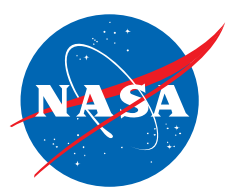


HRP Data Accessibility Current Status Investigators Workshop

3 February 2009

Clarence Sams



Perception of science community regarding the “stealth” medical data...

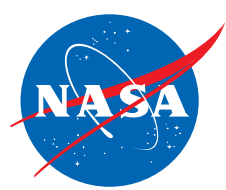


Human Research Program

I know it's there...I just can't see it!!



AHAJOKES.COM



Overview of talk



Human Research Program

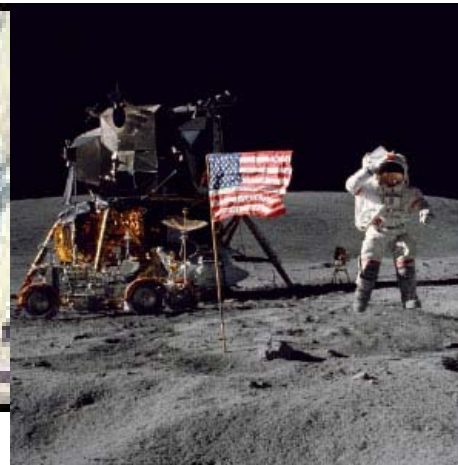
- Content of Human Life Science data
- Data archive structure
- Applicable legal documents and policies
- Methods for data access



50 Years of Spaceflight Data



Human Research Program





What Data Does NASA Have?



Human Research Program

- Life Science Data Archive
- (LSDA)
- Contains *research data* from NASA-funded experiments, primarily data from flight experiments and ground analog data collected at NASA facilities
- <http://lsda.jsc.nasa.gov>

Longitudinal Study of Astronaut Health (LSAH)

- Contains electronic health records (*medical data*) of all astronauts, including mission data
- Data are collected for clinical purposes
- Clinical data are analyzed by LSAH epidemiologists to identify trends in crew health and implement changes in pre-, in-, or post-flight medical care
- Repository more than study



Data Access: LSDA



Human Research Program

<http://lsda.jsc.nasa.gov>



National Aeronautics
and Space Administration

Life Sciences Data Archive
@ Johnson Space Center, Houston, Texas

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NASA's Life Sciences Data Archive (LSDA) is a work in progress that provides information and data from space flight experiments funded by the National Aeronautics and Space Administration (NASA). The archive includes investigations from 1961 (Mercury Project) through current missions (International Space Station and Shuttle) involving human, plant and animal studies. The Life Sciences Data Archive is a part of the Human Health and Performance Program of the Exploration Systems Missions Directorate which is dedicated to "safe, sustained, affordable exploration of the Moon, Mars, and beyond..." This site is intended for all audiences, from scientists and teachers to the general space enthusiast.

What's New for Researchers

- + [View NASA Research Opportunities](#)
- + [View NASA Astronaut Medical Requirements](#). + [View NSBRI Research Opportunities](#).

The National Space Biomedical Research Institute (NSBRI) was established in 1997 through a NASA competition to work on countermeasures to the health-related problems and physical and psychological challenges men and women will face on long-duration missions.

- + [View NSBRI Website](#).



+ Popular Search Terms

AGSLEEP

Apollo 16

Apollo 9

Cosmos 782

Cosmos 936

ED52

Expedition 2

Expedition 3

Expedition 4

Gemini 7

Human

ISS

LMLSTP

Rat

STS-

40

STS-41D

STS-58

Skylab 3

Tissue

Water

apollo

blood

New Content on this Web site

- + [Bone Mineral Loss and Recovery after Shuttle/Mir Flights \(9401598\)](#)
- + [In-Flight LBNP: Countermeasure to Reduce Post-Space Flight Orthostatic Intolerance \(DSO 478\)](#)
- + [In-flight Evaluation of a Portable Clinical Blood Analyzer \(DSO 492\)](#)
- + [Muscle Biopsy \(DSO 475\)](#)
- + [Pre- and Postflight Echocardiography \(DSO 465\)](#)
- + [The Evaluation of Concentric and Eccentric Skeletal Muscle Contractions Following Space Flight \(DSO 477\)](#)

