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# NASA Procedural Requirements

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**COMPLIANCE IS MANDATORY**

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## NASA Health and Medical Requirements for Human Space Exploration

**Responsible Office: Office of the Chief Health & Medical Officer**

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# Preface

## P.1 Purpose

- a. This document provides the procedural requirements and processes for the NASA Health and Medical System for Human Space Exploration.
- b. NASA shall fulfill all requirements of this NASA Procedural Requirements (NPR) to protect the health and safety of crewmembers involved in space flight activities and enable successful human space exploration.

## P.2 Applicability

- a. This NPR is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This NPR applies to the Jet Propulsion Laboratory, a Federally Funded Research and Development Center, other contractors, grant recipients, and parties to agreements only to the extent specified or referenced in the appropriate contracts, grants, or agreements.
- b. The requirements in this NPR shall apply to all human space exploration activities including, but not limited to, space systems, space suits, planetary habitats, planetary rovers, and surface vehicles.
- c. The requirements in this NPR shall apply to internationally provided space systems as documented in distinct separate agreements, such as joint or multilateral agreements.
- d. The requirements in this NPR shall supplement requirements imposed by other Federal Government agencies.
- e. In this directive, all document citations are assumed to be the latest version unless otherwise noted.
- f. In this NPR, a requirement is identified by "shall," a good practice by "should," permission by "may" or "can," expected outcome or action by "will," and descriptive material by "is" or "are" (or another form of the verb "to be").

## P.3 Authority

- a. 51 U.S.C. 20113(a) of the National Aeronautics and Space Act, as amended.
- b. NPD 1000.0, NASA Governance and Strategic Management Handbook.
- c. NPD 1000.3, The NASA Organization.
- d. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

## P.4 Applicable Documents and Forms

- a. NPD 7100.8, Protection of Human Research Subjects.
- b. NPD 7120.4, NASA Engineering and Program/Project Management Policy.

- c. NPR 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight Programs.
- d. NPR 8900.3, Astronaut Medical and Dental Observation Study and Care Program.
- e. NPR 1382.1, NASA Privacy Procedural Requirements.
- f. NPR 1441.1, NASA Records Retention Schedules.
- g. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.
- h. NPR 7120.8, NASA Research & Technology Program and Project Management Requirements.
- i. NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.
- j. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.
- k. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health.
- l. OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification.
- m. 5 U.S.C. 552a, The Privacy Act of 1974, as amended.
- n. JSC-66306, Data Sharing Policy for Release of NASA Protected Health and Research Information.

## **P.5 Measurement And Verification**

P.5.1 Measurements of compliance for this NPR is determined by whether operational managers adhere to the requirements and follow the processes specified in this NPR. The Chief Health and Medical Officer (CHMO) through Agency authority and its Health and Medical Technical Authority (HMTA) function will monitor compliance. This will include appropriate reviews by, and reporting to, the CHMO.

## **P.6 Cancellation**

NPR 8900.1, NASA Health and Medical Requirements for Human Space Exploration, dated May 28, 2008.

/S/

Dr. Richard S. Williams  
Chief Health and Medical Officer

# Chapter 1. Institutional and Programmatic Health and Medical Requirements and Responsibilities for Human Space Exploration

## 1.1 Overview

1.1.1 As stated in NASA Policy Directive (NPD) 8900.5, NASA Health and Medical Policy for Human Space Exploration, it is NASA policy to provide a safe and healthy environment for crewmembers, including provision of health, medical care, environmental systems, programs, and countermeasures for all mission phases; establishment of health and medical, human performance, habitability, and environmental standards; and sponsorship of health-related and clinical research.

1.1.2 This NPR establishes health and medical requirements for human space flight and the responsibilities for their implementation.

1.1.3 The policies for NASA medical operations and astronaut care are provided in NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight Programs, and NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.

1.1.4 The policy for protection of human research subjects is provided in NPD 7100.8, Protection of Human Research Subjects.

1.1.5 The requirements for implementation of the Health and Medical Technical Authority are provided in NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.

## 1.2 NASA Health and Medical Standards for Human Space Exploration

1.2.1 NASA health, human performance, and medical standards for human space exploration will be established according to the process presented in Appendix C.

