

| [NODIS Library](#) | [Program Formulation\(7000s\)](#) | [Search](#) |



NASA Procedural Requirements

NPR 7100.1

Effective Date: March 28, 2003

Expiration Date: March 28,
2019**COMPLIANCE IS MANDATORY**

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

Responsible Office: Office of the Chief Health & Medical Officer

TABLE OF CONTENTS

Change History

Preface

- P.1 PURPOSE
- P.2 APPLICABILITY
- P.3 AUTHORITY
- P.4 APPLICABLE DOCUMENTS AND FORMS
- P.5 MEASUREMENT/VERIFICATION
- P.6 CANCELLATION

CHAPTER 1. Responsibilities

- 1.1 Authorized NASA Official (ANO)
- 1.2 NASA Center Directors
- 1.3 Center IRBs
- 1.4 NASA Contracting Officers (NCO)
- 1.5 Academic Institutions, Nonprofit Institutions, or Business Enterprises

CHAPTER 2. NASA Institutional Review Boards (IRB)

- 2.1 IRB Authority
- 2.2 Membership
- 2.3 Conflict of Interest
- 2.4 Meetings
- 2.5 Documentation and Preparation
- 2.6 Required Documents
- 2.7 Retention, Accessibility, and Inspection of Records

CHAPTER 3. NASA Flight IRB

- 3.1 Function
- 3.2 Center Designation and Meeting Location
- 3.3 Membership
- 3.4 Health and Safety Monitor
- 3.5 NFI Review Guidance
- 3.6 Conformance

CHAPTER 4. Informed Consent

- 4.1 Principle Investigator
- 4.2 Elements of Informed Consent
- 4.3 Withdrawal from Research
- 4.4 Consideration for Withdrawal from Space-based Research
- 4.5 Other Elements of Informed Consent
- 4.6 Waiver
- 4.7 Disclosure of Information
- 4.8 Emergency Medical Care
- 4.9 Documentation and Retention
- 4.10 Forms

CHAPTER 5. Criteria for IRB Approval of Research Involving Human Subjects

- 5.1 Approval Requirements

CHAPTER 6. Expedited Review

- 6.1 Expedited Review Process

CHAPTER 7. Research Mishaps, Adverse Events, Injuries, Illness, and Disease and Medical Care

- 7.1 Mishap/Adverse Event Reporting and Investigation
- 7.2 Medical Care and Reporting

CHAPTER 8. Documentation of Informed Consent

- 8.1 Modification of Protocol
- 8.2 Reporting and Approval

CHAPTER 9. Assurances from Participating Institutions

- 9.1 Multiple and Single Project Assurances (MPA and SPA)
- 9.2 IRB Review and Approval
- 9.3 Term of MPA
- 9.4 Evaluation and Reporting
- 9.5 Site Visit
- 9.6 Factors for Approval
- 9.7 Noncompliance

CHAPTER 10. Sanctions and Potential Disciplinary Action

- 10.1 Determination of Sanctions and Potential Disciplinary Action

Appendix A. Definitions

Appendix B. Acronyms

Appendix C. Information Portion of a NASA Human Subject Research Proposal

Appendix D. Types of Research Activities That May Be Reviewed Through Expedited Review Procedures

Appendix E. Guidance for Human Research Subject Mishap Investigation by an IRB

Appendix F. Multiple Project Assurance Compliance Oversight Procedures

NPR 7100.1, Protection of Human Research Subjects w/Change 1 (07/07/08)

Chg #	Date	Description/Comments
1	07/07/08	Admin changes to correct deletions/changes in punctuations, misspelled words, and changing NPG to NPR.
2	6/25/14	Admin changes to bring into 1400 compliance, also note that the brevity of the revised document from the original NPR was the result of consolidation of requirements and reorganization of text to make the language more concise and specific, added Appendix B Acronyms, and renumbered Appendix C and Appendix D. Appendix F was originally Chapter 15.

Preface

P.1 PURPOSE

a. This NASA Procedural Requirements(NPR) outlines the implementing procedures and guidelines for the Agency to conduct or support research involving human subjects. These guidelines follow the provisions of "Federal Policy for the Protection of Human Subjects" as codified for NASA in Title 14 CFR Part 1230 and for the U. S. Department of Health and Human Services (DHHS) in Title 45 CFR Part 46. These regulations are implemented by the DHHS, Office for Human Research Protections (OHRP).

b. The primary intent of these guidelines is to provide instructions on setting up oversight protection for the rights, medical safety, and well-being of human subjects involved in research. This will cover all volunteers who participate in any research utilizing NASA facilities, including NASA aircraft and spacecraft, directed by NASA personnel or onsite contractors, and in any NASA-conducted or supported research.

P.2 APPLICABILITY

a. This NPR is applicable NASA Headquarters (HQ), and all NASA Centers and Component Facilities and Technical and Support Centers, engaged in experiments involving human subjects conducted or supported by NASA, conducted in NASA facilities, aircraft and spacecraft, or which involve NASA to any degree. The terms and conditions of this NPR, as applicable, are required to be incorporated in any contract, space act agreement, cooperative agreement, grant, or reimbursable arrangement, which involves human subject research entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity.

b. Any reference to Center Director(s) includes the Executive Director for Headquarters Operations, and the Executive Director of the NASA Shared Services Center.

c. All mandated actions (i.e., requirements) are denoted by statements containing the term "shall." The terms "may" or "can" denote discretionary privilege or permission, "should" denotes a good practice and is recommended, but not required, "will" denotes expected outcome, and "are/is" denotes descriptive material.

P.3 AUTHORITY

a. 51 U.S.C. 20113(a), The National Aeronautics and Space Act, as amended.

b. 14 CFR Part 1230, Protection of Human Subjects.

c. 45 CFR Part 46, Protection of Human Subjects.

d. NPD 7100.8, Protection of Human Research Subjects.

