Tri-University Research Administration Conference

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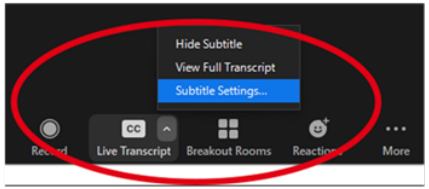

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Land Acknowledgement

The **Arizona State University** (ASU) acknowledges the twenty-three Native Nations that have inhabited this land for centuries. Arizona State University's four campuses are located in the Salt River Valley on ancestral territories of Indigenous peoples, including the Akimel O'odham (Pima) and Pee Posh (Maricopa) Indian Communities, whose care and keeping of these lands allows us to be here today. ASU acknowledges the sovereignty of these nations and seeks to foster an environment of success and possibility for Native American students and patrons. We are advocates for the incorporation of Indigenous knowledge systems and research methodologies.

Northern Arizona University sits at the base of the San Francisco Peaks, on homelands sacred to Native Americans throughout the region. We honor their past, present, and future generations, who have lived here for millennia and will forever call this place home.

We respectfully acknowledge the **University of Arizona** is on the land and territories of Indigenous peoples. Today, Arizona is home to 22 federally recognized tribes, with Tucson being home to the O'odham and the Yaqui. Committed to diversity and inclusion, the University strives to build sustainable relationships with sovereign Native Nations and Indigenous communities through education offerings, partnerships, and community service.

Navigating the 2023 NIH Data Management and Sharing Policy

Understanding the impact on Research Administrators

Fernando Rios, Research Data Management Specialist, UA Libraries

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Maliaca Oxnam, Deputy Director, Data Science Institute, UA
Stephanie Carroll, Assistant Professor, Public Health and American Indian Studies, UA

Tri-University Research Administration Conference

Goals & Overview

Goals

- Provide an overview of the new NIH DMSP grant requirements
- Ability to help researchers on most aspects at least a basic level
- Knowledge of where to go for help

Overview

- Background
- High-level understanding of what should go in a DMSP
- Compliance and costing aspects
- Resources
- Walkthrough of an example

The new NIH data management & sharing policy

NOT-OD-21-013

What and why

- The NIH has a new data management and sharing (DMS) policy that came into force in January 25 2023
- There is an associated requirement to submit a data management and sharing plan (DMSP) that is substantially different than the prior policy
- The DMSP is a short, structured document that outlines how data will be shared
    - Becomes part of the terms and conditions of the award

Prior requirement (2003)

- Only for grants seeking $500,000 per year or more in direct costs
- A short paragraph explaining what will be shared and how (or an explanation of why it can't be shared

The proposed research will include data from approximately 500 subjects being screened for three bacterial sexually transmitted diseases (STDs) at an inner city STD clinic. The final dataset will include self-reported demographic and behavioral data from interviews with the subjects and laboratory data from urine specimens provided. Because the STDs being studied are reportable diseases, we will be collecting identifying information. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

New requirement

"NIH is now asking for more details on how the investigator plans to manage and share their data, Wolinetz says. 'This is a little bit weightier than the previous plan' and applies to all NIH-funded research, not just large programs."

https://www.science.org/content/article/why-nih-beefing-its-data-sharing-rules-after-16-years

ALL proposals producing Scientific Data must submit a DMSP

- 2 pages or fewer recommended
- Must address 6 key areas
- The focus is on describing plans for Preparing data for sharing
  - Where, how, for how long data will be shared
  - Addressing privacy concerns
  - Who will be responsible

- Requirement does NOT apply if proposal does not produce Scientific Data
- E.g., Training (T), Fellowship (F), Construction (C06), Conference (R13), Resource (G), Infrastructure (e.g., S06)
- See NIH's comprehensive list of activity codes https://sharing.nih.gov/sites/default/files/flmngr/List-of-Activity-Codes-Applicable-to-DMS-Policy.pdf

"Scientific Data"

"Scientific data is the recorded factual material commonly accepted in the scientific community as **of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications**."

