HRP Data Accessibility
Current Status
Investigators Workshop
3 February 2009

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

I know it’s there...I just can’t see it!!
Overview of talk

- Content of Human Life Science data
- Data archive structure
- Applicable legal documents and policies
- Methods for data access
50 Years of Spaceflight Data
What Data Does NASA Have?

- **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](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

http://lsda.jsc.nasa.gov
Data Access: LSDA
Data Access: LSDA

<table>
<thead>
<tr>
<th>Dataset Archive Holdings</th>
<th>Show</th>
<th>20</th>
<th>50</th>
<th>100</th>
<th>results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Area</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone and calcium physiology</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parameters Measured</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any parameters)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cells, Tissues, Organs and Samples</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any tissue)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species Studied</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homo sapiens (Human)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experiment Title</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any experiments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payload Title/Payload</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any Payload title/payload)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hardware Item</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any Hardware)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol/Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Any protocol/approach)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reset</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GO</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

#### DATA ELEMENT INFORMATION

<table>
<thead>
<tr>
<th>Data Element Name:</th>
<th>Intervertebral Disc Cross-Sectional Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Files:</td>
<td>[Available online]</td>
</tr>
<tr>
<td></td>
<td>+ JMLMS284054_46.xls (Download)</td>
</tr>
<tr>
<td>Data Element Description:</td>
<td>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.</td>
</tr>
<tr>
<td>Parameters Measured:</td>
<td></td>
</tr>
<tr>
<td>Parameter</td>
<td>Intervertebral disc size, lumbar spine</td>
</tr>
<tr>
<td></td>
<td>Spine length</td>
</tr>
<tr>
<td>Data Element Review or Technical Comments:</td>
<td>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.</td>
</tr>
<tr>
<td>Measurement or Analysis Technique:</td>
<td>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 Te=7 msec and a recovery time of Tr=400 msec with acquisition and a 256 x 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.</td>
</tr>
<tr>
<td>Experiments:</td>
<td>+ Magnetic Resonance Imaging After Exposure to Microgravity (284054)</td>
</tr>
<tr>
<td>Payload:</td>
<td>+ Life and Microgravity Spacelab (LMS)</td>
</tr>
<tr>
<td>Hardware Items:</td>
<td>+ Magnetic Resonance Imaging (MRI) Device + Magnetic Resonance Imaging (MRI) Device</td>
</tr>
<tr>
<td>Data Source:</td>
<td>Final report, Table7</td>
</tr>
<tr>
<td>Data Collection Site:</td>
<td>Kennedy Space Center FL</td>
</tr>
</tbody>
</table>
Data Access: LSDA

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

<table>
<thead>
<tr>
<th></th>
<th>T12-L1</th>
<th>L1-L2</th>
<th>L2-L3</th>
<th>L3-L4</th>
<th>L4-L5</th>
<th>Average</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-(50/51)</td>
<td>1</td>
<td>1</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>L-(29/31)</td>
<td>-1</td>
<td>-1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>R+0</td>
<td>-4</td>
<td>-2</td>
<td>-3</td>
<td>-5</td>
<td>-1</td>
<td>-2</td>
<td>NS</td>
</tr>
<tr>
<td>R+2</td>
<td>-4</td>
<td>-2</td>
<td>-2</td>
<td>-0</td>
<td>1</td>
<td>-2</td>
<td>NS</td>
</tr>
<tr>
<td>R+10</td>
<td>-9</td>
<td>-5</td>
<td>-7</td>
<td>-9</td>
<td>-6</td>
<td>-6</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>R+30</td>
<td>-1</td>
<td>-1</td>
<td>-3</td>
<td>-4</td>
<td>-2</td>
<td>-1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Each data point 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

- 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](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
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](http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.cfm)
Data Access: LSAH
**Data Access: LSAH**

![Data Access: LSAH](image)

<table>
<thead>
<tr>
<th>Discipline</th>
<th>MRID#</th>
<th>Medical Requirement Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MEDB 5.4</td>
<td>+ calf Volume Measurement</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR006L</td>
<td>+ Exercise Treadmill Test</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR019L</td>
<td>+ Heart Rate Monitoring</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR026L</td>
<td>+ Postflight Rehabilitation</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR025L, MEDB 1.11</td>
<td>+ bone Densitometry</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR038L, MEDB 6.3</td>
<td>+ Arm Ergometry Test</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR078L</td>
<td>+ Physical Fitness Evaluation: Functional Fitness</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR079L, MEDB 5.3</td>
<td>+ isokinetic Testing</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR080L, MEDB 4.1</td>
<td>+ cycle Ergometer Test/Aerobic Functional Capacity</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR081L</td>
<td>+ Physical Fitness Evaluation: Handgrip Dynamometry</td>
</tr>
<tr>
<td>Bone, Muscle, Exercise</td>
<td>MR082L, MEDB 5.2</td>
<td>+ on-Orbit Strength &amp; Conditioning Monitoring</td>
</tr>
</tbody>
</table>
Data Access: LSAH

• 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

• 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

- 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

• 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

BMD Absolute Loss from Preflight Expeditions 1-14 (n=18)

Average

BMD absolute loss (g/cm²)

Lumbar Spine
F. Neck
Trochanter
Whole Body
Heel
Pelvis
De-Identified Data - Pooled

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

• 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

- 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

Average - 68.1 days

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

- 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

- MRIDs posted on web and pointed to by the NRA
  - http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.cfm
- Evidence Reports available to community
- 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