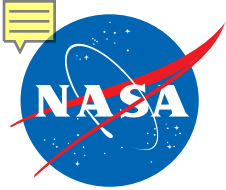
RSS

+ [NASA PRIVACY STATEMENT](#) | + [FEEDBACK](#) | + [SITE MAP](#) | + [SURVEY](#) | + [GLOSSARY](#) | + [RELATED LINKS](#)

- + Web Accessibility and Policy Notices at JSC
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- + Equal Employment Opportunity Data Posted Pursuant to the No Fear Act
- + Information-Dissemination Priorities and Inventories



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 Webmaster: Abul A Chowdhury
 NASA Official: Mary A. Fitts
 Baseline: 7/15/2004
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Data Access: LSDA



Human Research Program



National Aeronautics
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Life Sciences Data Archive
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SEARCH

DATABASE





Experiment



Mission



Personnel



Photo Gallery



Biospecimens



Documents




Hardware



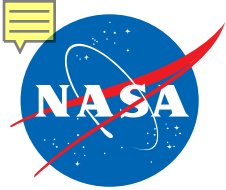
Dataset

+ NASA PRIVACY STATEMENT |
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Data Access: LSDA



Human Research Program

+ Dataset Archive Holdings Show 20 50 100 results

Research Area
Bone and calcium physiology

Parameters Measured
(Any parameters)

Cells, Tissues, Organs and Samples
(Any tissue)

Species Studied
Homo sapiens (Human)

Experiment Title
(Any experiments)

Payload Title/Payload
(Any Payload title/payload)

Hardware Item
(Any Hardware)

Protocol/Approach
(Any protocol/approach)



Data Access: LSDA



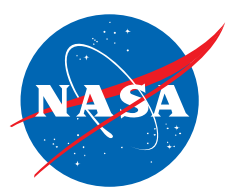
Human Research Program

Search Results 1 - 20 of 27 total results.

Page 1 of 2 1 2 Next >>

Available online

- + Average Serum Calcium, Preflight, Inflight and Postflight for Four Astronauts (JMLMS074031)
- + Brushite Supersaturation on Mir 18 (JMMIR012)
- + Calcium Oxalate Supersaturation on Mir 18 (JMMIR011)
- + Calf Muscle T2 Values (JMMIR9401586_629)
- + Change in Bone Density in the Central Os Calcis of Bed Rest Units for Specified Number of Days (J0001155)
- + Daily Urinary Output on Mir 18 (JMMIR010)
- + Data Collection Timetables for Experiment 284036 (JMLMS284036_63)
- + Data Collection Timetables for Experiment 284074 (JMLMS284074_999)
- + Early Postflight Muscle Volume Changes Compared to Preflight Values (JMMIR9401586_628)
- + Early Postflight Muscle Volume Percent Change from Baseline (JMMIR9401586_662)
- + Expected Negative Correlation Between Serum Calcium and Parathyroid Hormone (PTH) (JMLMS074027)
- + Intervertebral Disc Cross-Sectional Area (J0000869)
- + Muscle Atrophy with Bed Rest (JMMIR9401586_654)
- + Muscle Volume Changes (J0000868)
- + Muscle Volume Loss and Recovery (JMMIR9401586_627)
- + Percent Change in the Central Os Calcis Bone Mass of Bedrest Subjects (J0001154)
- + Relationship between Serum Calcium and Parathyroid Hormone (PTH) (JMLMS074028)
- + Response of Serum Bone Formation Markers -- Osteocalcin and Bone Specific Alkaline Phosphatase L-1 to R+2 (JMLMS074032)
- + Response of Serum Osmolality to Flight, L-1 to R+2, and Serum Hydrogen Concentration (JMLMS074033)
- + Serum Ionized Calcium and Parathyroid Hormone (PTH) Preflight and Early Inflight (JMLMS074026)