1.2.2 Health, human performance, and medical standards for human space exploration will be established and documented as follows:

a. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health establishes standards to ensure a healthy and safe environment for crewmembers and to provide crewmembers with optimal health and medical practices and systems during all phases of space flight. These include appropriate levels of medical care, permissible exposure limits, fitness-for-duty criteria, and permissible outcome limits as a means of defining successful operating criteria for the human system.

b. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health addresses habitability and environmental health, focuses on human physical and cognitive capabilities and limitations and defines standards for spacecraft (including vehicles, habitats, and suits), internal environments, in-space facilities, payloads, and related equipment, hardware, and software systems with which the crew interfaces during space operations.

c. OCHMO 80771201MED, NASA Crewmember Medical Standards, establishes and documents standards that address health and medical screening, evaluation, and certification of crewmembers.

1.2.3 The health, human performance, and medical standards described in 1.2.2 applies to all NASA human space flight programs and NASA-contracted human space flight programs, as specified in contractual specifications.

1.2.4 Management and privacy of medical information and data are as follows:

a. Collection, control of records, communications, and public release of all astronaut medical care, biomedical, and medical research data will comply with the privacy requirements of NPR 1382.1, NASA Privacy Procedural Requirements, and the provisions of the Privacy Act of 1974, as amended.

b. Records will be disposed of in accordance with NPR 1441.1, NASA Records Retention Schedules.

c. Requests, reviews, and potential release of human medical and research data will also comply with the established NASA policy (JSC-66306, Data Sharing Policy for Release of NASA Protected Health and Research Information).

## **1.3 Institutional and Programmatic Roles and Responsibilities**

### **1.3.1 General**

a. The roles and responsibilities of senior management are defined in part in NPD 1000.0, NASA Governance and Strategic Management Handbook, and NPD 1000.3, The NASA Organization.

b. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration, defines explicit health and medical responsibilities for human space exploration. NPD 7120.4, NASA Engineering and Program/Project Management Policy; NPR 7120.5, NASA Space Flight Program and Project Management Requirements; NPR 7120.8, NASA Research & Technology Program and Project Management Requirements, and other NASA directives define the explicit program/project management responsibilities of program and project managers.

c. The NASA CHMO shall serve as the office of primary responsibility providing leadership, policy direction, assessment, and coordination of the technical requirements and process compliance verification for this NPR.

### **1.3.2 The CHMO shall:**

a. Promulgate health and medical policy for human space flight.

b. Serve as the NASA Health and Medical Technical Authority (HMTA).

c. Ensure Agency-wide implementation of HMTA (including HMTA awareness), as described in NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.

d. Establish and maintain human health, human performance, and medical standards for space flight.

e. Establish and maintain mission-specific human health, human performance, and medical standards for space flight for commercial space flight in collaboration with the Federal Aviation Administration.

f. Review and approve all human health-related, human performance, and medical requirements for

space exploration.

- g. Review and deliberate on requests for waivers/deviations to human health-related, human performance, and medical requirements originated by human space flight programs and projects.
- h. Review and approve all human health-related and human performance research and technology recommendations and deliverables that enable human space exploration.
- i. Approve operational implementation of research and technology deliverables that enable human space exploration.
- j. Approve operational use of health and medical systems and technologies prior to their use in space exploration.
- k. Consult with the Science Mission Directorate (SMD) to ensure that human health and medical-related planetary protection requirements for space exploration are coordinated with existing health and medical policy for human space exploration.

1.3.3 The Associate Administrator of the Human Exploration and Operations Mission Directorate (HEOMD) shall:

- a. Support the formulation of human health-related, human performance, and medical requirements that meet Agency-level human system standards.
- b. Designate a senior manager for space crew health and safety to advise the Mission Directorate Associate Administrator (AA) on crew health and medical issues.
- c. Recommend requirements for health, human performance, medical care, and environmental systems, programs, and countermeasures for all mission phases and establish milestones for deliverables.
- d. Provide on-orbit resources necessary to meet these milestones.
- e. Recommend policies applicable to crew health and medical matters.
- f. Implement human health-related, human performance, and medical requirements.
- g. Review space medicine operations and results on a periodic basis.
- h. Define, plan, conduct, and oversee NASA-sponsored, human health-related research, and technology development.
- i. Develop human health-related research and technology deliverables to an appropriate stage of readiness level for final review, approval and implementation and recommend timelines for implementation.
- j. Oversee the implementation of health-related research and technology deliverables once approved.

