable to any individual.

4.7 Disclosure of Information

The informed consent requirements in this NPR shall not preempt any applicable Federal, State, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

4.8 Emergency Medical Care

Nothing in this NPR limits the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable Federal, State, or local law.

4.9 Documentation and Retention

Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed and dated by the subject or the subject's legally authorized representative. The PI will keep the original signed consent for at least 3 years after the completion or termination of the research protocol; and a copy shall be given to the person signing the form. The PI will make the signed consent form available to the IRB for inspection and copying.

4.10 Forms

4.10.1 The informed consent form will be either of the following:

- a. A written consent document containing the elements of informed consent required in chapter 4 of this NPR. This form may be read to the subject or the subject's legally authorized representative, but in all instances, the PI shall give either the subject or the representative adequate opportunity to read, understand, ask questions, and consult with additional experts if so desired before it is signed.
- b. A "short form" written consent document stating that the elements of informed consent required in chapter 4 has been presented orally to the subject, or the subject's legally authorized representative. When this method is used, there will be an independent witness to the oral presentation.
- c. The IRB shall approve a written summary of that which is to be said to the subject or the representative. Only the "short form" itself is to be signed by the subject or the representative. However, the witness will sign both the "short form" and a copy of the summary. The person actually obtaining the consent may sign a copy of the summary. A copy of the summary will be given to the subject or the representative, in addition to a copy of the "short form."

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