P.4 REFERENCES

a. 5 U.S.C. 552a, The Privacy Act of 1974, as amended.

b. NPR 1441.1D, NASA Records Retention Schedules.

c. NPD 8621.1H, NASA Mishap and Close-Call Reporting, Investigating, and Recordkeeping Policy.

P.5 MEASUREMENT/VERIFICATION

Adherence to this NPR will be measured through strict tracking of requirements outlined herein and detailed in NASA NPD 7100.8, Protection of Human Research Subjects. In general terms, for all NASA-sponsored research involving human subject, the requirements will include verification of accreditation and certifications, regular monitoring of research activities and sanctions imposed, and corrective actions taken.

P.6 CANCELLATION

NPR 7100.1, Protection of Human Research Subjects, dated March 28, 2003.

**REVALIDATED 6/25/14 WITH CHANGE 2, ORIGINAL
SIGNED BY: /s/ Richard Williams, M.D. FACS
Chief Health and Medical Officer**

CHAPTER 1. Responsibilities

1.1 Authorized NASA Official (ANO):

1.1.1 The NASA Chief Health and Medical Officer (CHMO) is the Authorized NASA Official (ANO) and shall be responsible for the protection of human subjects. All or part of the authority may be redelegated, without power of further redelegation, to (a) a senior NASA HQ employee who reports to the ANO, or (b) the NASA Center Director(s).

The ANO shall be responsible for:

- a. Informing the Administrator, the appropriate Associate Administrators (AA) sponsoring research involving humans, and the AA for the Office of Safety and Mission Assurance (OSMA), through official channels, of significant actions, problems, or other matters of substance related to the exercise of this authority.
- b. Approving all NASA Center Multiple Project Assurances (MPA) or Single Project Assurances (SPA), indicating that NASA-conducted or -sponsored research complies with NASA policy and the body of existing law pertaining to research involving human subjects.
- c. Approving each NASA Center's annual summary of the research and Institutional Review Board (IRB) activities for the preceding year including review of compliance activities, membership, initial and continuing education, and an updated IRB membership list.
- d. Developing and administering a NASA Human Protection Training program for IRB members and investigators that is congruent with requirements for Federal funding by DHHS. This or similar training will be mandatory for all NASA IRB members and investigators using human subjects receiving NASA funds or involved in NASA-sponsored research.

1.2 NASA Center Directors

1.2.1 NASA Center Directors shall be responsible for:

- a. Ensuring that their MPA is filed with the ANO. For NASA Center Directors not filing an MPA or SPA, the Center Director must certify to the ANO that research involving human subjects will not be conducted or sponsored by that Center during the following calendar year.
- b. Establishing a Center IRB to review all ground-based, aerospace, and aeronautical flight research that their respective Centers conduct or that utilize NASA facilities, equipment, or personnel (NASA-conducted or -sponsored research). If this is not done, then another NASA IRB, by prior arrangement, will review the research proposals using human subjects.
- c. Appointing the members of the Center IRB and selecting a full-time, senior-level NASA employee as the Chairperson.

1.3 Center IRBs

1.1.3 The Center IRBs are responsible for:

- a. Protecting the rights and ensure the safety of every person who is a research subject in any NASA facility, including NASA aircraft or spacecraft. This applies to subjects involved in any research conducted or supported by NASA.
- b. Reviewing all proposals for NASA-conducted or -sponsored, ground-based, aeronautical, and space flight research (applies to the NASA Flight IRB (NFI) only, chapter 3), that apply to human subjects prior to funding, approval, or execution of research. Except when an expedited review procedure is used, this review of proposed research will be held only at convened meetings at which a majority of the members of the IRB are present including at least one member whose primary concerns are in a nonscientific area. For the research to be approved by the IRB, it will receive the approval of a majority of those members present at the meeting. If human subjects are to participate in multiple research protocols at the same time, the IRB shall review all the research proposals as an integrated protocol to assess the risks and benefits to the research subject.
- c. Conducting a continuing review of research involving humans at intervals appropriate to the degree of risk, but not less than once per year. This continuing review shall include the informed consent particulars, the adequacy of safety precautions taken to date, and a determination as to whether or not proper and comprehensive information was given to the subject during the process.
- d. Reviewing all adverse events (whether expected or not), which occur during the conduct of research. In all cases in which there has been an adverse incident reported to the IRB, the IRB shall notify the appropriate NASA safety and legal representatives, the ANO, and other AA's.
- e. Defining for each approved experiment the extent to which the actual consent process and/or the conduct of the research will be monitored. If monitoring is deemed necessary, this may be accomplished by appointment of a monitor with specified responsibilities or direct monitoring by selected members of the IRB.
- f. Maintaining documentation of IRB activities as prescribed in Chapter 2 of this NPR.
- g. Reviewing and monitoring non-NASA research using NASA facilities, equipment, or personnel involving human subjects.
- h. Reviewing human-used, ground-based simulators. The IRB shall determine the potential risks of the simulator operations to the research subjects. The IRB may then determine that all or some of the operations in the simulator may be IRB exempt, requires expedited review or requires full IRB review.
- i. Investigating research subject mishaps resulting in an injury or illness to an individual or individuals (i.e., Type C, D, or CC mishaps per NPR 8621.1) according to processes established by the Institutional Review Board (IRB) approving the human research study, following the guidance provided in Chapter 7 and Appendix E.

1.4 NASA Contracting Officers (NCO)

1.1.4 The NCO shall be responsible for:

Ensuring that all research proposals involving human subjects (including grants, contracts, cooperative agreements, memoranda of understanding, or other similar legal arrangements) are reviewed by an approved IRB prior to funding. The NCO shall maintain a record of all such IRB approvals.

1.5 Academic Institutions, Nonprofit Institutions, or Business Enterprises

1.1.5 Academic institutions, nonprofit institutions, or business enterprises performing NASA-funded research involving human subjects at non-NASA facilities, and not involving NASA permission to use Government equipment, will be responsible for:

Obtaining approval for their proposed research from an approved IRB, which will generally be the IRB at the institution performing the research. NASA reserves the right to have all such research reviewed by a NASA IRB prior to funding or implementation of this research involving human subjects.

