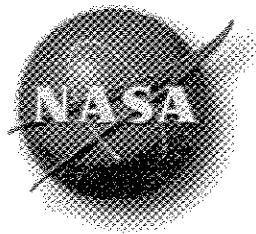


# Data Sharing Policy for Release of NASA Protected Health and Research Information

Space Life Sciences Directorate

March 1, 2012

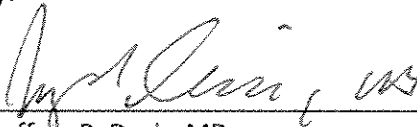


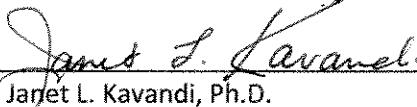
National Aeronautics and Space Administration  
Lyndon B. Johnson Space Center  
Houston, Texas 77058

## Space Life Sciences Directorate

# Data Sharing Policy for Release of NASA Protected Health and Research Information

Approved by:

 3/1/2012  
Date  
Dr. Jeffrey R. Davis, MD  
Director, Space Life Sciences Directorate  
NASA Johnson Space Center

 3/5/2012  
Date  
Dr. Janet L. Kavandi, Ph.D.  
Director, Flight Crew Operations Directorate  
NASA Johnson Space Center



# Table of Contents

- 1 INTRODUCTION.....5**
  - 1.1 PURPOSE ..... 5
  - 1.2 SCOPE ..... 5
  - 1.3 STAKEHOLDER DEFINITION AND ADVOCACY ..... 5
  - 1.4 CHANGE AUTHORITY ..... 5
  
- 2 POLICY .....5**
  - 2.1 MEDICAL DATA DEFINITION ..... 6
  - 2.2 RESEARCH DATA DEFINITION ..... 6
  - 2.3 SPACE LIFE SCIENCE DIRECTORATE DATA GOVERNANCE ..... 7
  - 2.4 DATA ACCESS POLICY ..... 7
    - 2.4.1 *Attributable Medical Data* ..... 8
    - 2.4.2 *Attributable Research Data* ..... 8
    - 2.4.3 *Unattributable Medical and Research Data* ..... 9
  - 2.5 USER RESPONSIBILITIES ..... 9
  - 2.6 POLICY VIOLATIONS ..... 9
  
- APPENDIX A – REFERENCE DOCUMENTS.....10**
  - APPLICABLE DOCUMENTS ..... 10
  - REFERENCE DOCUMENTS ..... 10
  
- APPENDIX B – FLOW DIAGRAM .....11**

## **1 INTRODUCTION**

### **1.1 PURPOSE**

The purpose of this document is to establish and document a policy by which NASA Johnson Space Center (JSC) allows for request, review of and potential release of human medical and research data. This policy further defines access controls for personally identifiable information (PII) under the Privacy Act of 1974, as Amended (5 U.S.C. 552a) and within the scope of NASA 10HIMS—Health Information Management System and NASA 10HERD - Human Experimental and Research Data regulations which govern the control of each system of records (data).

This policy will help ensure the integrity and protection of these data while also clarifying the process for those who request data access to further understand and mitigate the risks of human space flight on behalf of NASA and/or for the benefit of the larger U.S. population. The specific processes by which data is requested, used, released, and published and the requirements for personnel accessing this data will be located in Space Life Sciences Directorate (SLSD) work instructions.

### **1.2 SCOPE**

The scope of this document includes request for, review of, release and sharing of PII (attributable/identifiable) and unattributable (de-identified) data collected under the auspices of NASA or NASA-related programs on human subjects (astronauts and non-astronauts) for clinical/medical and research purposes.

This document does not address the standard medical records access by medical professionals as already defined by the Privacy Act .

### **1.3 STAKEHOLDER DEFINITION AND ADVOCACY**

The Agency is the primary stakeholder for this document. The Agency's goals are to ensure crew health and enable long term space exploration. Sharing of these data directly benefits the Agency's spaceflight missions.

### **1.4 CHANGE AUTHORITY**

This document is under configuration management control of the SLSD. Changes to this document will result in issuance of change pages or a full re-issue of the document.

## **2 POLICY**

The following sections outline the definition of medical and research data; the rationale for sharing and safeguarding of data; and the processes required to enable data sharing. See Appendix B for a flow diagram of the process for data access.