Does not include

- laboratory notebooks
- preliminary analyses
- completed case report forms
- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects, such as laboratory specimens

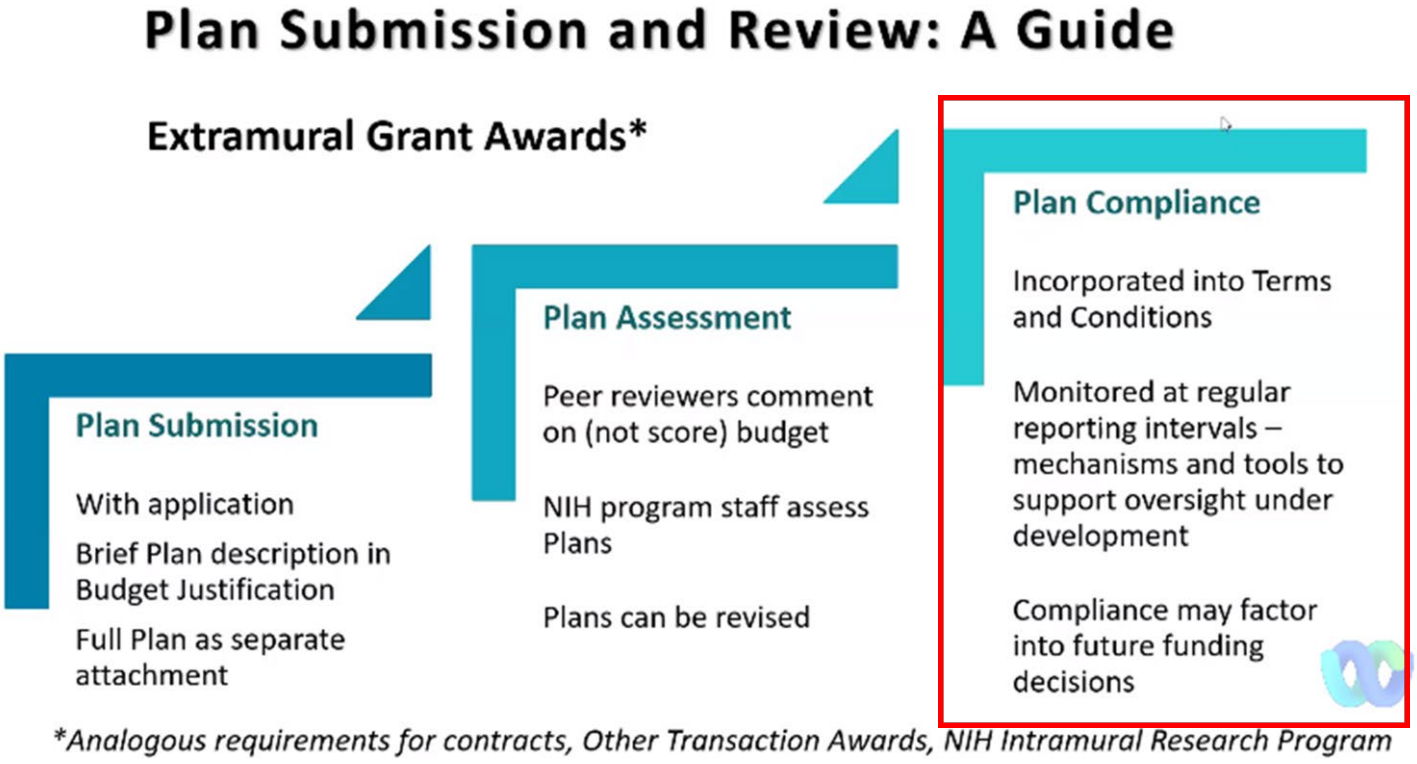
Final NIH Policy for Data Management and Sharing
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

Why is the NIH doing this?

- Long championed policies that make research available to the public
  - Original 2003 policy
  - 2014 Genomic Data Sharing Policy
- Tenor of conversation around data sharing has changed – desire for data sharing to be impactful
- Data management is the gateway to data sharing
  - E.g., reproducibility requires well-structured data
- System-wide culture change is needed -- See OSTP Nelson Memo (Aug ‘22)

Bottom line: NIH now has the expectation that all Scientific Data will be shared if possible

How does it work?



Institutional Responses [UA]