3.4 The AA for the Science Mission Directorate (SMD) shall coordinate with the CHMO regarding health and medical issues related to planetary protection for human space exploration.

1.3.5 The Johnson Space Center (JSC), through the Center Director or designee, shall:

- a. Concur with the CHMO appointment of a JSC Chief Medical Officer (CMO).
- b. Develop a JSC HMTA Implementation/Awareness Plan, as described in NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.

- c. Medically screen, evaluate, and certify crewmembers.
- d. Conduct clinical evaluations and monitor astronaut health at regular intervals to determine medical status during ground-based training and space flight.
- e. Provide medical care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.
- f. Provide health maintenance and preventive care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.
- g. Provide post-flight health rehabilitation to assist the astronaut to return to functional baselines in the areas of physical fitness and physiological and behavioral health.
- h. Provide mission-specific medical and behavioral health training for crewmembers.
- i. Provide programs aimed at maintaining the health status and performance of crewmembers to enable the ability to function and perform all assigned duties over the duration of their career as an astronaut.
- j. Establish, implement, and update a program of preventative medicine based on research findings, health and medical lessons-learned, current standards of medical practice, risk management data (health effects), and expert recommendations.
- k. Develop and manage the Lifetime Surveillance of Astronaut Health.
- l. Establish, document, and implement a NASA policy which allows for request, review of, and potential release of human medical and research data.

#### 1.3.6 The JSC CMO shall:

- a. Exercise HMTA for activities conducted at JSC and delegated human space flight HMTA activities at other NASA Centers, as described in NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.
- b. Assign a point of contact for human space flight HMTA issues at other NASA Centers as, described in NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.
- c. Provide recommendations for health and medical and environmental and human factors standards and requirements.

#### 1.3.7 Per NPR 7120.11, Health and Medical Technical Authority Implementation, the CMOs at Centers other than JSC, shall:

- a. Establish interfaces with assigned points of contact from the JSC.
- b. Assist with the identification and resolution of HMTA human space flight issues.
- c. Provide recommendations for health and medical and environmental and human factors standards and requirements.

1.3.8 Clinical decision will be made in accordance with the NASA Medical Policy Board (MPB) and Aerospace Medicine Board (AMB) responsibilities, as specified in NPD 1000.3, The NASA Organization.

# Chapter 2. Human Health-Related System Design Requirements

## 2.1 System Design Requirements

2.1.1 Program/Project Managers shall formulate human health-related system design requirements in compliance with NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health and NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health.

2.1.2 The space system will provide the following systems and capabilities:

- a. Diagnostic and treatment systems in compliance with established level of medical care standards.
- b. Capability for medical services to support all phases of a mission in compliance with established level of medical care standards.
- c. Health maintenance, preventive, performance, and countermeasure systems in compliance with established space flight crew health standards.
- d. Medical communications, consistent with privacy requirements and the Privacy Act of 1974, and established level of medical care and space flight crew health standards.
- e. A healthy and safe environment in compliance with established habitability and environmental health standards.
- f. System implementations that meet both established human performance and constraints related to human health.

2.1.3 The NASA HMTA shall approve all human health-related system design requirements.

# Chapter 3. Human Health-Related Research and Technology

## 3.1 Requirements

3.1.1 HEOMD shall develop and recommend human health-related research and technology development requirements.

3.1.2 The Office of the Chief Technologist, Space Technology Program, shall develop research and technology deliverables for human health and performance, with cross-reference to the portfolio managed by the AA of HEOMD, to an appropriate stage of readiness level for final review, approval, and implementation.

3.1.3 The CHMO shall review and approve, with modifications as needed, all proposed health-related research and technology development requirements.

3.1.4 The CHMO shall review and assess the progress of human health-related research and technology development programs against established health and medical standards.

## 3.2 Operational Implementation

The CHMO shall approve, approve with revision, defer, or reject, as necessary, all health-related research deliverables and contractor health and medical technology and systems deliverables prior to implementation by the appropriate operational community using the process described in Appendix D.

# Appendix A. Definitions

**Health:** The physiological, psychological, performance, and dental status and well-being of an individual.

**Health and Medical Technical Authority (HMTA):** HMTA provides independent oversight of all health, medical, and crew performance matters that either arise in association with the execution of NASA programs or projects or are embedded in NASA programs or projects. HMTA implements the responsibilities of OCHMO to assure that Agency health and medical policy, requirements, and technical standards are addressed in program/project management, when applicable and appropriate.