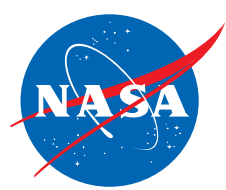
Data Access: LSDA



Human Research Program

DATA ELEMENT INFORMATION

Data Element Name:	Intervertebral Disc Cross-Sectional Area											
Data Files: [Available online]	+ JMLMS284054_46.xls (Download)											
Data Element Description:	The spreadsheet lists the average changes in intervertebral disc cross-sectional area observed in four subjects after 17 days of space flight. Listed are the percentage changes for five intervertebral discs of the lumbar spine. The average of the two preflight measurements was used as the baseline, and the postflight measurements were compared with this value. Statistical analysis was performed.											
Parameters Measured:	<table border="1"> <thead> <tr> <th>Parameter</th> <th>Tissue 1</th> <th>Tissue 2</th> </tr> </thead> <tbody> <tr> <td>Intervertebral disc size, lumbar spine</td> <td></td> <td></td> </tr> <tr> <td>Spine length</td> <td></td> <td></td> </tr> </tbody> </table>			Parameter	Tissue 1	Tissue 2	Intervertebral disc size, lumbar spine			Spine length		
Parameter	Tissue 1	Tissue 2										
Intervertebral disc size, lumbar spine												
Spine length												
Data Element Review or Technical Comments:	Data element was part of the NASA Final Report, submitted by the PI. The data represents mean data from four subjects. Standard deviation and the statistical significance are reported.											
Measurement or Analysis Technique:	Magnetic Resonance Imaging (MRI). For the spine imaging, the subjects were positioned so that the imaging area was centered within the L3 vertebra, determined from a sagittal scout view. A coronal scout image was used to position a 1 cm slice of interest through the center of the spinal column. A three slice gradient echo sequence, with an echo time of $T_e=7$ msec and a recovery time of $T_r=400$ msec with acquisition and a 256×256 matrix was used. A phantom was imaged during each session to correct for any changes in pixel size. Disc area measurements were obtained for discs T12-L1, L1-2, L2-3, L3-4, and L4-5 from the number of pixels in each image.											
Experiments:	+ Magnetic Resonance Imaging After Exposure to Microgravity (284054)											
Payload:	+ Life and Microgravity Spacelab (LMS)											
Hardware Items:	+ Magnetic Resonance Imaging (MRI) Device + Magnetic Resonance Imaging (MRI) Device											
Data Source:	Final report, Table7											



Data Access: LSDA



Human Research Program

Flight Crew-Intervertebral Disc Cross-Sectional Area,
Percent Change From Baseline

	T12-L1	L1-L2	L2-L3	L3-L4	L4-L5	Average	P
L-(50/51)	1	1	-1	-1	-1	0	
L-(29/31)	-1	-1	1	1	1	0	
R+0	-4	-2	-3	-5	-1	-2	NS
R+2	-4	-2	-2	-0	1	-2	NS
R+10	-9	-5	-7	-9	-6	-6	<0.01
R+30	-1	-1	-3	-4	-2	-1	NS

Each data points represents the average from four subjects.

Preflight measurements (L-50/51 and L-29/31) were combined and were the baseline the postflight measurements were compared with.



Data Access: LSDA



Human Research Program

- Key Points and limitations about LSDA
 - Contains *research data* from NASA-funded experiments, primarily data from flight experiments and ground analog data collected at NASA facilities
 - Collected under specific informed consent
 - Each dataset collected under different circumstances defined by the original investigation
 - Data on main web site is from published reports
 - <http://lsda.jsc.nasa.gov>

NOTE: Quality of data in = quality of data out. PIs are responsible to populate this database at the end of their NASA sponsored research



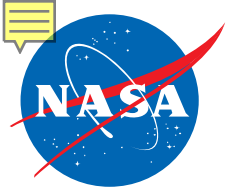
Data Access: LSAH



Human Research Program

Longitudinal Study of Astronaut Health (LSAH)


