

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

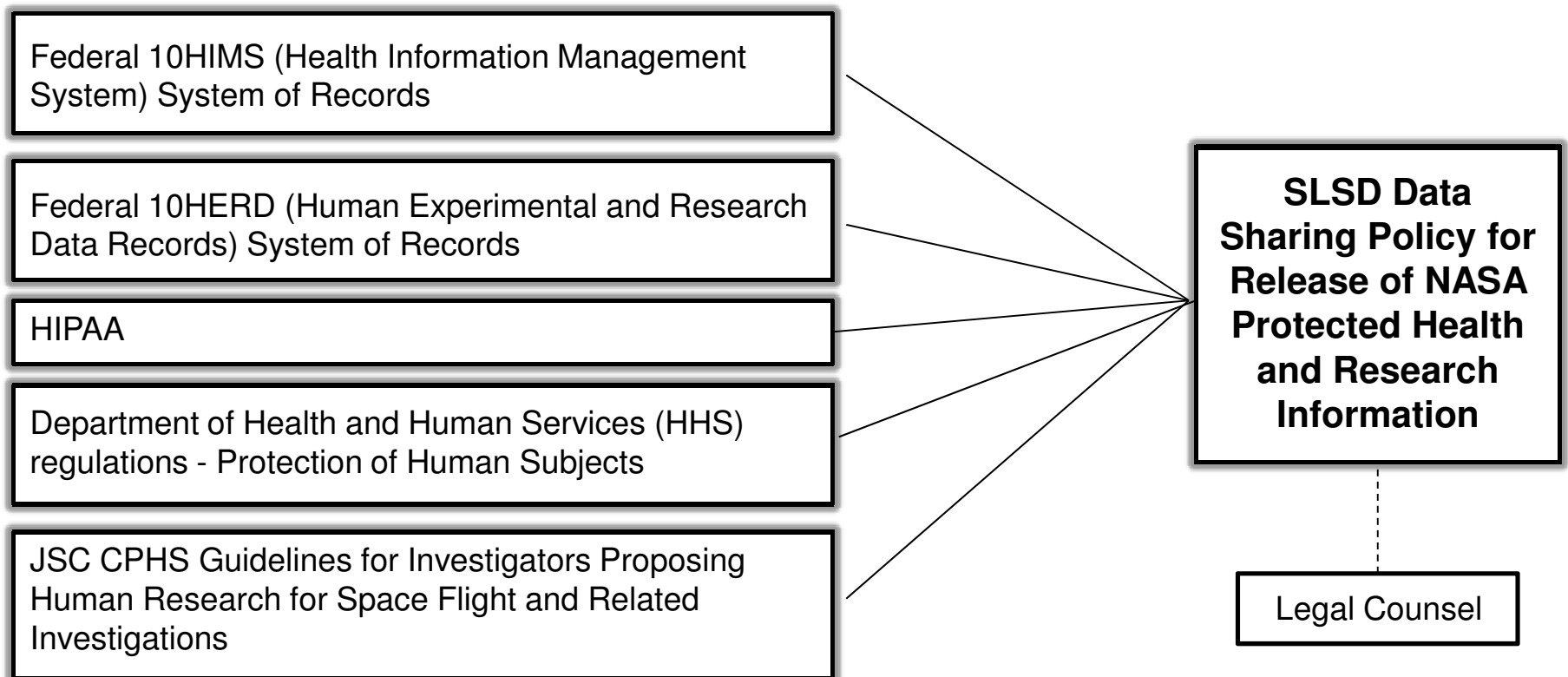
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SLSD Data Sharing Policy for Release of NASA Protected Health and Research Information Overview

Why do we need a policy? To 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 U.S. population.

There are no new “regulations” in this policy. This policy integrates the content of several regulations to provide one integrated end to end look at the responsibilities, processes, and requirements for data sharing.



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What doesn't this policy cover? This policy does not address the standard medical records access by medical professionals as already defined by the Privacy Act.

Who controls the data? *As per 10HIMS* the Medical Records Administrator (SD/Medical Operations Division Chief) is the ultimate authority on what data is released.

What are the data definitions?

Medical and Occupational Data definitions:

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.

Research Data Definition

Research data requires informed consent by the subject and the data may only be used as stated in the informed consent.

What is Occupational Surveillance? 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.

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

Board Formation for disposition of requests: 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 disposition at this board.

Why/when would data be released? Access to attributable medical data may be granted by the Medical Records Administrator 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 other release of attributable medical data must have a written patient release.

Will medical records be annotated? This Policy also contains 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.

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

Will the data be published? 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.** Any releases of attributable data must have prior approval/release from the subject.

What are the 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. SLSD provides training for individuals.