## **2.1 MEDICAL DATA DEFINITION**

Medical data consists of all PII as contained in the NASA 10HIMS (Health Information Management System) system of records, including personal health information (PHI) such as: records of medical care, first aid, emergency treatment, examinations (e.g., surveillance, hazardous workplace, certification, flight, special purpose and health maintenance), exposures (e.g., hazardous materials and ionizing radiation), and consultations by non-NASA physicians.

SLSD gathers much of this medical data for crewmembers in the form of required medical exams for flight certification and required medical testing and monitoring in association with space flight. These requirements are referred to as Medical Requirements Integration Documents (MRIDs), and Occupational Requirements Integration Documents (ORIDs).

- MRIDs are required medical tests performed on crewmembers in order to evaluate and monitor health and medical risk before, during and following space missions.
- ORIDs are medical tests and environmental monitoring performed on crewmembers before, during, and following space missions in order to evaluate risks and health impacts to the individual and the spaceflight population as a result of the work environment.

NASA medical records follow:

- The Privacy Act of 1974 (Public Law 93-579), 5 U.S.C. § 552a
- Privacy Act, NASA Regulations (14 CFR Part 1212)
- Federal 10HIMS System of Records
- Health Insurance Portability and Accountability Act (HIPAA) of 1996 (45 CFR Part 160 and Part 164, Subparts A and E)

Collection of medical data (PII) generally does not require informed consent and may only be used for the care of the individual or for occupational surveillance. All other uses of the data, if attributable, require patient release authorization.

## **2.2 RESEARCH DATA DEFINITION**

Research data consists of all information as contained in the NASA 10HERD system of records, including personal information acquired as part of research investigations. These investigations follow:

- U.S. Department of Health and Human Services' Protection of Human Subjects Regulations (45 CFR Part 46) and 14 CFR Part 1230
- NASA Procedural Requirements (NPR) 7100.1, "Protection of Human Research Subjects"
- NASA Policy Directive (NPD) 7100.8, "Protection of Human Research Subjects"
- HIPAA of 1996 (45 CFR Part 160 and Part 164, Subparts A and E)

Collection of research data requires informed consent by the subject and the data may only be used as stated in the informed consent. No attributable data may be released beyond the scope of the informed consent without written authorization from the subject.

### **2.3 SPACE LIFE SCIENCE DIRECTORATE DATA GOVERNANCE**

SLSD shall form and maintain a cross-division board which will disposition requests for personally identifiable information (PII) medical information. This board will be chaired by the physician who is the Medical Records Administrator or his/her physician designee. All requests for PII medical data shall be processed and dispositioned at this board. This board will review the request for relevance to NASA's mission and for merit.

Based on relevance to NASA's mission, NASA may or may not require funding from the requestor to process the request/generate the data. If funding from the requestor is required, then a reimbursable Space Act Agreement will be negotiated.

All PII requests for research data must be covered by an informed consent and will be processed and dispositioned by the Committee for the Protection of Human Subjects (CPHS).

### **2.4 DATA ACCESS POLICY**

The intent of this policy is to define process and conditions by which individuals may request access to PII for the purposes of benefitting the individual, population and/or the Agency's mission while maintaining the privacy and security of PII, both clinical and research in nature.

SLSD shall develop and maintain a set of specific Guidelines for the Handling and Release of NASA Protected Health and Research Information which will contain the detailed specific processes by which research and medical personnel may request attributable and unattributable data in order to be compliant with this policy, and the process for evaluation, and approval or denial of these requests.

These guidelines shall also contain provisions to establish mechanisms, policies and procedures for annotating data records to indicate that information contained within them has been disclosed for those approved activities.

The following sections define requirements for the sharing of both attributable and unattributable sets of medical and research data.

#### **2.4.1 Attributable Medical Data**

The data request will be reviewed by the Chief of Space Medicine in his/her role as Medical Records Administrator. The intent is to have the review/release of each data request delegated to a control board where the Medical Records Administrator acts as Chair (or his physician delegate), such as the Lifetime Surveillance of Astronaut Health Control Board.

The access will be granted pursuant to the Privacy Act of 1974, as amended.

Access to attributable medical data may be granted on a case-by-case basis for the purposes of:

- a) Assisting the medical community in the assessment of health and medical risk to the individual or population of interest
- b) Assisting the Agency in the determination of space flight induced health and medical risk as it pertains to the occupational environment.