- Irrespective of the title, this is an ongoing data repository not a specific study
- Contains electronic health records (*medical data*) of all astronauts, including mission data
- Data are collected for clinical purposes
- Clinical data are analyzed by LSAH epidemiologists to identify trends in crew health and implement changes in pre-, in-, or post-flight medical care
- Task makes available information from the medical requirements (MRIDs) – descriptions available at <http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.cfm>



Data Access: LSAH



Human Research Program

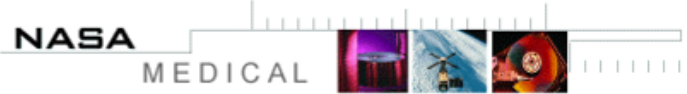


National Aeronautics
and Space Administration












Life Sciences Data Archive
@ Johnson Space Center, Houston, Texas

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+ [View MRID overview](#) or Click on a category image for relevant MRID information:

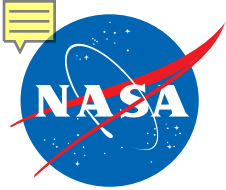
 Behavioral Health and Performance	 Bone, Muscle, Exercise	 Cardiovascular
 Environmental Health	 Extravehicular Activity (EVA)	 Immunology
 Neurology	 Nutrition	 Radiation
 Therapeutics and Clinical Care	 View All Medical Requirements	

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Webmaster: Abul A Chowdhury
NASA Official: Mary A. Fitts
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Data Access: LSAH



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+ [View MRID overview](#) or Click on an category image for relevant MRID information:

Behavioral Health and Performance

Bone, Muscle, Exercise

Cardiovascular

Environmental Health

Extravehicular Activity (EVA)

Immunology

Neurology

Nutrition

Radiation

Therapeutics and Clinical Care

View All Medical Requirements

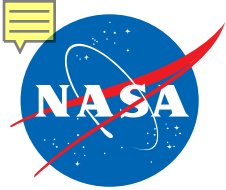
Bone, Muscle, Exercise

Discipline	MRID#	Medical Requirement Title
Bone, Muscle, Exercise	MEDB 5.4	+ Calf Volume Measurement
Bone, Muscle, Exercise	MR006L	+ Exercise Treadmill Test
Bone, Muscle, Exercise	MR019L	+ Heart Rate Monitoring
Bone, Muscle, Exercise	MR026L	+ Postflight Rehabilitation
Bone, Muscle, Exercise	MR035L MEDB 1.11	+ Bone Densitometry
Bone, Muscle, Exercise	MR038L MEDB 6.3	+ Arm Ergometry Test
Bone, Muscle, Exercise	MR078L	+ Physical Fitness Evaluation: Functional Fitness
Bone, Muscle, Exercise	MR079L MEDB 5.3	+ Isokinetic Testing
Bone, Muscle, Exercise	MR080L MEDB 4.1	+ Cycle Ergometer Test/ Aerobic Functional Capacity
Bone, Muscle, Exercise	MR081L	+ Physical Fitness Evaluation: Handgrip Dynamometry
Bone, Muscle, Exercise	MR082L MEDB 5.2	+ On-Orbit Strength & Conditioning Monitoring

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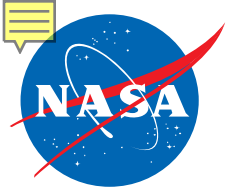


Data Access: LSAH



Human Research Program

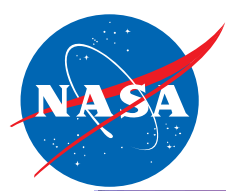
- Limitations of the Data
 - Taken for clinical purposes
 - Flight Surgeons assess health of crew members using numerous inputs
 - Data may not always be taken for each crew member
 - Data taken on crew members may be taken in different circumstances
 - Example: Soyuz vs. Shuttle crew returns change times and tests
 - Much of data content is driven by crew surgeon need
 - Data may list outcome (e.g., “normal”) not the detailed measures
 - Raw data may be recoverable, but will require deeper retrieval



Privacy Law



- Privacy Act of 1974 prohibits disclosure of records contained in a system of records maintained by a federal agency (or its contractors) without the written request or consent of the individual to whom the record pertains.
 - Privacy Act permits agencies to disclose information for other purposes defined as “routine uses” which are defined and published in the Federal Register Systems of Record Notice.
 - 10HIMS – Health Information Management System
 - 10HERD – Human Experimental and Research Data
 - Access on a need-to-know basis.
- Subjects have the right to decide the extent to which their data is used, i.e. Informed Consent. Reviewed and enforced by JSC Committee for the Protection of Human Subjects (CPHS).