CHAPTER 2. NASA Institutional Review Boards (IRB)

2.1 IRB Authority

2.1.1 The IRB Authority shall be defined as follows:

- a. The IRB has authority to approve, disapprove, or require changes in the proposed research protocols and procedures involving human subjects covered by this NPR. Another authority cannot overturn a decision of disapproval; however, a decision of ANO, Center Director, or their designee may change a decision of approval to disapproval.
- b. The IRB may conditionally approve a protocol or recommend changes to disapproved protocols that could result in protocol approval. Any changes must be approved by the IRB prior to initiation or continuation of the protocol.
- c. The IRB has the authority to suspend or terminate its approval of research activities that are not being conducted in accordance with the approved protocol, or the policies set forth in this NPR, or that have been associated with serious harm to human subjects. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and shall be promptly reported to the Principle Investigator (PI), the NASA Center Director, and the ANO.
- d. If an IRB disapproves, suspends, terminates, or conditionally approves a research activity, the PI shall be given the opportunity to respond to the decision by either meeting with the IRB or through written correspondence with the Chairperson of the IRB.
- e. When a NASA Center funds research involving human subjects not involving NASA facilities, personnel or equipment, the Center IRB may evaluate such proposals prior to their funding, or the NASA IRB may accept IRB certification for the research proposal from a DHHS OHRP approved non-NASA IRB.
- f. The NASA Center IRB overseeing any human subject research for units responsible to that Center shall be responsible for appropriate oversight.

2.2 Membership

2.2.1 IRB Membership requirements shall be defined as the following:

- a. Each IRB shall have at least five members consisting of persons of varying backgrounds knowledgeable of the experimental environment and conditions to provide a complete and adequate review of research activities conducted by the institution or investigator.
- b. The IRB members shall be experienced, possess adequate expertise, and sufficient familiarity to exercise due diligence and consideration in the sensitive matters of race, gender, ethnic, and cultural backgrounds, and prevalent community attitudes toward human experimentation, to promote respect for IRB advice and counsel in safeguarding the rights and welfare of human research subjects.
- c. The members shall have the competence required to review the research activities involving human subjects covered by this NPR and to determine the acceptability of the proposed research

relative to applicable laws, safety regulations, health standards, scientific and statistical merit, and ethical codes.

d. The IRB shall include culturally diverse members not entirely of one gender or race.

e. The IRB shall include:

(1) a member of the Center's Safety and Mission Assurance Office;

(2) at least one member whose expertise is in a nonscientific area such as medical ethics;

(3) at least one member cognizant of the operational aspects of the aerospace or aeronautic environment;

(4) at least one member who is not otherwise affiliated with NASA who is not a part of the immediate family of a person affiliated with NASA; and

(5) a subject representative (in the case of Johnson Space Center [JSC] IRB, an astronaut should serve in this function).

f. The JSC IRB also includes a NASA-employed physician. The Center Office of Chief Counsel shall provide legal advice to the IRB.

g. The IRB may invite nonvoting experts to help review and resolve special or difficult issues which require competence beyond or supplementing that available on the Board.

h. The Chairperson shall designate one of the members as their alternate.

i. The Chairperson of the IRB shall appoint a recording secretary of the IRB for recordkeeping and for general administrative Board functions.

j. IRB members shall be appointed for up to two consecutive 3-year terms and may be reappointed after a hiatus of 3 years. The Center Director cannot remove IRB members from their positions before the end of their terms except in cases of misconduct.

2.3 Conflict of Interest

2.3.1 No IRB member may participate in the review of any proposal in which that member has a conflicting interest, except to provide information requested by the Board.

2.4 Meetings

2.4.1 IRB meetings shall be convened by the Chairperson of the IRB on a regular basis or when a request is made by the Chief Health and Medical Officer (CHMO), NASA HQ; or the NASA Center Director. The IRB may be convened if requested by a spaceflight Mission Manager or a test subject to evaluate a research protocol which may affect the health or well-being of participating human subject(s).

2.5 Documentation and Preparation

2.5.1 The IRB shall prepare and maintain documentation of its activities including the following:

a. Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals approved; final consent documents; progress reports submitted by PIs; and reports of

illness or injuries to subjects.

b. Minutes of IRB meetings, which will include members, alternates, and visitors in attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and resolutions of same; and a statement for each approved proposal that the proposal is approved and all IRB concerns have been addressed.

c. Minority reports will be filed in all cases in which there is no consensus.

d. Records of continuing review and monitoring activities.

e. Copies of all correspondence between the IRB, the investigators, and between other NASA Centers, including NASA HQ.

f. A list of IRB members identified by name, earned degrees, representative capacity, areas of proficiency such as board certification and licenses, and any current or previous employment or other relationship between each member and NASA or NASA contractors. A copy of this list and changes including IRB members' continuing education thereto will be forwarded to the ANO yearly or as updated.

g. Written procedures for the operation of the IRB.

h. Statements of significant new findings provided to subjects, as required below by section 4.5.e of this NPR.

i. Written procedures for assuring prompt reporting to the IRB and the ANO of any problems, whether anticipated or not, involving risks to subjects or to others; serious noncompliance or continuing noncompliance with NASA research policy, with the PI's protocol, or with the requirements of the IRB; or suspension or termination of IRB approval.

j. An annual report of IRB activities based on the minutes.