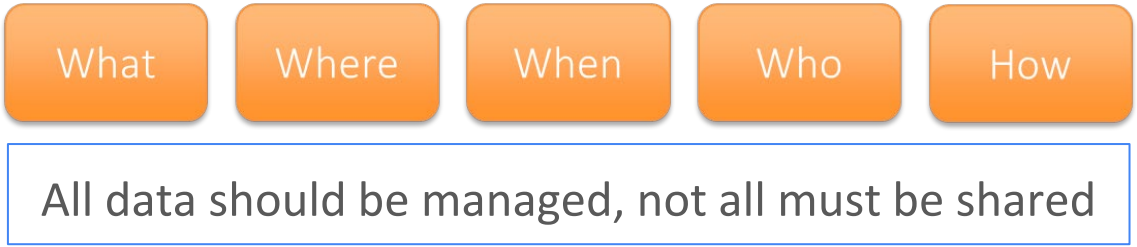
- At UA, among Federal funding sources, HHS (including NIH) = 50% [FY 22 HERD data] - so, important!
- UA's team response, launched Fall 2021, included RII, Libraries, UITS, Data Science Institute, and others
- Subteam focused on executing communications strategy, used RII instance of Trellis under authority of Sr VP for Research and Innovation
- Built website "hub" to provide direction, learning objects and examples
- Extensive outreach to Research Administrators, senior PI's, campus stakeholders; leveraged library liaisons to reach research investigators
- Working now on sensitive data components

Institutional Response [ASU]

- Tri-University Research Data Policy proposal and request for comment Fall 2022
- NIH DMS policy guidance (Library)
- NIH policy Community Conversation Zoom call (November 2022)
- ASU Library and Research Development Data Management joint calls April 18, 2023, kick-off
- Expansion of services and new positions in recruitment

Overview of the DMSP

DMSP overview



Plan elements

- Data Type
- Related Tools, Software and/or Code
- Standards
- Data Preservation, Access, and Associated Timelines
- Access, Distribution, or Reuse Considerations
- Oversight of Data Management and Sharing.