Methods for Access to Data

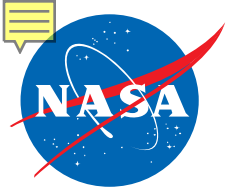


Human Research Program

- Data can be given under these circumstances
 - Informed Consent has been obtained from each crew member, specifying the purpose for which the data are to be used
 - Based on Informed Consent, limitations may be placed on publication of data
 - Review by LSAH Executive Committee to ensure data submitted for publication are properly de-identified

OR

- Data are “De-Identified” prior to delivery to the researcher
 - Data have identifiers such as mission length, gender, etc removed or “binned” to preclude individuals from determining the crew member’s identity
 - e.g. Mission length is one of 12, 13, 14, etc. days vs specification of mission length to days, hours and minutes
 - Data are reported in pooled manner to preclude any specific individual from being identified



NRA Proposals



Human Research Program

- Proposers to an NRA could include the use of biomedical data as part of their research plan
 - Researcher reviews the MRIDs and defines the requirement for access to data in their proposal
 - If proposal is selected
 - Review by the Committee for the Protection of Human Subjects
 - Brief subjects on use of data
 - Obtain informed consent
 - Use data
 - Publication may be subject to LSAH Executive Committee review to ensure data are properly de-identified prior to publication



Obtaining De-Identified Data



Human Research Program

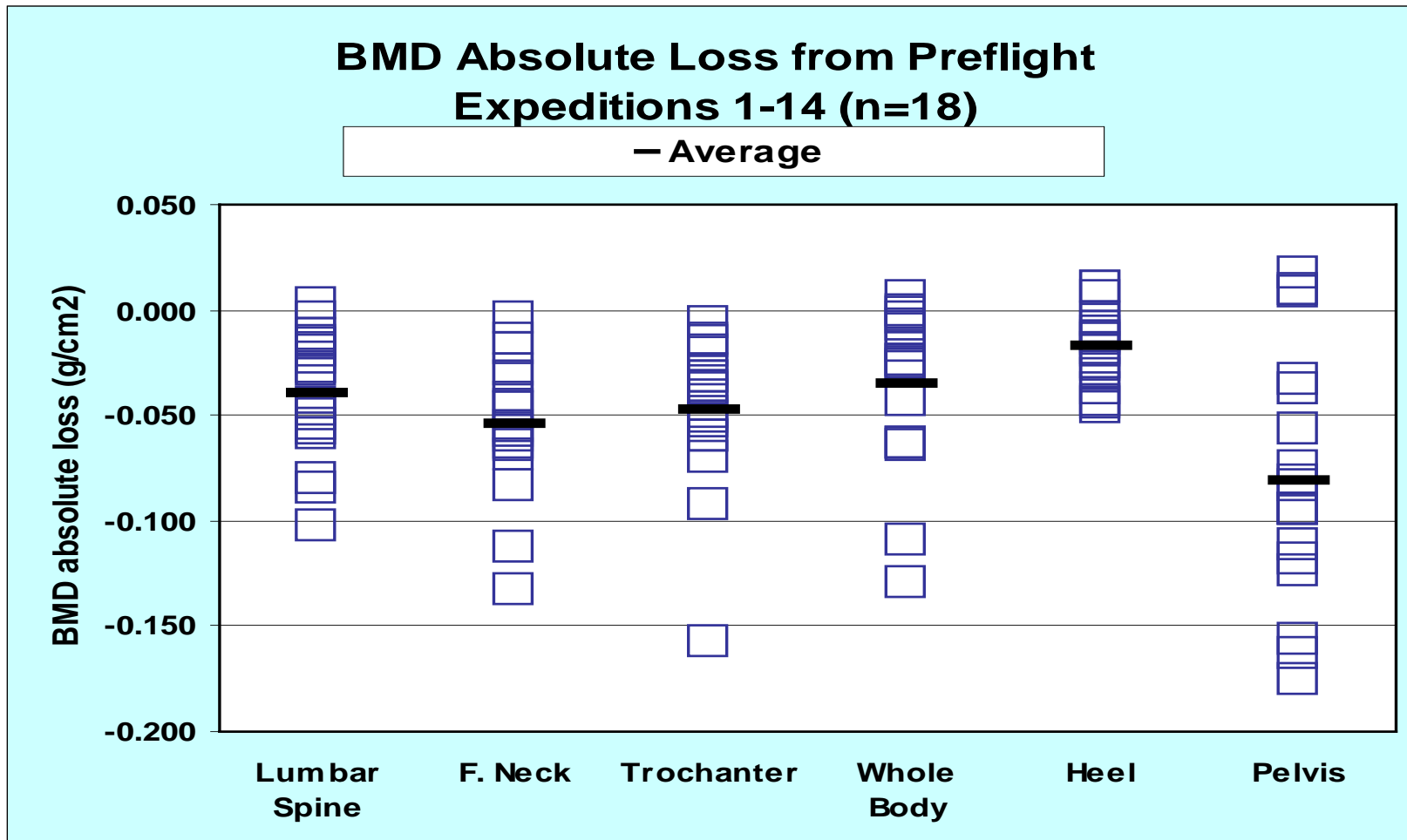
- The most expedient way to obtain access to data is to obtain de-identified pooled or grouped data
- NASA has a staff of epidemiologists that work to provide de-identified datasets that address the researcher's specific need
- Since the data were taken in varied circumstances, it usually takes some iteration to determine the best way to provide the data to the researcher