2.6 Required Documents

2.6.1 The IRB shall maintain records of the following metrics:

a. Number of research proposals reviewed by the IRB.

b. The number of proposals approved and disapproved by the IRB.

c. Number of research proposal renewals.

d. Number of adverse reactions or equipment failures or modifications reported to the IRB by the PI, the IRB Compliance Officer (if mandated), crew surgeon, or other responsible monitors or officials.

e. Tracking of action item responses from PI's.

f. Number of IRB letters of reprimand or more serious sanctions imposed.

g. Number of audits and follow up corrective actions adopted as a result of complaints to the IRB.

h. Number of official mishap investigations instituted or completed and corrective action taken to avoid repetitions.

i. Number of cases of research misconduct occurring in IRB-approved protocols.

j. Number of investigators taking the NASA Bioethics training. Number of first-time training certifications versus number of re-certifications.

k. Number of DSMB reviews, corrective actions, and lessons learned.

2.7 Retention, Accessibility, and Inspection of Records

2.7.1 IRB records relating to research conducted by an investigator will be retained for at least 3 years beyond the last action of the IRB on that protocol or specific issue. The IRB shall retain records that will then be dispositioned in accordance with NPR 1441.1, NASA Records Retention Schedules. All records will be entered into a secure database, under the management of the Recording Secretary of the IRB, and accessible for inspection and copying by authorized representatives of NASA at reasonable times and in a reasonable manner. The information contained in the records and the database shall be maintained in conformity with prescribed NASA policies, guidelines, and procedures.

CHAPTER 3. NASA Flight IRB (NFI)

3.1 Function

The ANO shall establish a NASA Flight IRB (NFI) whose function is to review all research proposals that (1) propose the use of astronauts/crewmembers as research subjects and/or research technicians; (2) all space flight or aircraft research proposals that use non-crew human research subjects; (3) all aircraft research proposals that use non-crew as research technicians if it is deemed that their participation could affect their health or safety; and (4) all space flight or aircraft research proposals that use animals, biological, or toxic materials that could be expected to interact with the humans onboard the space or aircraft. The NFI may also evaluate other proposals at the discretion of the ANO.

3.2 Center Designation and Meeting Location

The NFI shall be located at Johnson Space Center (JSC); however, meetings of the NFI may be at any appropriate location.

3.3 Membership

3.3.1 In consultation with the JSC Center Director, the ANO shall appoint the membership of the NFI which will include (1) the Chairperson; (2) a NASA safety representative; (3) an active NASA Astronaut; (4) a NASA flight surgeon (5) a non-NASA employee from the bioethics or health profession communities; and (6) other members as required to have sufficient expertise and diversity to adequately evaluate research proposals. The Center Office of Chief Counsel or the Headquarters Office of General Counsel (OGC) shall provide legal advice to the NFI.

3.3.2 No NFI member may participate in the review of any proposal in which that member has a conflicting interest, except to provide information requested by the Board.

3.3.3 The NFI may invite nonvoting experts to help review and resolve special or difficult issues, which require competence beyond or supplementing that available on the Board.

3.3.4 The recording secretary shall be appointed by the Chairperson of the NFI for recordkeeping and for general administrative Board functions.

3.3.5 NFI members shall be appointed for up to two 3-year terms and may be reappointed after a 3year hiatus. NFI members may not be removed from their positions before the end of their terms except in cases of misconduct.

3.4 Health and Safety Monitor

The NFI may require that a NASA safety and health monitor (which may be the crew surgeon) must be available to observe all research studies involving NASA astronauts/crewmembers.

3.5 NFI Review Guidance

3.5.1 If human subjects are to participate in multiple flight research protocols at the same time, the NFI shall review all the research proposals as an integrated protocol to assess the risks to the research subject.

3.5.2 All research proposals that are required for review by the NFI shall be approved by the NFI prior to the initiation of astronauts/crew or subject briefing.

3.5.3 The NFI will review only those proposals that have undergone successful scientific peer review, are funded for definition and/or feasibility studies, and are proposed as part of a flight payload complement.

3.5.4 No waiver or reciprocity with any other IRB shall be accepted for any research proposal falling under chapter 3.

3.6 Conformance

The NFI shall conform to all appropriate parts of this NPR.

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."

CHAPTER 5. Criteria for IRB Approval of Research Involving Human Subjects

5.1 Approval Requirements

5.1.1 The following requirements will be satisfied for the IRB to approve the research involving human subjects covered by this NPR:

a. The PI shall always protect the safety and minimize health risk to subjects:

(1) by selecting methodologies and procedures which are consistent with sound research design and conduct and which do not unnecessarily expose subjects to undue risk; and

(2) by using procedures already being performed on the subjects for other experiments, so as to minimize the collective impact of multiple protocols on the subject.

b. In evaluating safety risks and benefits, the IRB shall ensure that risk to subjects be reasonable in relation to anticipated benefits, if any, and the importance of the new knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits, taking into account the collective impact of multiple protocols that may result from the research. The IRB should not consider possible long-range effects of new knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks or benefits that are its responsibility.

c. The PI shall obtain and document the voluntary informed consent of each prospective subject or the subject's legally authorized representative. The human research consent form will contain at least all elements listed in section 4.2 (and section 4.5). The PI will inform the subject that not all risks are readily identifiable.

d. The PI may ensure that the subject or the subject's beneficiaries receive compensation by means of insurance, worker's compensation, or the like in the event that the subject suffers illness, disease, injury, loss, or death as a direct result of the research. The lack of this provision may serve as a basis for disapproval of the research. Such provisions for compensation will be required for all studies performed at a NASA Center, uses NASA equipment or facilities, or for which a NASA employee or on-site contractor is the principal investigator.

e. The research proposal contains provisions for monitoring the data collected to ensure the safety of the subjects. Other informational items that should be included in a human research proposal are listed in Appendix C.

f. The PI shall provide safeguards to protect the privacy of subjects and the confidentiality of data, especially electronically stored data. Biomedical data, if held by NASA and if retrievable by personal identifier, are subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and are maintained under the NASA System of Records, Human Experimental and Research Data (HERD) Records. Such data held by other institutions must have similar safeguards. The PI maintains the records relating to the conducted research and will retain these records for at least 3 years after completion of the research.

g. No human subject shall participate in any portion of the research until the protocol is approved by the IRB.

h. The PI shall ensure that selection of subjects is equitable and representative of the population that its biomedical research intends to represent. The IRB should assess the purposes and setting of the research. In the case of space flight, considerations should be given to the habitability conditions and the level of medical care available in the event of illness or injury.