It will be required that the data analysis progress be reported on a regular basis to the Chief of Space Medicine (or his physician delegate) and/or the control board. All publications generated related to the findings must also be approved by the Chief of Space Medicine (or his physician delegate) and/or the control board prior to release. No publication shall contain attributable data.

All other release of medical data must have a written patient release.

#### **2.4.2 Attributable Research Data**

Access may be granted on a case by case basis to attributable research data to personnel who are not part of the original research team for the purposes of assisting the Agency in the determination and mitigation of health and medical risks, (occupational surveillance) for ground and/or flight activities. Requests for this access will be processed by the Chief of Space Medicine (or his physician delegate) and/or the control board prior to release. All publications generated related to the findings must also be approved by the Chief of Space Medicine (or his physician delegate) and/or the control board prior to release. No publication shall contain attributable data.



These circumstances for attributable data release will be disclosed on the Informed Consent Form to the subject prior to admission into the study. All other releases of attributable research data must have prior approval/release from the subject.

### **2.4.3 Unattributable Medical and Research Data**

Release of unattributable medical and research data is permissible without informed consent provided the conditions of the NASA 10HIMS and 10HERD are met, in conjunction with the Privacy Act of 1974, as amended and to the HIPAA Privacy Rule (45 CFR Part 160 and Part 164, Subparts A and E) .

### **2.5 USER RESPONSIBILITIES**

All aspects of the Privacy Act, Common Rule, Federal law, and NASA regulations (reference Appendix A) must be strictly adhered to by those with access to any PII. It is the responsibility of the individual to maintain the privacy and security of the data in their possession at all times.

### **2.6 POLICY VIOLATIONS**

Violations of this policy will be brought forward to the SLSD and Office of Chief Counsel by the Medical Records Administrator or other responsible party. Violations will be assessed on a case-by-case basis and while the violation is evaluated, the individual is denied access to the database and use of the data in question.

Consequences of violating this policy may include the following:

- 1) Temporary or permanent denial of access.
- 2) Return of any outstanding data to NASA
- 3) Disciplinary action by the employer including removal from the position and/or employment

In addition the patient must be informed of the breach of confidentiality.

## APPENDIX A – REFERENCE DOCUMENTS

### APPLICABLE DOCUMENTS

Document Number	Document Title
5 USC, Section 552a	Privacy Act of 1974, As Amended
14 CFR 1212	Privacy Act, NASA Regulations
14 CFR Part 1230	Protection of Human Subjects - NASA
45 CFR Part 46	Department of Health and Human Services regulations - Protection of Human Subjects
45 CFR Part 160 and Part 164, Subparts A and E	HIPAA Privacy Rule
<a href="http://irb.nasa.gov/?p=pnp">http://irb.nasa.gov/?p=pnp</a>  (formerly JSC 20483, Rev. C)	Policies and Procedures for the JSC CPHS, e-IRB  JSC CPHS Guidelines for Investigators Proposing Human Research for Space Flight and Related Investigations
JSC 28330, Rev. C	Space Life Sciences Directorate Configuration Control Management Plan
NPD 7100.8 and NPR 7100.1	Protection of Human Research Subjects
NPR 1382.1	NASA Privacy Procedural Requirements
NPR 1800.1C	NASA Occupational Health Program Procedures w/Change 1 (12/31/2009)
NPR 1800.2C	NASA Occupational Health Program (Revalidated 7/26/2010)
Public Law 104-191	Health Insurance Portability and Accountability Act (HIPAA) of 1996
Public Law 110-233, 122 Statute 881	Genetic Information Nondiscrimination Act (GINA) of 2008

### REFERENCE DOCUMENTS

Document Number	Document Title
<a href="http://www.nasa.gov/privacy/nasa_sorn_10HIMS.html">http://www.nasa.gov/privacy/nasa_sorn_10HIMS.html</a>	Federal 10HIMS (Health Information Management System) System of Records
<a href="http://www.nasa.gov/privacy/nasa_sorn_10HERD.html">http://www.nasa.gov/privacy/nasa_sorn_10HERD.html</a>	Federal 10HERD (Human Experimental and Research Data Records) System of Records

## APPENDIX B – FLOW DIAGRAM