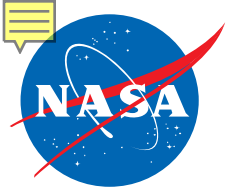


De-Identified Data - Individual



Human Research Program



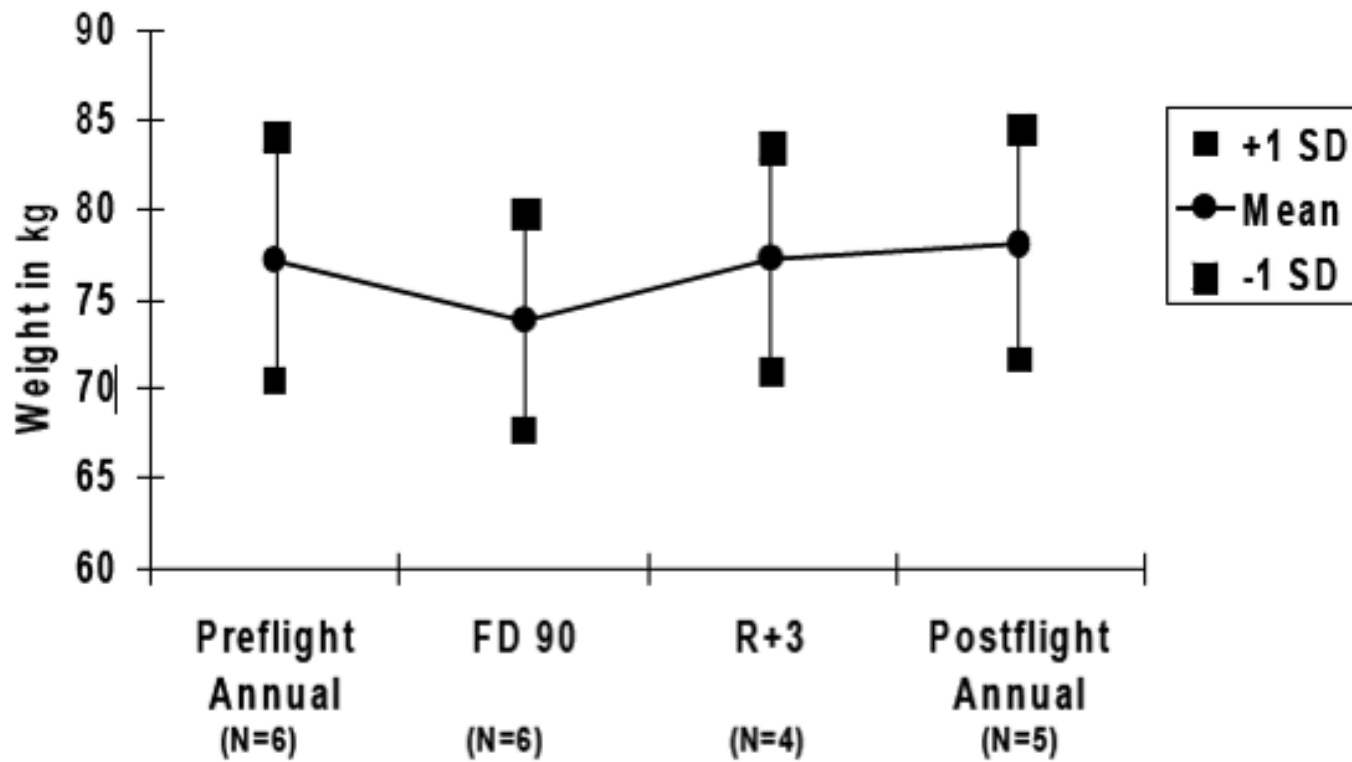


De-Identified Data - Pooled

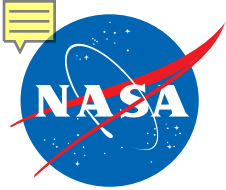


Human Research Program

Mean Weight in kg at Preflight, Inflight, Postflight, and Annual Examinations for NASA/MIR Program



Inflight data obtained using the Body Mass Measurement Device (BMMD).

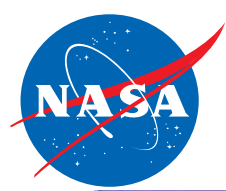


Obtaining De-Identified Data



Human Research Program

- Researcher
 - Searches the MRIDs
 - Formulate data request per format posted at <http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.cfm>
 - Purpose/Description
 - Information on peer review
 - Data requested
 - Contact information
 - Email form to jsc-lsah@mail.nasa.gov or mail to address on form
 - Epidemiologist contacts the researcher to further understand request
 - Epidemiologist provides de-identified data