CHAPTER 6. Expedited Review

6.1 Expedited Review Process

6.1.1 In the case of research involving minimal risk to human subjects (Appendix A), the IRB may conduct an expedited review (Appendix D) which shall be conducted as follows:

- a. It consists of a review by the Chairperson or one or more experienced reviewers designated by the Chair from among the members of the IRB.
- b. It will be based on the same criteria as a non-expedited review but shall not require consideration by the entire IRB.
- c. In conducting an expedited review, the reviewer(s) exercises all the authority of the IRB, except that the reviewer(s) may not disapprove the research, which can only occur through the non-expedited procedure described in this NPR.
- d. A reviewer must recommend that the proposal be reviewed by the full IRB if the research involves more than minimal risk.
- e. The reviewer(s) who approves research proposals using the expedited review procedure will either directly or through the Chairperson report to the Board on such approvals at the next meeting of the IRB. The minutes of the IRB reflects the expedited approval with the concurrence of the full IRB.
- f. The IRB may also use the expedited procedure to review minor changes in previously approved research during the period for which approval is authorized.

CHAPTER 7. Research Mishaps, Adverse Events, Injuries, Illness, and Disease and Medical Care

7.1 Mishap/Adverse Event Reporting and Investigation

7.1.1 In the case of an active research protocol being conducted at a NASA Center or facility, and/or using NASA hardware or equipment, and/or involving a NASA investigator, the PI shall inform the responsible NASA IRB within 24 hours of discovery of any injury, illness, disease, or death, whether expected or not, incurred by a research subject. Such an event is termed a research subject mishap.

7.1.1.1 An adverse event is any untoward or unfavorable medical occurrence involving a human research subject occurring while associated with the subject's participation in the research. An adverse event is not necessarily a mishap if the protocol-related documents or informed consent documents identify the potential for the medical occurrence.

7.1.1.2 An adverse event that causes death, hospitalization or serious injury or is deemed to place research subjects or others at greater risk or harm than what was previously known or anticipated, is classified as a research subject mishap.

7.1.1.3 The determination of whether an adverse event is classified as a research subject mishap will be made by the Chair of the responsible IRB.

7.1.2 Within 3 working days upon being notified, the IRB Chairperson shall notify the NASA Center Safety Officer, the ANO, the NASA Center Chief Medical Officer (where applicable), the relevant NASA research funding program, and the Crew Medical Officer in the case of crew involvement in the event of a reportable incident, of the incident.

7.1.2.1 When the injury results in a loss of life, a permanent disability, or when a person requires hospitalization, and/or a person requires extensive first aid or lost workday(s), the mishap will be reported to the ANO immediately.

7.1.3 For a research subject mishap involving a fatality, life threatening injuries, permanent or partial disability, or requiring hospitalization (i.e. Type A, Type B mishaps per NPR 8621 NASA Procedural Requirements for Mishap and Close Call Reporting, Investigating, and Recordkeeping) an investigation will be initiated as soon as possible per NPR 8621.1 by a board convened by the appropriate Appointing Official (AO).

7.1.3.1 For research subject mishaps occurring at a Center, the Center Director will serve as the AO, with concurrence from the CHMO.

7.1.3.2 For research subject mishaps involving a human research subject participating in NASA-funded research at a grantee site or at another offsite location involving a NASA investigator, and/or using NASA hardware or equipment, the CHMO will serve as the AO.

7.1.4 Research subject mishaps resulting in an injury or illness to an individual or individuals (i.e., Type C, D, or CC mishaps per NPR 8621.1) will be investigated in accordance to processes established by the Institutional Review Board (IRB) approving the human research study, following the guidance provided in Appendix E.

7.1.4.1 If the IRB Chair and/or the CHMO believe that there is an inherent conflict of interest for the IRB to convene or perform the investigation, the convening authority defaults to the appropriate AO, as described above.

7.1.5 OCHMO will inform and/or seek concurrence through telephone or email contact with OSMA Mishap Investigation Program Manager on applicability and implementation of NPR 8621.1 requirements associated with all human research subject related mishaps.

7.1.6 Upon being notified of a mishap the IRB Chairperson shall determine whether the research should be immediately suspended with subsequent IRB concurrence.

7.1.6.1. Once a research protocol involving human subjects is suspended, IRB review and approval will be required before the experiment can resume.

7.1.7 During the mishap investigation all researchers shall cooperate with the NASA mishap investigators, grant interviews, and provide data as requested.

7.1.8 In the case of NASA funded research by a non-NASA PI at a non-NASA facility or institution, the PI shall notify all institutional IRB's that approved his or her proposal of any research subject mishap. The research subject mishap, and if the research has been suspended, will be reported to NASA as the funding agency by the PI, IRB and/or the entity responsible for the oversight of the grant or contract.

7.2 Medical Care and Reporting

7.2.1 For all occurrences requiring medical attention, the PI shall maintain a record of all pertinent information acquired through the research protocol, such as physiologic monitoring and/or imaging data that is acquired, and make them available to the subject's physician.

7.2.2 In the case of research being conducted at a NASA Center or facility, and/or using NASA hardware or equipment, and/or involving a NASA investigator, the PI shall inform the NASA IRB in the event of any change in the experimental environment or in the subject that could forecast medical problems.

7.2.3 In evaluating the research proposal the NASA IRB shall review the health care provisions provided to the research subject, and the availability of appropriate medical care for possible injury or illness that could occur during the course of the research.

7.2.4 To inform the research subject, the provisions for access to medical care shall be included in the consent form.

7.2.5 The medical care for astronaut research subjects shall include the assigned NASA flight surgeon who shall have access to all research data that pertains to the health of the astronaut research subject. The flight surgeon may use this data for the ongoing health monitoring of the astronaut.