What happens if there is a Policy Violation? 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. Consequences of violating this policy may include the following:

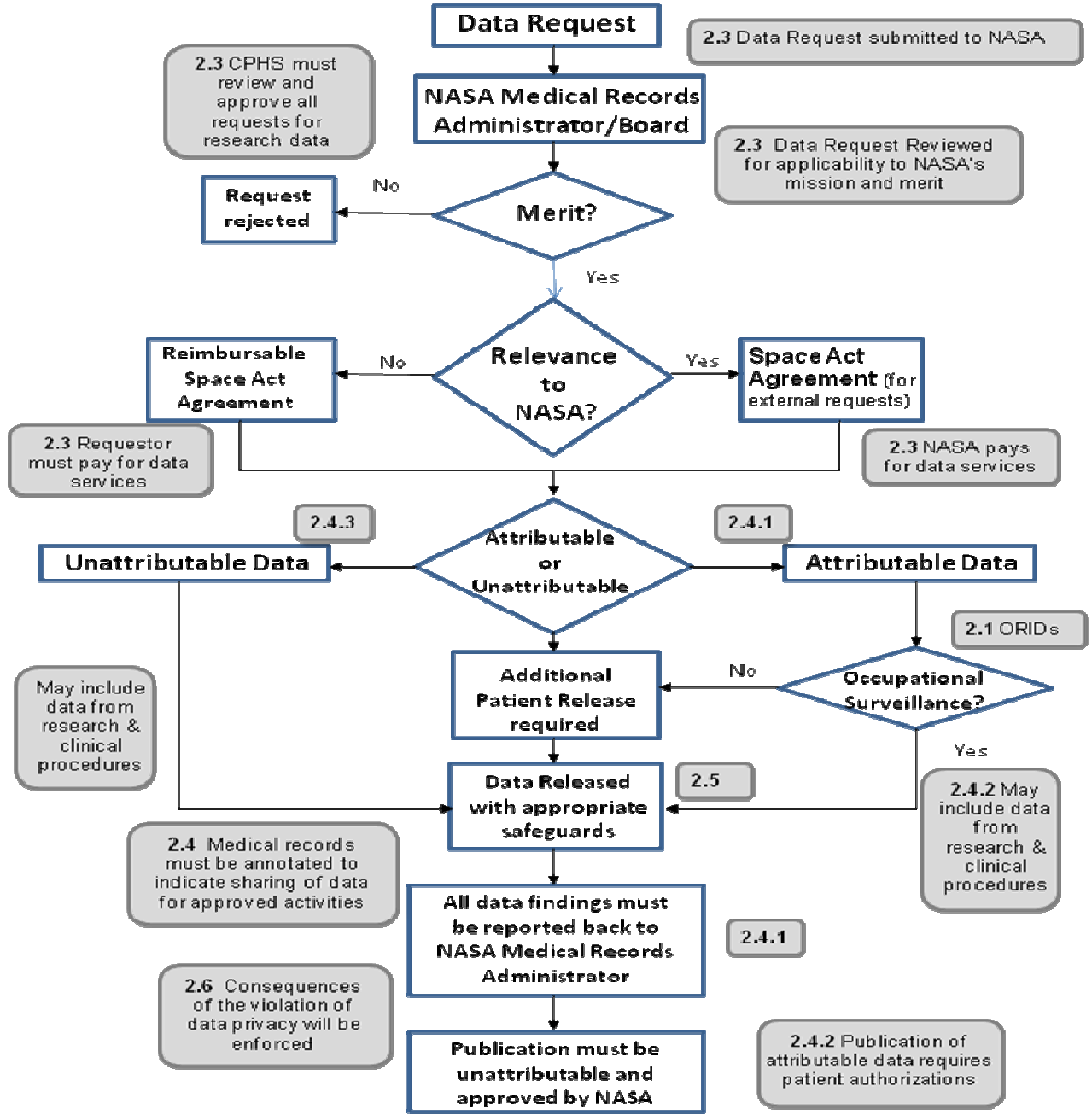
- Temporary or permanent denial of access.
- Return of any outstanding data to NASA
- Disciplinary action by the employer including removal from the position and/or employment and

The patient must be informed of the breach of confidentiality.

Summary: The Policy has been reviewed and agreed to by the SLSD and Flight Crew Operations and is in the final signature process.

Backup

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



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

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 (HHS) regulations - Protection of Human Subjects |
| 45 CFR Part 160 and Part 164, Subparts A and E | HIPAA Privacy Rule |
| http://irb.nasa.gov/?p=pnp (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 |
|---|---|
| http://www.nasa.gov/privacy/nasa_sorn_10HIMS.html | Federal 10HIMS (Health Information Management System) System of Records |
| http://www.nasa.gov/privacy/nasa_sorn_10HERD.html | Federal 10HERD (Human Experimental and Research Data Records) System of Records |