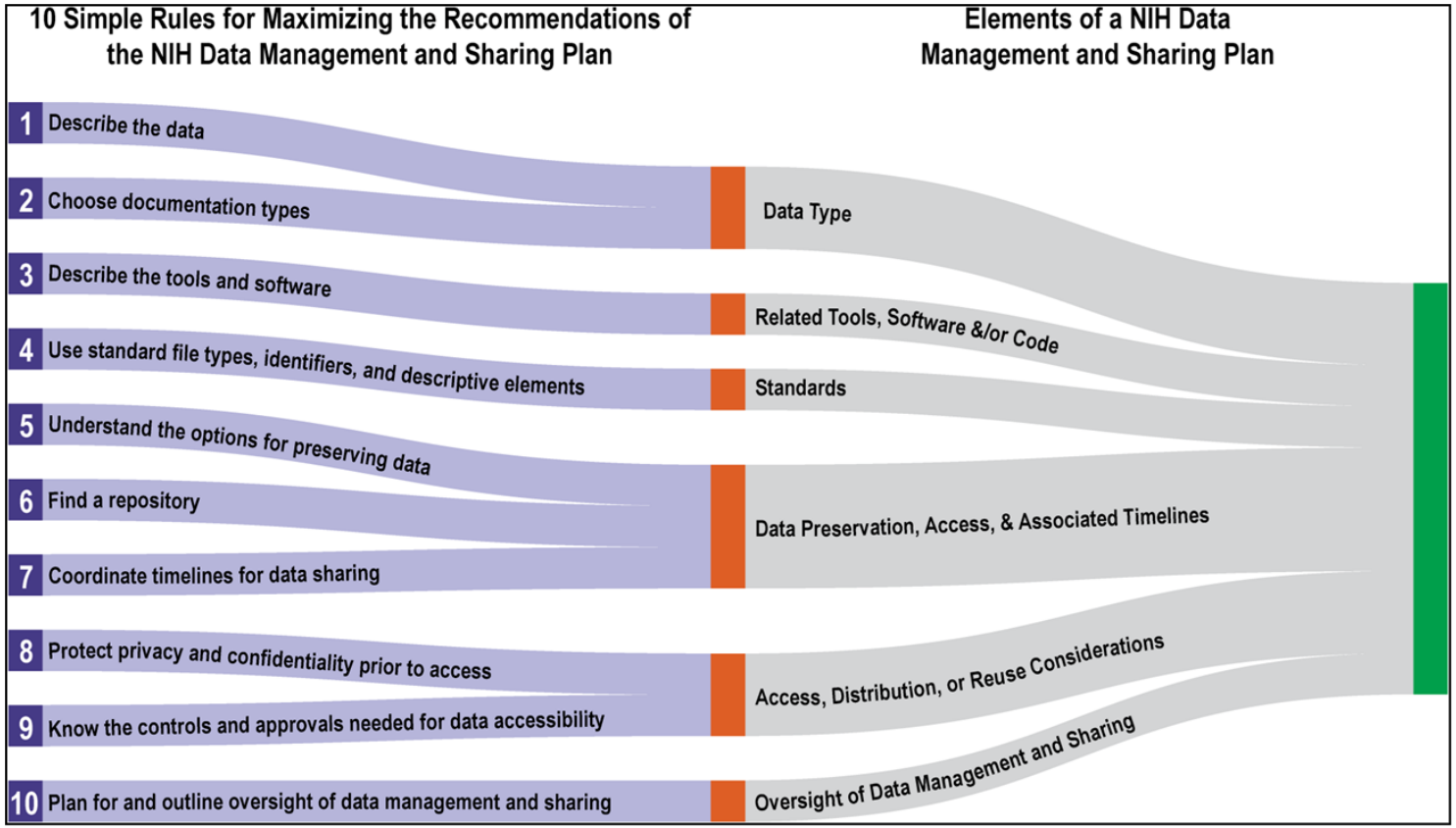
Plan expectations

- Sharing should be the default
- Sharing at time of publication or at end of performance period (whichever is first)
- Reasons for not sharing must be justified
- Must outline how privacy, rights, confidentiality will be protected

The Six Elements of the DMSP

Source: PLOS Computational Biology: Ten simple rules for maximizing the recommendations of the NIH DMSP

https://doi.org/10.1371/journal.pcbi.1010397



Drafting the DMSP

- 2 pages or fewer recommended
- Any format acceptable (as long as it addresses the elements)
- Recommended tools
  - NIH format page
  - DMPTool
- Must address the genomic data sharing policy requirements
  - No longer a separate genomic data sharing plan
- No hyperlinks

https://grants.nih.gov/sites/default/files/DMS-Plan-blank-format-page.docx

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project,

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

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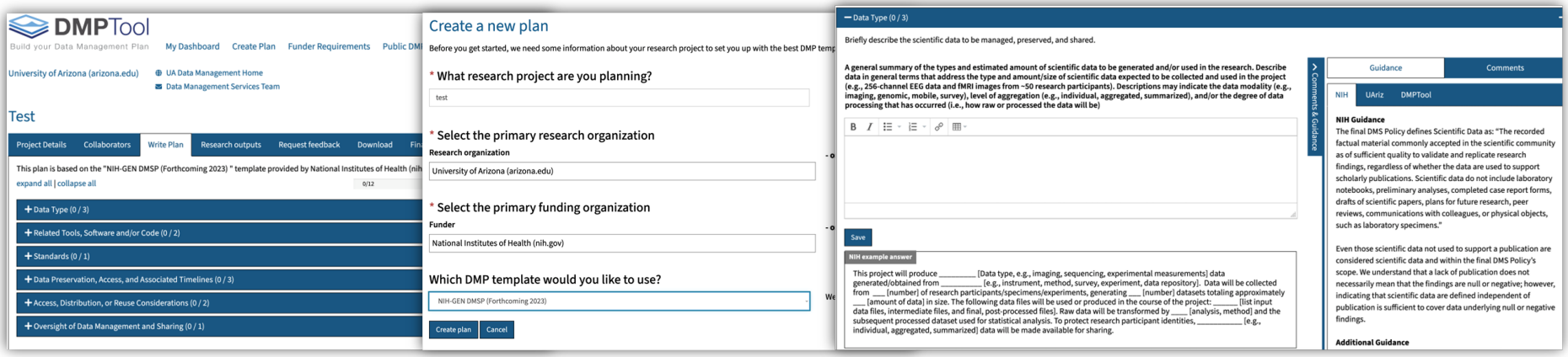
State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

DMPTool

Log in at dmptool.org. Use institutional credentials



- Guided templates for all federal funders (not just NIH)
- Plans can be downloaded and shared
- User can submit for feedback to institutional rep
  - At UA, they come to my colleague Jim Martin and Fernando.
  - At ASU they go to the Office of Research Data Management and the Library

Many other issues to be aware of

- Privacy
  - What can and can't be shared
  - informed consent issues
  - Work with indigenous populations
  - Justifiable reasons for not sharing
- Roles and responsibilities
  - UA's and ASU's position: PI will be generally be responsible for ensuring the execution of the plan
    - Differs from the example plans
    - See institutional guidance for what various offices are responsible for.
- Refer to NIH guidance and institutional officials

Invalid reasons

- Dataset too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository

Pitfalls and challenges

Plans must contain all 6 elements

Avoid using boilerplate text

- There is no one size fits all
- PI must read their plan and are responsible for the plan
- Verify with service providers

Roles and responsibilities section - PI is accountable

Non-justified reasons for not sharing

Insufficient detail on what data will be produced and shared

Specific institutes or centers may have additional requirements.