CHAPTER 8. Documentation of Informed Consent

8.1 Modification of Protocol

A protocol shall not be modified unless the IRB or the reviewer (in the case of an originally expedited review) approves a formal request with appropriate justification. If the IRB determines that the modification increases the risk(s) to the subject, a revised informed consent will be required.

8.2 Reporting and Approval

8.2.1 Space flight experiment research protocols may require modification during flight, as procedures are refined to comply with operational constraints. Substantive human research protocol changes during flight shall require the majority approval of a quorum of the NFI IRB.

8.2.2 The Mission Operations Control Room Surgeon shall be immediately informed of this requested substantive change and has the authority to temporarily suspend the experiment until the IRB can review the request.

8.2.3 All such approved changes to the research protocol will also be approved by the crewmember volunteering for the research prior to the initiation of the research protocol changes.

Chapter 9. Assurances from Participating Institutions

9.1 Multiple and Single Project Assurances (MPA and SPA)

All NASA Centers or other institutions proposing research involving human subjects supported by NASA shall give written institutional multiple project assurance (MPA), or a single project assurance (SPA) (Appendix F), as provided in 14 CFR 1230.103, to the ANO. Assurances from international institutions must follow the U.S. ethical and legal standards.

9.2 IRB Review and Approval

For any protocol by a non-NASA investigation, which utilizes NASA facilities, equipment, or personnel, in addition to the IRB of the extramural participants, a NASA IRB review and approval shall be required. Therefore, in this instance, other institutional assurances certified by DHHS OHRP or international oversight bodies for extramural projects will not suffice.

9.3 Term of MPA

The term of an MPA shall not exceed 5 years.

9.4 Evaluation and Reporting

9.4.1 The ANO shall evaluate the MPAs from NASA Centers and shall certify such MPA's that are deemed appropriate for the protection of human subjects if the submissions are satisfactory and meet the requirements in NPD 7100.8, Protection of Human Research Subjects, and this NPR (NASA Centers not conducting or supporting human research will file an annual notice with the ANO).

9.4.2 Other interested institutions, including public, private, and international institutions may submit an application for a NASA-approved MPA. The ANO with the concurrence of the OGC shall evaluate these MPA's and may certify such MPA's that are deemed appropriate for the protection of human subjects if the submissions are satisfactory, meet the requirements in NPD 7100.8, and this NPR, and are in NASA's best interests.

9.5 Site Visit

9.5.1 A site visit may be required for evaluation of either a new or renewal MPA to assess the adequacy of the NASA Center or other institution's procedures for protecting human research subjects. The site visit for a new approval shall evaluate the facilities to determine:

- a. the institution's ability to safely perform research involving human subjects;
- b. the expertise of the officials who shall oversee the assurances;
- c. the facilities for maintaining adequate records;
- d. the institutional commitment for adequately funding the oversight efforts; and

e. compliance may be audited at a site visit for renewal or at other times and the training of IRB and staff members shall also be monitored.

9.6 Factors for Approval

9.6.1 Approval of an MPA shall be based on the evaluation of the following factors:

- a. administration including jurisdiction of the IRB, establishment and membership of the IRB, recordkeeping, institutional responsibilities, the assurance itself, staff, space, and supplies, communication, institutional procedures and guidelines, identification of the authorized NASA Center or other institutional official, training of IRB and staff members, and process for internal audits;
- b. regulations and policies regarding Federal laws and the common rule and their use by the IRB;
- c. description of the way the IRB interacts with other interested oversight bodies, e.g., safety, legal;
- d. basic IRB review policies including risk or benefit analysis, requirement for the disclosure of risks and benefits in the consent form, continuing review and monitoring of data, requirements and documentation for the informed consent
- e. policies for monitoring and observation of research activities; and
- f. appropriate guidelines for the use of special classes of subjects.

9.7 Noncompliance

The ANO shall investigate any allegation or indication of noncompliance with NPD 7100.8, or with this NPR, which comes to his or her attention with regard to NASA-conducted or supported research, following the procedures for MPA compliance described in Appendix F.

Chapter 10. Sanctions and Potential Disciplinary Action

10.1 Determination of Sanctions and Potential Disciplinary Action

10.1.1 Sanctions and potential disciplinary actions for non-compliance with this NPR and the requirements contained within shall be determined according to the following:

- a. Any NASA PI participating in research involving human subjects, who does not comply with this NPR or with the IRB-approved protocol, may have his or her research immediately suspended or terminated by the appropriate IRB, NASA Center Director, or the ANO. Such noncompliance may be cause for revocation of funding. It may also be the cause for other appropriate remedies including disciplinary action against the PI, i.e. sanctions addressed in this section do not exclude possible personnel actions.
- b. PI's not employed by NASA, who are responsible for research involving human subjects that is sponsored by NASA or is performed in NASA facilities, aircraft, or spacecraft and who do not comply with this NPR or do not comply with the NASA IRB approved protocol, may have their research immediately suspended or terminated and will also be subject to appropriate sanctions. NASA shall suspend or terminate funding approval if the investigator's research is suspended or terminated by the originating institution for any reason. NASA may immediately suspend or terminate grant approval for research involving human subjects from non-NASA institutions funded by NASA if that institution's MPA or Federal Wide Assurance (FWA) is suspended or terminated.
- c. If an MPA/FWA for a NASA Center or any institution is suspended or terminated for cause, the ANO with the concurrence of the OGC and the Office of Procurement may recommend to the NASA Administrator that all NASA funding for human research to that institution be suspended or terminated.
- d. Any evidence of alleged criminal wrongdoing at any level related to information obtained from IRB activities and oversight by the Office of the CHMO shall be forwarded to the NASA Office of the Inspector General.

