Help Our Principal Investigators Stay Compliant
Completing a Data Sharing Agreement and Plan
A Guide for Elements and Principal Investigator Teams

The who, what, where, how, and when of Data Sharing Agreements and Plans!

The Who? The Research Operations & Integration (ROI) Data Science Team is here to help you with your data sharing needs.

- The What? **Data Sharing Plans** document spaceflight and flight analog data and sample sharing for crew members between investigations and Medical Operations to meet science objectives. **Data Sharing Agreements** document sharing details between investigators and right of publication.
- The Where? Data Sharing Plan and Agreement Templates are housed by the ROI Data Science Team (jsc-hrp-data-science-team@mail.nasa.gov).
- Read on to learn how and when these agreements should be implemented.

Sharing Agreements vs. Sharing Plans

Data Sharing Agreements (DSA)
- A collaborative agreement between two or more investigators documenting how to exchange information as well as any stipulations and **their individual rights to publications**.
- DSAs are not Crew/Surgeon consent to share data.
- ROI provides a template for DSAs but it is customizable; PI's have the freedom to make their own template.
- Finalization of a DSA is the responsibility of the PI requesting data but may be provided to ROI for reference in DSP development. PI's may request that ROI maintain record of established DSAs, but this is not required.
- DSAs are strongly recommended, especially for complex data shares, or data shares between PI's that include a large amount of data (e.g. CIPHER).

DSAs are not Crew/Surgeon consent to share data.

Don't forget!
- DSAs do not cover crew and crew surgeon consent to prospective data sharing. All investigations are subject to informed consent by each intended participant. Data sharing between investigations will be authorized by each subject in the respective Data Sharing Plans.
- DSAs are finalized before development of a DSP, as the information feeds into the DSP

It's best if DSAs are finalized well before flight - the earlier the better.

Data Sharing Plans (DSP)
- A Crewmember or campaign-specific document that describes data and sample sharing, specifically focused on minimizing redundant testing, between research experiments and medical operations.
- For spaceflight, DSPs are the final Crew and Surgeon consent for data sharing. For flight analogs, Crew consent for data sharing is covered by the Informed Consent Forms.
- DSPs are developed by the ROI Data Science team and reviewed by the ROI Experiment Science Teams, ROI Increment Science Coordinators, IP Science Personnel, and signatories.
- DSPs are approved by the NASA Institutional Review Board (IRB), NASA Export Compliance, International Partner Medical Boards, Human Research Medical Review Board (HRMRB), and signatories.
- Compared to a DSA, DSPs are not templates that can be modified. The formatting is managed by ROI Element, in concurrence with NASA IRB, Export Control, IP Medical Boards, Human Research Medical Review Board, (HRMRB), and signatories. ROI Data Sharing Team handles production of DSPs.

The DSA template can be modified.

The DSP template may be modified upon request.

	What is this?	Where does it go?	Data Delivery
Data Sharing Plan (DSP)	**1 DSP per Crew Member for each Mission** - Documents data and sample sharing for crew member data between investigations and Medical Operations - Documents Operational ("efficiency") and Supplemental Medical and Research data sharing - Developed by ROI Data Science Coordinator	ROI submits to: - NASA IRB & IP Medical Boards to crew home agency (JAXA, ESA, CSA) - Investigators included in crew members' complement - Crew Member for consent - Crew Surgeon to authorize release of medical data - Flight Scientist	- PI to PI requests can be shared directly - ROI Data Science Team delivers medical data requests
Data Sharing Agreement (DSA)	- Agreement between any 2+ experiments to collaborate and/or share data - Documents data sharing details and rights to publications	- Signed by Element or HRP Representative - Incorporated into the ROI DSP - Stored on Multilateral Human Research Panel for Exploration (MHRPE) SharePoint	**No data is delivered as a result of DSA, as it is not considered crew member consent.** - Data Sharing are placed in DSP, Informed Consent Form, and/or Data Request where crew & crew surgeon consent and authorization are obtained.

Reminders for DSPs

Prospective Data vs. Retrospective Data – Classified by Timing of Request

- Prospective – Requested before or during Pre-, In-, or Post-Flight. Data Science Team will assess availability of data and assist EST/PI on how to capture data
- Retrospective - LSAH and LSDA will assess data availability in archived data and level of effort required by LSAH and/or LSDA to fulfill the request

Two Types of Prospective Data – Classified by PI

- Operational – Data required for PI to meet the objectives of their study ("efficiency data sharing").
- Supplemental – Data not required, but requested by PI to further inform data interpretation and science

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The ROI Data Science Team maintains templates for both Data Sharing Agreements (DSAs) and Data Sharing Plans (DSPs). For questions, templates, and more please contact the ROI Data Science Team at jsc-hrp-data-science-team@mail.nasa.gov.

Acronyms

AOR	Authorized Organizational Representatives
DMP	Data Management Plan
DSA	Data Sharing Agreement
DSP	Data Sharing Plan
DMIO	Data Management Integration Office
HRP	Human Research Program
LSDA	Life Sciences Data Archive
RDSA	Research Data Submission Agreement
ROI	Research Operations & Integration

Best Practices

- When developing study documentation (e.g. ED, mini-ED, SRD) include for data sharing requests:
  - MEDB number for each medical data request
  - Identify if each data request is Operational or Supplemental
  - Keep Institutional Review Board (IRB) and ED/Mini-ED/SRD in-sync.
- Shared data must be listed in the agency-approved IRB Protocol and consent form.
- Identifiable data cannot be released without crew consent.
- Principal Investigators must complete data sharing in a timeframe that allows each PI to complete all work before the end of the funded period(s).