Modular budget direct cost limit has not changed in 20+ years.

Costing

Data Management and Sharing Costs

Allowable Costs

- Curating data/developing supporting documentation
- De-identification
- Preserving/sharing data through repositories
- Local data management considerations
- IMPORTANT: Must be incurred during the performance period

Unallowable Costs

- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

See NIH's page on Budgeting for Data Management & Sharing for details

Slide from NIH Webinar: https://sharing.nih.gov/sites/default/files/flmngr/DMS%20Webinar_Resource_Slides.pptx

Budgeting & NIH Forms

- Modular budgets (up to $250,000 in direct costs annually)
  - Include a section titled “Data Management & Sharing Justification” and the requested dollar amount on the modular budget form

- Detailed R&R Budget form (>$250,000 in direct costs in any year, or as required by the FOA)
  - All direct costs for data management are included in one single line in the budget, including personnel costs
  - Line item: Data Management & Sharing Costs. Enter 0 if no costs will be incurred.
  - Supporting details must be outlined in the budget justification

Subawards

- Data Management & Sharing Policy applies to subrecipients
  - But only a single DMSP

- Who will have data collection/storage/management responsibilities?
  - Subrecipients may be a partner in creating the DMSP
  - Subrecipients must budget for their costs of DM&S

- Each subrecipient must budget their DM&S costs on the Modular Budget form or R&R budget form

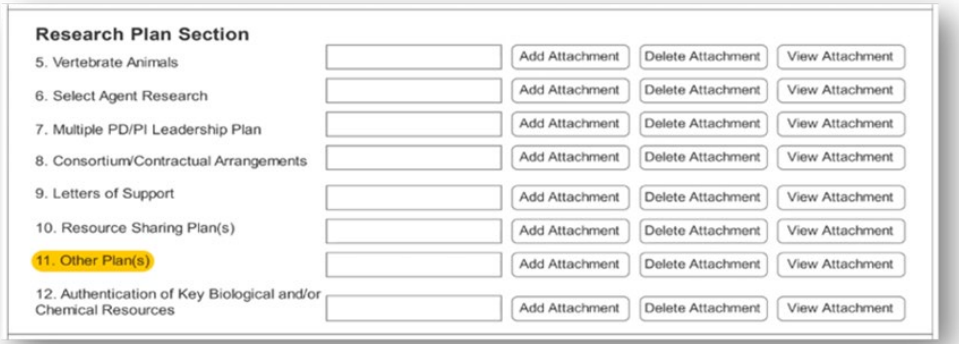
FAQs: https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm

Submitting the DMSP

Assembling the submission

Where to put the DMSP?

- “Other Plans” section



Research Plan Section				
5. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
6. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
7. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
8. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
9. Letters of Support		Add Attachment	Delete Attachment	View Attachment
10. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
11. Other Plan(s)		Add Attachment	Delete Attachment	View Attachment
12. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

DMS Plan not visible to peer reviewers (except if grant is data-sharing focused)

- Reviewers can comment on budget (but not scored)

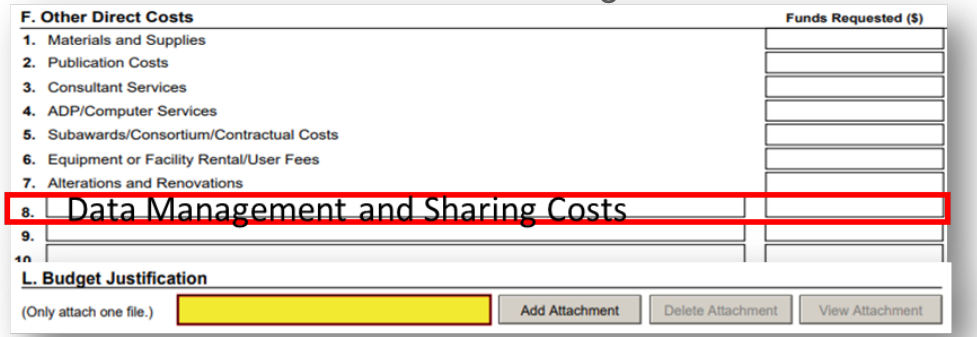
No more separate Genomic Data Sharing plan. Include GDS plans within DMSP

If you get validation errors in eRA see
https://nexus.od.nih.gov/all/2023/02/07/helping-you-comply-with-the-data-management-and-sharing-policy-through-era-system-validations/