APPENDIX A: Definitions

Assurances are either a Single Project Assurance (SPA) or Multiple Project Assurance (MPA) which is a formal, written statement in which an institution promises to comply with applicable rules governing research with human subjects. An SPA or MPA must be provided by the IRB prior and accepted by the appropriate Federal agency prior to commencing of any NASA research involving human subjects. An SPA or MPA must cover all research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

Authorized NASA Official (ANO) is the official designated by the NASA Administrator who is empowered, subject to conditions and limitations imposed by an immediate supervisor, to authorize research involving human subjects. This has been designated in NPD 7100.8 as the Chief Health and Medical Officer (CHMO).

Conducted Research is research involving a PI or subordinate researcher who is a NASA employee or onsite contractor.

Crewmember is an astronaut, payload specialist, or aviation personnel assigned to a spacecraft or an aircraft mission who may volunteer as a research subject and/or participate as a research technician for a research experiment as part of their employment.

Funded Research is research that is partially or completely underwritten by NASA through a contract, cooperative agreement, grant, or other funding mechanism, and which does not also involve permission by NASA to utilize NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles.

Human Subject is a living person who is an integral part of a test, or other substantive evaluative procedure and about whom the PI (whether professional or student) obtains (1) research data through intervention or interaction; or (2) identifiable private information.

Informed Consent consists of oral or written acknowledgement by a research subject that he/she understands the nature of the research to be performed and his/her obligations in participating in the research, the potential risks to health and well-being by participating as a research subject, and other tests or therapies available if the subject is a medical patient seeking health care; that he/she has been allowed to ask questions relating to the research to be performed; and is allowed to quit the research activity at any time (except if it would cause greater harm to the subject). The elements of informed consent are full disclosure, adequate comprehension, and voluntary choice to and for the research subject.

An Institutional Review Board (IRB) is a committee approved by NASA and established in accordance with this NPR under a current Multiple Project Assurance (MPA) or approved by the DHHS FWA to review research involving human subjects and their activities for the adequacy of procedures that protect human subjects in research.

Interaction includes communication or interpersonal contact between the investigator and the subject.

Intervention includes both physical testing procedures by which data are collected (for example, equipment used on a person) and manipulation of the subject or the subject's environment for research purposes.

Life Sciences Research includes biomedical, biological, human factors, psychological, environmental health, and life-support experimentation.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Persons employed in hazardous occupations are not expected to submit to greater risks than persons employed in non-hazardous occupations. Examples of minimal risk activities are presented in Appendix D.

Principal Investigator is the researcher who has overall responsibility for all aspects of the funded and/or sponsored research project.

Private information includes information provided for specific purposes about a subject's medical, physiological, or behavioral status or history about which the individual can reasonably expect that no observation or recording is taking place and which the individual can reasonably expect it not to be made public.

Research is a systematic investigation, including development, testing, and evaluation, which may be designed to test a hypothesis, enable conclusions to be drawn and, thereby, develop or contribute to knowledge in general. The research is described in a formal protocol that sets forth an objective and a set of procedures designed to reach the stated objective.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

Serious Harm is a temporary or permanent illness, injury, disability, or death.

Sponsored Research is investigative and commercial experimental work approved by NASA to permit the utilization of NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles, whether or not NASA funds are used to support the research.

Supported Research is NASA-funded or -sponsored research.

Appendix B. Acronyms

AA - Associate Administrator

ANO - Authorized NASA Official

CHMO - Chief Health and Medical Officer

DHHS - Department of Health and Human Service

DSMB - Data Safety Monitoring Board

FWA - Federal Wide Assurance

IRB - Institutional Review Board

JSC - Johnson Space Center

OHRP - Office of Human Research Protections

OSMA - Office of Safety and Mission Assurance

OGC - Office of General Counsel

MPA - Multiple Projects Assurance

NCO - NASA Contracting Officer

NFI - NASA Flight IRB

PI - Principle Investigator

SPA - Single Project Assurance

Appendix C. Information Portion of a NASA Human Subject Research Proposal

C.1 The following information will be included with the proposal submitted for IRB review:

- a. Name of the organization conducting the research or for which the research is being conducted.
- b. Name and qualifications of persons who conducts the research involving human subjects.
- c. The reasons for the use of human subjects and a plan to ensure equitable selection of research subjects with reference to race and gender.
- d. Possible inconveniences, discomforts, illnesses, diseases, injuries, pain, and risks to the subject.
- e. A description of the hazard controls and safety precautions to be applied.
- f. Expected duration of the study, including approximate beginning and ending dates.
- g. The extent of any physical examinations to be given by medical personnel:
 - (1) Initially, to ascertain the subject's health status and to certify that the subject is capable of undertaking the proposed research,
 - (2) During the course of the research, and
 - (3) At the completion of the research.
- h. Wage, salary, or other payment, if any, to be paid to the subject for participating in the research.
- i. Source (Federal or State compensation acts and insurance) and general description of compensation, if any, to be received by a subject or the subject's legally authorized representative in the event of injury or death. Assistance in the preparation of this information may be obtained from the appropriate NASA Center OGC or, if the subject is a Government employee, from the NASA Center Personnel Office.
- j. Availability of medical personnel, and an adequate medical facility within a reasonable distance of the location where research is performed. Indicate whether a physician will be present at all times or on call; if on call, the physician's location during the research.
- k. Information about the research involving human subjects that will be given to the subject while obtaining the subject's informed consent.
- l. The research involving human subjects consent form, including the provision that subjects concerned about protocol violations may request a meeting with the relevant IRB.
- m. Evidence of review and approval by the sponsoring organization's IRB.
- n. A plan for ensuring privacy and protecting the confidentiality of data with particular attention to data contained in an electronic database.
- o. Data Safety Monitoring plan, where applicable.