**Medical:** The care and treatment of an individual for illness or injury.

**Planetary Protection:** Policies, requirements, and procedures designed to prevent biological contamination of other solar system bodies that might jeopardize scientific investigations on the origins and evolution of life, as well as to prevent the potential for harmful contamination of the Earth by extraterrestrial materials carried on board returning spacecraft.

**Transition to Operations Review Process (TORP):** An assessment of the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results and technology development that can impact crew health and performance for transition to tools available to support Agency human space flight programs.

## Appendix B. Acronyms

AA	Associate Administrator
AMB	Aerospace Medicine Board
CMO	Chief Medical Officer
CHMO	Chief Health and Medical Officer
HMTA	Health and Medical Technical Authority
HSRB	Human System Risk Board
HEOMD	Human Exploration and Operations Mission Directorate
JPL	Jet Propulsion Laboratory, (a Federally Funded Research and Development Center)
JSC	Johnson Space Center
MPB	Medical Policy Board
NPD	NASA Policy Directive
NPR	NASA Procedural Requirements
OCHMO	Office of the Chief Health and Medical Officer
SLSD	Space Life Sciences Directorate
SMD	Science Mission Directorate
TORP	Transition to Operations Review Process
U.S.C.	United States Code

c. NPD 1000.3, The NASA Organization.

d. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

### P.4 Applicable Documents and Forms

a. NPD 7100.8, Protection of Human Research Subjects.

b. NPD 7120.4, NASA Engineering and Program/Project Management Policy.

c. NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight Programs.

d. NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.

e. NPR 1382.1, NASA Privacy Procedural Requirements.

f. NPR 1441.1, NASA Records Retention Schedules.

g. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

h. NPR 7120.8, NASA Research & Technology Program and Project Management Requirements.

- i. NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation.
- j. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.
- k. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 2 - Human Factors, Habitability and Environmental Health.
- l. OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification.
- m. 5 U.S.C. 552a, The Privacy Act of 1974, as amended.
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## **P.5 Measurement And Verification**

P.5.1 Measurements of compliance for this NPR is determined by whether operational managers adhere to the requirements and follow the processes specified in this NPR. The Chief Health and Medical Officer (CHMO) through Agency authority and its Health and Medical Technical Authority (HMTA) function will monitor compliance. This will include appropriate reviews by, and reporting to, the CHMO.

## **P.6 Cancellation**

NPR 8900.1, NASA Health and Medical Requirements for Human Space Exploration, dated May 28, 2008.

/S/

Dr. Richard S. Williams  
Chief Health and Medical Officer

# Appendix C. Process for Establishing Health and Medical Standards

## C.1 Standard Setting Process

C.1.1 Health, human performance, and medical standards are initiated by the NASA CHMO and are developed under the supervision of the delegated HMTA with participation of other Centers and external experts, as appropriate. Final approval is executed by the NASA CHMO.

C.1.2 Health, human performance, and medical standards are established by the OCHMO per the following process:

a. A recommendation for development of a new standard or revision of an existing standard may originate anywhere in the Agency, such as in the OCHMO, the HEOMD, the AMB, or the Space Life Sciences Directorate (SLSD) at JSC, and is forwarded to the NASA CHMO for consideration.

b. The NASA CHMO reviews the recommendations and, if warranted, initiates development or revision of a standard and establishes a standards development team under the supervision of the delegated HMTA.

*Note: The standards development team includes internal NASA experts and may include external discipline experts, as appropriate.*

c. The standards development team drafts the standard which is reviewed according to the process established by the delegated HMTA with the concurrence of the NASA CHMO.

d. The delegated HMTA then reviews the draft standard and provides a recommendation for approval of the new or revised standard to the NASA CHMO.

e. The NASA CHMO determines whether or not independent technical review of the draft standard is required by an external team and convenes a team to conduct the review, where appropriate.

f. The draft/revised standards are distributed to affected and interested parties (e.g., Flight Crew Operations Directorate/Astronaut Office, mission directorates, functional staff offices, Centers, etc.) for review and comment.

g. The draft/revised standards are presented to the NASA MPB, which provides a recommendation for approval to the NASA CHMO.

h. The NASA CHMO considers comments and recommendations and either rejects, recommends further modifications, or executes final approval of the standard.

i. Implementation of the standards is overseen by the delegated HMTA.

j. Periodic review of the standards occurs every five years or at more frequent intervals if new data or clinical observations indicate that a standard or standards need to be updated.