Screenshots: Julia Slutsman and Cindy Danielson, NIH Office of Extramural Research (OER), NIH Grants Conference February 1, 2023

Assembling the submission - Budget

R&R (detailed) budget: Section F. Justification in section L. Must use exact wording for line 8



Modular budget: within additional narrative justification

Justification (1/2 page) must include

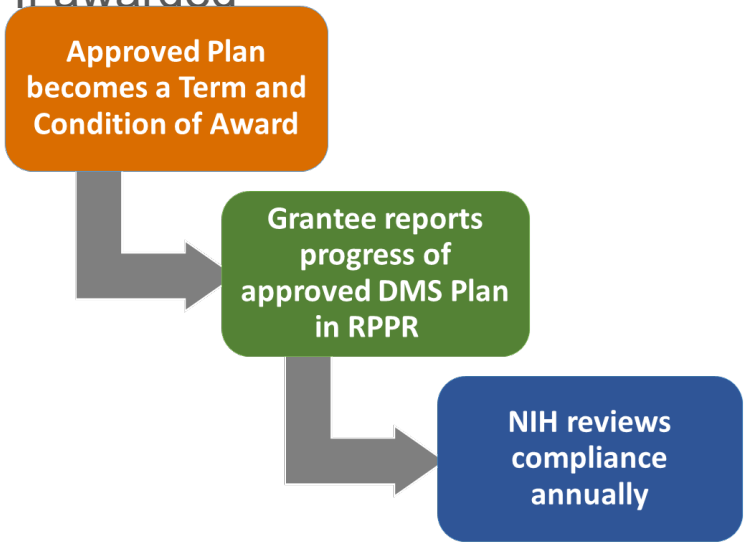
- Section titled "Data Management and Sharing Justification“
- Summary of type and amount of data to be shared/preserved
- Name of repository(ies)
- General cost categories