Appendix D. Types Of Research Activities That May Be Reviewed Through Expedited Review Procedures

D.1 Research activities involving no more than minimal risk and in which the involvement of human subjects may be in one or more of the following categories (carried out through standard methods), may be reviewed by the IRB through the expedited review procedure authorized in Federal Policy Regulations cited in 45 CFR 46.110 and 14 CFR 1230.110:

- a. Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if normal preventive patient care indicates a need for extraction.
- b. Collection of excreta and external secretions, including sweat, noncannulated saliva, and placentas removed at delivery, and amniotic fluid at the time of membrane rupture prior to or during labor.
- c. Recording of data from subjects 18 years of age or older, using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body, or at a distance, and do not involve input of matter or significant amounts of energy into the subject or an invasion of privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, and detection of naturally occurring radioactivity, diagnostic sonography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., X-rays, microwaves, ultraviolet light, and infrared lights).
- d. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- e. Voice recordings made for research purposes such as investigations of speech defects or stress.
- f. Moderate exercise performed by healthy subjects.
- g. The study of existing data, documents, records, pathological specimens, or diagnostic specimens. In the latter two instances, a new informed consent statement must be obtained.
- h. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, in which the PI does not manipulate the subject's behavior and the research does not involve stress to the subjects.

Appendix E. Guidance for Human Research Subject Mishap Investigation by an IRB

E.1 Introduction

Research subject mishaps resulting in an injury or illness to an individual or individuals (i.e., Type C, D, or CC mishaps per NPR 8621.1) will be investigated by the Institutional Review Board (IRB) approving the human research (Section 7.1.4), based on the guidance below.

E.2 IRB Investigation Panel

- a. Based on the nature of the research subject mishap the IRB Chair will determine the composition of the investigating panel.
- b. The panel may consist of the entire IRB membership, a sub-set, or a single member, but should always include the Office of Safety and Mission Assurance IRB member.
- c. The IRB Chair may supplement the IRB panel membership with additional expertise (e.g., physician with appropriate expertise within the area of interest; other technical experts).

E.3 IRB Process Description

- a. In investigating the mishap the panel should consider, at a minimum, the following factors:
 - (1) Relevant human factors issues, including psychological and physiological factors. Examples:
 - (a) Fatigue (work-rest cycles)
 - (b) Possible drug or alcohol influence
 - (c) Research team communication
 - (2) Management, operational and system factors. Examples:
 - (a) Research protocol design
 - (b) Proper procedure guidelines documented and implemented
 - (c) Biomedical/research equipment or technical failures
 - (d) Staffing and scheduling issues
 - (e) Proper training and appropriate certification of research personnel
 - (f) Competency of personnel to conduct and oversee research protocol.
 - (g) Proper supervision of research activities
- c. Witnesses - All witnesses will be informed that their statements may not be confidential and that they will be interviewed upon their consent.
- d. Possible Criminal Behavior - If a criminal violation is suspected, the appropriate NASA legal

counsel (i.e., the Office of General Counsel and the Office of Inspector General) and CHMO must be immediately notified. The investigation will stop pending further guidance from the appropriate NASA legal counsel and CHMO.

E.4 IRB Findings and Reporting

- a. The panel will determine the cause(s) of the mishap, identify all relevant factors that contributed to the mishap, and make recommendations regarding the implementation of the research protocol, personnel training and/or certification, hardware safety and study procedures, or any other aspect of the research deemed necessary.
- b. The panel may make a recommendation as to whether the protocol should be continued, and if suspended if it should be permanently cancelled, resumed with modification, or resumed as originally designed.
- c. The panel will report the findings and provide all relevant records and data collected to the IRB Chair, and submit recommendations for final disposition through the IRB.
- d. Based on the findings and recommendations of the panel, the IRB will make a determination regarding the status of the research protocol and any remedial actions that should be taken.
- e. The IRB Chair will inform the PI, the relevant NASA research funding program, and the CHMO in writing of the panel findings and actions taken.

Appendix F. Multiple Project Assurance Compliance Oversight Procedures

F.1 Allegations of Noncompliance

The ANO may at any time modify an MPA to require interim corrective actions to remedy any identified noncompliance. The ANO may also suspend an MPA during an investigation if it is necessary to protect human research subjects.

F.2 Center Responsibility

The ANO may request the NASA Center or other institution to either acknowledge the institution's report of noncompliance or notify the NASA Center or institution's Assurance Signatory Official (ASO) of the possible noncompliance and, as necessary, request that the institution investigate the matter and report back. The ANO may communicate directly with other affected institutional officials or personnel or, if the noncompliance involves a specific research investigator, may notify that investigator directly.

F.3 Onsite Evaluation

The ANO may initiate an onsite evaluation of protections under an MPA even in the absence of specific allegations or indications of noncompliance. The ANO may convene a NASA HQ review panel to investigate the circumstances surrounding any cases of noncompliance. A designated senior NASA HQ official who has no apparent or real conflict of interest will chair the review panel. The membership shall consist of five members, as a minimum, with participation from the OGC and the OSMA. After review of the circumstances, the ANO in consultation with the OGC may prescribe and publicize sanctions.

F.4 Reporting Requirements

If the Authorizing Official determines that a formal report of findings is warranted, he or she shall notify the NASA Center or other institution's ASO that a formal report is required. The report may include (1) an invitation to the Signatory Official for institutional identification of errors of fact, and/or (2) the complainant(s), with an invitation for individual identification of errors of fact.

4.1 The Authorizing Official will establish a Data Safety Monitoring Board (DSMB) to review clinical studies.

4.2 The DSMB membership will be multidisciplinary in nature and, as a minimum, will include experts in biostatistics, experimental design, and bioethics. The DSMB will be established for particularly high-risk research or research where the blinded nature of data might put subjects at risk in ways that are not immediately apparent to blinded researchers.

4.3 The relevant IRB's, in consultation with the Office of CHMO, will determine which protocols warrant the establishment of particular levels of DSMB oversight.

4.4 All investigators who work with human subjects must be trained in basic principles of human

subjects' protection. Minimum training should include the history and basic principles of human subject research protections, risk or benefit assessment and informed consent procedures, and institutional responsibilities. Research investigators must demonstrate that they have completed such training to be eligible to submit research proposals to a NASA IRB.