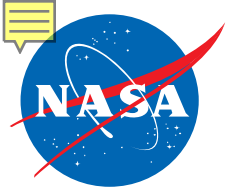


Obtaining identified or crewmember specific data



Human Research Program

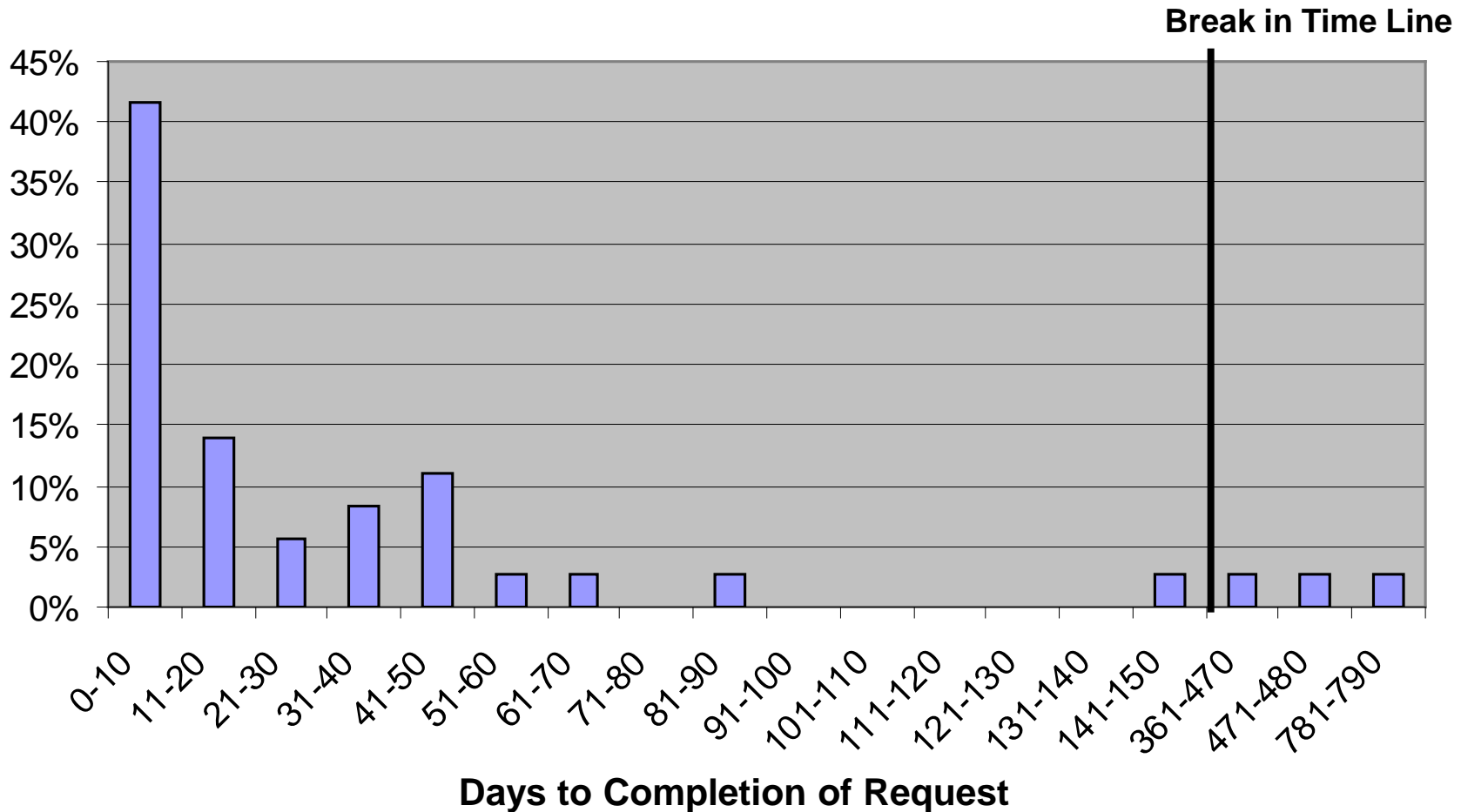
- Possible to obtain identified data
- Normally the requirement is defined during experiment development and is part of the data sharing plan
- Requests can be accommodated for approved studies
- Requires that individual approval be obtained from each crewmember via informed consent
- LSAH team can handle this with appropriate information from requesting PI
- Adds processing time to the data release



Response Time for Requests Jan-Oct 2008

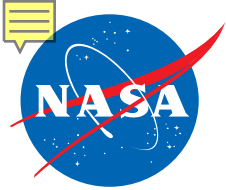


Human Research Program



Average - 68.1 days

- If the requests > 200 days are excluded, the average drops to 24.9 days



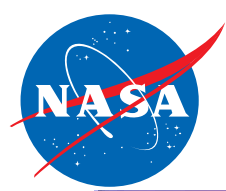
Evidence Reports



Human Research Program

- Evidence Reports are a scientific survey of all the evidence associated with a particular risk
- Experimental and Biomedical data from LSAH were used extensively to write these reports
- Specific discipline reports are submitted for publication in relevant journals
- Reports, publications and references are available on the HRP website

http://humanresearch.jsc.nasa.gov/elements/smo/hrp_evidence_book.asp



Data Accessibility Summary



Human Research Program

- MRIDs posted on web and pointed to by the NRA
 - <http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.cfm>
- Evidence Reports available to community
 - http://humanresearch.jsc.nasa.gov/elements/smo/hrp_evidence_book.asp
- Information regarding process for obtaining data on web
 - Email jsc-lsah@mail.nasa.gov with any questions
- Survey results will provide a baseline
 - The HRP will conduct the survey annually to monitor areas to improve