



NASA Procedural Requirements

COMPLIANCE IS MANDATORY

NPR 7100.1

Effective Date: March 28,
2003

Expiration Date: March 28,
2019

[Printable Format \(PDF\)](#)

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

[| TOC](#) | [ChangeHistory](#) | [Preface](#) | [Chp1](#) | [Chp2](#) | [Chp3](#) | [Chp4](#) | [Chp5](#) | [Chp6](#) | [Chp7](#) | [Chp8](#) |
[Chp9](#) | [Chp10](#) | [AppdxA](#) | [AppdxB](#) | [AppdxC](#) | [AppdxD](#) | [AppdxE](#) | [AppdxF](#) | [ALL](#) |

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 PI's; 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.

| [TOC](#) | [ChangeHistory](#) | [Preface](#) | [Chp1](#) | [Chp2](#) | [Chp3](#) | [Chp4](#) | [Chp5](#) | [Chp6](#) | [Chp7](#) |
[Chp8](#) | [Chp9](#) | [Chp10](#) | [AppdxA](#) | [AppdxB](#) | [AppdxC](#) | [AppdxE](#) | [AppdxF](#) |
[ALL](#) |

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

DISTRIBUTION: **NODIS**

This Document Is Uncontrolled When Printed.

Check the NASA Online Directives Information System (NODIS) Library
to Verify that this is the correct version before use: <http://nodis3.gsfc.nasa.gov>