Do not combine DMS costs with other costs

If no DMS costs, enter 0. Don’t leave blank

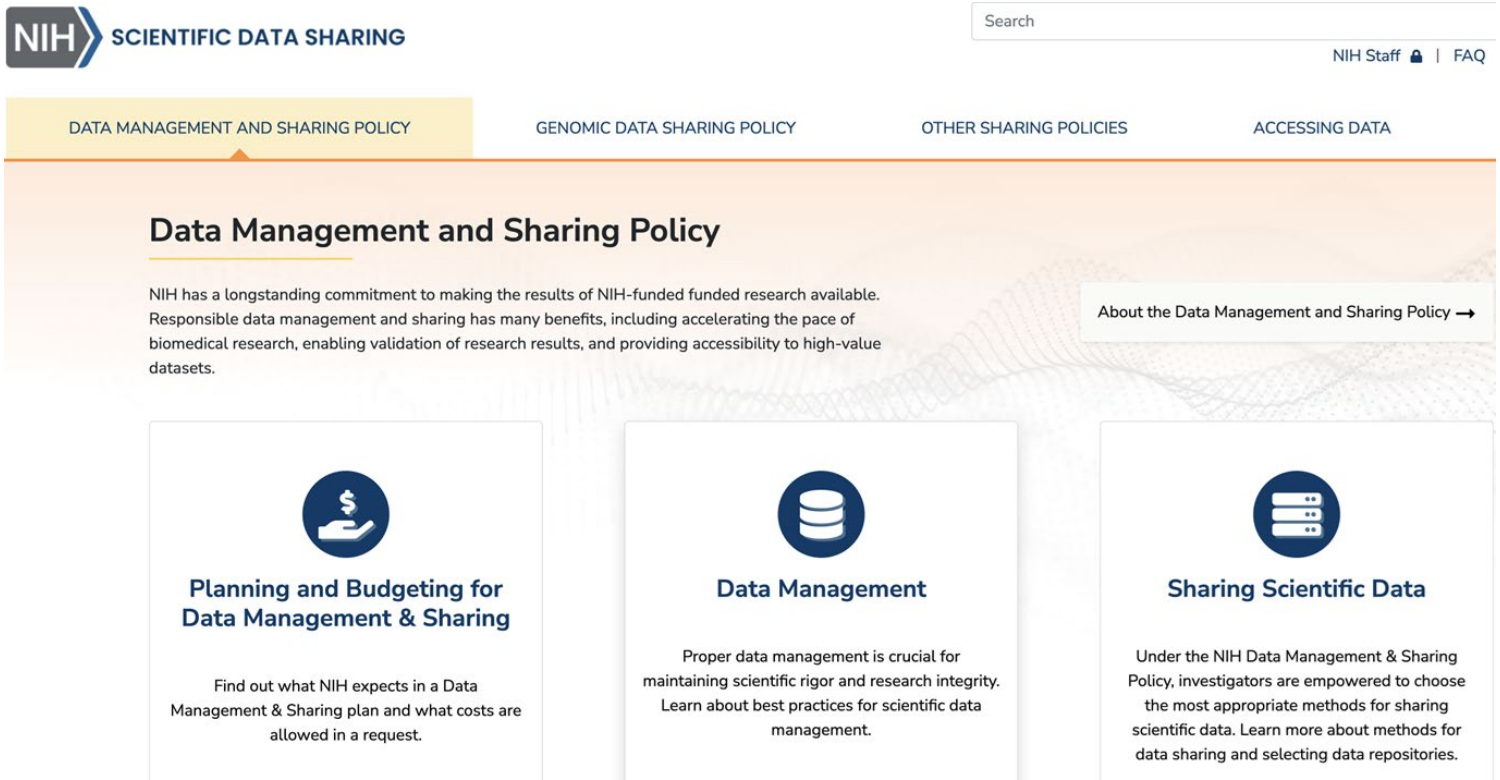
Post-submission

- Plans reviewed by ICO
- Plans updated/changed during JIT (if requested)
- If awarded



Failure to comply…. may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

NIH page: sharing.nih.gov



Walkthrough of an Example

Walkthrough: Examples from recent NIH submissions

- First submission cycle since policy (Jan 25, 2023)
- Principal Investigator (PI) use of UA resources
  - UA Libraries and Data Cooperative
  - UA DMP tool and team
  - UA pre-award and research offices: University of Arizona Health Services (UAHS), Sponsored Projects, Engineering Research Administration Services (ERAS), College of Agriculture and Life Sciences (CALS), Research Development Services (RDS)
  - Colleague network
- NIH Template
- Technical review
  - NIH guidance
  - Scientific review specificity

Walkthrough: Examples from recent NIH submissions

- Four diverse examples
  - Proposals in R series (R01, R01-A1, R33/R61)
  - NIH Institutes/Centers (I/C), i.e., HEAL Initiative and NIAID/DMID Omics Centers
  - Data types: human participants; vertebrate animals; metadata, mass spectrometry and evolutionary sequence datasets
- Examples
  - Human A
  - Human B
  - Animal
  - Mass Spec

Walkthrough: Examples from recent NIH submissions

OMB No. 0925-0001 and 0925-0002 *(Rev. 07/2022 Approved Through 01/31/2026)*

DATA MANAGEMENT AND SHARING PLAN

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Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

B. How scientific data will be findable and identifiable:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

OMB No. 0925-0001 and 0925-0002 *(Rev. 07/2022 Approved Through 01/31/2026)*

C. When and how long the scientific data will be made available:
Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:
NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

B. Whether access to scientific data will be controlled:
State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).)

C. Protections for privacy, rights, and confidentiality of human research participants:
If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Element 6: Oversight of Data Management and Sharing:
Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

Element 1 “Data Type”

Types and amount of scientific data expected to be generated in the project

Human A

This study will generate **demographic information (e.g, age, education, time post onset, handedness), neuropsychological scores (language and cognitive assessments) and neuroimaging data (structural and functional MRI, DWI)** from **100 participants** with logopenic variant of Primary Progressive Aphasia (lvPPA) and 25 age and education matched unimpaired controls. The data will include video and audio recordings of treatment sessions and accuracy on pre and post treatment probes. Study data will be collected at varying frequencies. **Pre and post Treatment data** will be collected daily before and after each treatment session (5 times a week for two weeks Phase 1 and 2). Language assessments will be repeated at 2 weeks following Phase 1 of the study (tDCS + language therapy), immediately prior to the Phase 2 (2 months after the end of the Phase 1), at two weeks after Phase 2, and again at 2 months follow-up after Phase 2. Neuroimaging will be performed at baseline and at each assessment point. Numerical data will be recorded at the individual level into the central lab’s database. **Neuroimaging data will be converted to NIFTI format** and stored on the secure laboratory server. **Original DICOM data** will be archived to preserve data providence and integrity. All data will be de- identified prior to receipt by the repository.

