

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

Talking Points

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.

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? The Medical Records Administrator (SD/Medical Operations Division Chief) is the ultimate authority on what data is released.

Why/when would data be released? 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 other release of medical data must have a written patient release.

What training is required to access data? Completion of the CITI Collaborative Institutional Training Initiative, Basic Course on Biomedical Research is required before data will be released. Medical Professionals (MDs) are not required to have this training.

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.

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.

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.

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

When will the Cross Directorate Board be formed to review data requests? The work instruction for this board will be approved in the near future. Presently the Medical Records Administrator in the Space Medical Operations Division is processing requests via the Occupational Surveillance Board.