# Appendix D. Transition to Operations Review Process

D.1 The Transition to Operations Review Process (TORP) is designed to assess the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results, and technology development that can impact crew health and performance, for transition to tools available to support Agency human space flight programs.

D.2 The TORP review process will be conducted according to the process described below. It will be applied to newly proposed health and medical procedures, practices, processes (including, when deemed appropriate, "off-label" uses of medications, therapies, and technologies), countermeasures, or technologies resulting from NASA-sponsored research or technology development that are designed to maintain the health, performance, and/or support the medical care of space flight crews. The initial evaluation will be through JSC human space flight HMTA management structure before a recommendation is made to the CHMO for the final review.

D.2.1 The submitting organization presents a proposal for TORP review of a research or technology deliverable or product to the appropriate JSC configuration control board and/or the Aerospace Medicine Board (AMB); for subsequent consideration by the JSC Human System Risk Board (HSRB). The proposal will include the following documentation:

- (1) A detailed description of the deliverable or product, its intended use or application, and a description of how the deliverable or product addresses a NASA-identified critical risk, medical, health or performance issue, or application.
- (2) Data demonstrating the efficacy, effectiveness, or utility of the deliverable or product.
- (3) Data demonstrating the operational validation of the deliverable or product.
- (4) An implementation plan of how the product or deliverable is to be used or applied (e.g., protocol, dosing regime, scope of use).
- (5) An analysis of the mission resources (e.g., crew time, volume, power, etc.) necessary to implement the product or deliverable.
- (6) A summary of the developmental process and milestones the product or deliverable underwent.

D.2.2 Upon recommendation by the HSRB, the submitting organization provides a written request for TORP review of a research or technology deliverable or product to the JSC CMO. The JSC CMO recommends to the NASA CHMO that a panel be convened.

D.2.3 The submitting organization provides the documentation package described above and board recommendations to the NASA CHMO in advance of the TORP review.

D.2.4 Depending on the nature of the product or deliverable, at least one of the reviews below will be conducted to evaluate the operational readiness of the product or deliverable. The CHMO determines which type of review(s) should be conducted.

- (1) Operational assessment - The developmental history and overall utility and effectiveness of the product or deliverable will be assessed by a panel of NASA internal experts with relevant technical and operational expertise for the product or deliverable.

(2) Scientific/technical review - The underlying scientific and/or technical basis and rationale, as well as operational utility and effectiveness, of the product or deliverable will be assessed by a panel of NASA internal and external experts with relevant scientific, technical, and operational expertise for the product or deliverable.

(3) Medical Policy Board review - The product or deliverable supporting documentation, and any results and recommendations from the other two reviews, will be reviewed by the Medical Policy Board for concurrence on recommended course of action.

D.2.5 The TORP panel(s) provides one of the following recommendations for consideration by the NASA CHMO:

- Approve: The CHMO will certify the product or deliverable for NASA medical practice.
- Approve with Revision/Recommendation: The CHMO will certify the product or deliverable as NASA medical practice, with revisions or recommendations to the implementation plan or scope of use, as indicated by the TORP review panel.
- Defer: A decision regarding the product or deliverable will be deferred until additional information can be supplied to the review panel. This may be a request for additional supporting documentation or for additional data collection and/or experimentation.
- Reject: The product or deliverable will not be certified as NASA medical practice.

D.2.6 The OCHMO will convey, in writing, the results of the TORP review to the submitting organization and to the JSC CMO.

D.2.7 Once approved, the product or deliverable will be available for use according to established NASA policy.

# Appendix E. References

- E.1 NPD 1080.1, Policy for the Conduct of NASA Research and Technology (R&T).
- E.2 NPD 1800.2, NASA Occupational Health Program.
- E.3 NPD 8020.7, Biological Contamination Control for Outbound and Inbound Planetary Spacecraft.
- E.4 NPD 8700.1, NASA Policy for Safety and Mission Success.
- E.5 NPR 8705.2, Human-Rating Requirements for Space Systems.
- E.6 NASA/SP-2010-3407, Human Integration Design Handbook.