Human B

The proposed research will include data from approximately **500 people over the 2-year R61 project period and approximately 3500 during the R33 project period** (to be updated pending R61 power calculations). These people **include staff members and patients of opioid treatment programs (OTPs)** who will self-report trauma symptoms and histories, histories of treatment for substance use disorder, person-centered care provided and received, trauma-informed care provided and received, and (for staff only) feasibility of intervention implementation. Data will also include **self-reported demographic**s. The **R61 data will include staff and patients in two Arizona clinics** along with a national sample of OTP staff members; and the **R33 data will include enrolled staff and patients in clinics across the country** (locations TBD in the R61). In addition, the project will recode raw survey data to characterize missing values or for top coding or collapsing values as needed.

Element 1 “Data Type”

Types and amount of scientific data expected to be generated in the project

Animal

All shared data will be documented as text and excel files accompanied by statistical analysis and media files (e.g. diagrams, images, and videos).

Mass Spec

- Evolutionary sequence data including multiple sequence alignments and phylogenetic trees
- Mass spectrometry data
- Flow cytometry based data
- (live cell) images
- ELISA based data
- Biochemical data
- metadata

Element 5 “Access, Distribution or Reuse Considerations”

Protection for privacy, rights, and confidentiality of human research participants

Human A

Informed consent documents used for the proposed clinical trial will include explicit language informing the participant or legally authorized representative that scientific data may be stored in a repository for other scientific investigations. The informed consents will contain language permitting secondary use with broad data sharing under controlled access with general research use restrictions in ReDATA repository and as allowed by the Human Subject Protection Program at the University of Arizona. Patients will not be contacted or re-consented for future sharing or accessing data through repositories.

Privacy and confidentiality protections consistent with applicable federal, Tribal, state, and local laws, regulations, and policies will be followed. Data will be deidentified by removing all 18 HIPAA identifiers prior to sharing, and the study will have a Certificate of Confidentiality from NIH.

Element 5 “Access, Distribution or Reuse Considerations”

Protection for privacy, rights, and confidentiality of human research participants

Human B

The national survey of OTP staff will be anonymous with only the clinic identifier which will be removed and replaced by a unique code, and maintained in a separate file accessible by approved staff as part of the project duties within a secure environment. For enrolled staff and patients, their respondent identifiers will be collected only once and at that time will be removed and maintained in a separate file accessible by approved staff as part of the project duties within a secure environment. **If, upon review, respondent categories are easily geomapped or identified, we will code them as such to cloak their geocode or location for the protection of human subjects. Deidentification will be reviewed and confirmed by the end of data processing, prior to the finalization of the public use and restricted data files (whichever files are restricted and whichever files are identified for public use).**

Study respondents will be asked to consent to data collection and sharing with the wider research community. The privacy, rights, and confidentiality of human subject participants in this study will be protected through the suppression of all direct respondent identifiers, the careful classification of any potentially identifying data as restricted access, and through the project’s Certificate of Confidentiality.

Element 5 “Access, Distribution or Reuse Considerations”

Protection for privacy, rights, and confidentiality of human research participants

Animal

Not applicable

Mass Spec

Not applicable to this study.

Element 6 “Oversight of Data Management and Sharing”

Human A

Data will be submitted by a project data manager from the PI’s project team. The data manager will oversee data collection, analysis, storage, and sharing. Compliance with the plan will be monitored by the PI routinely. The PI will conduct monthly meetings with key study personnel to ensure the timeliness of data entry and will review data to ensure quality of data entry. The PI will ensure data are submitted and shared according to this DMSP.

Human B

Monitoring of and compliance with this Data Management and Sharing Plan will be the responsibility of the project’s Principal Investigator with consultation by the lead statistician/methodologist. The plan will be implemented and managed by professional staff working under the direction of the PI.

Animal

The PI will be overseeing execution of this Data Management and Sharing Plan. The PI will be assessing quality metrics and will determine when data are of a sufficient quality to be shared broadly. All personnel on this project will be properly trained to document scientific data and ensure all data are properly archived. All contributions to publications, design, or consultation will be recognized appropriately through co-authorship and acknowledgements.

Mass Spec

Sponsored Projects Services (SPS) and the Office of Research Contracts (ORC) at the University of Arizona have created a system to ensure that a DMSP is submitted as part of the grant application and to allow for PIs to submit progress to the NIH via annual progress reports.

Common questions, thus far…

Element 4: “Data Preservation, Access, and Associated Timelines”-

What archive?

Element 5: “Access, Distribution, or Reuse Considerations”-

How to write *vis a vis* the template and different human subjects protection (i.e., compared to consent forms)?

Element 6: “Oversight of Data Management and Sharing”-

What is the institutional role/support?