Final NIH Policy for Data Management and Sharing

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text

Email me for a consultation appointment, or to set up a custom workshop

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Essential documents

Final NIH Policy for Data Management and Sharing, Notice NOT-OD-21-013

Elements of an NIH Data Management and Sharing Plan, Notice NOT-OD-21-014

Allowable Costs for Data Management and Sharing, Notice NOT-OD-21-015

Selecting a Repository for Data Resulting from NIH-Supported Research, Notice NOT-OD-21-016
Effective date

January 25, 2023

You can relax! some
Basic overview
Studies affected

All NIH extramurally-funded research that produces scientific data, regardless of funding amount or mechanism.
Sharing focus

Data Sharing:

• “Maximize the appropriate sharing of scientific data”
  - They mean sharing beyond the study team
• Emphasizes established repositories built for sharing to the public or restricted public
Proposal development and pre-award:
Submit a data management and sharing plan (DMSP) and budget with every proposal producing research data.
Just-in-time and negotiation stage: NIH staff assess DMSP merits and may require changes (peer reviewers may also have comments)

PI may say in the DMSP that no data will be shared for participant privacy. The implication is that if it’s something that can be deidentified, the PO may send it back at this stage for revision.
Post-award:
If Plan revisions are necessary, Plans should be updated by researchers and reviewed by the NIH ICO in annual RPPRs or sooner.
Post-award (cont): Shared data should be made accessible “no later than the time of an associated publication, or the end of the performance period, whichever comes first.”
Closeout: Requires compliance with the awardee’s DMSP plan, as it was approved by NIH staff. (no guidance on how to report on this, yet)
Post-closeout:
Any repository fee or action planned for after closeout must have been paid for before closeout
Key differences
Definition of data

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.

Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
No later than closeout

Data Preservation and Sharing Timelines: Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

NOT-OD-21-013
Budgeting: Allowable categories

But remember! Direct costs cannot duplicate charges covered in facilities and administrative costs. Furthermore, data collection or access fees go in the research budget, not the DM&S budget.

1. Curating data and developing supporting documentation
2. Local data management considerations, such as unique and specialized information infrastructure
3. Preserving and sharing data through established repositories
Budgeting: Think personnel time

Example: The NIMH Data Archive cost estimator

- suggests for NDA deposit, 150 grad student or data manager hours and 47 PI hours for two specific aims collecting 12 submeasures, submitted semiannually for a 5 year grant
  - Budget estimated is $11,505 direct costs
  - Deposit stage only! Not addressing transformations, documentation, metadata, or other ongoing management
- Admittedly, this is a particularly complicated repo for sensitive human data deposits
ICO-specific requirements

- This policy represents the *minimum* expectation for data management and sharing practices across the NIH
- ICOs can set more specific rules, particularly about preferred repositories and formats for interoperability

  Take-away: Work towards interoperability
Ethics

- Sharing is subject to all other policies, laws, guidance, and regulation
  - Subject to data use agreements, IP protection, proprietary ownership, etc.
- Consistent with field’s validation norms
- Respect native data sovereignty
- Align with human subjects plans, DUAs
Ethics and human subjects

Three concepts emphasized:

1) Consider how to address data management and sharing in the informed consent process, such that prospective participants will understand what is expected to happen with their data.

2) Limitations on subsequent use of data should be communicated to individuals or entities preserving and sharing the scientific data. This ensures that factors that may affect subsequent use of data are properly communicated and will travel with the data.

3) Considering, in choosing where and how to make their data available, whether access to scientific data derived from humans should be controlled, even if de-identified and lacking explicit limitations on subsequent use.
Elements of a DMSP

Notice NOT-OD-21-014

1. Data type
2. Related tools, software, and code
3. Standards
4. Data Preservation, Access, and Associated Timelines
5. Access, Distribution, or Reuse Considerations
6. Oversight of Data Management and Sharing
Supports and assistance
Resources: Sharing platforms

• Repositories on the **generalist list** are already in place
  - eID access to OSF available through OVPRI, SOM, and Vcul
• Scholar’s Compass fits the “Institutional repository” qualifications if needed
Resources: DMSP authoring

• eID access to DMPtool templating system is in place
• DMPtool has a template with the DMSP structure plus guidance excerpts for the 2023 DMS Plan format
Discussion Q1: What supports are needed? What might VCU’s NIH-focused research enterprise need in place to prepare?
Discussion Q2: Do we need to pursue PI awareness, changed workflows, etc? What (if anything) will PIs need to meet these guidelines, and what would help meet those needs?
Discussion? Questions?
Thank you for your time!

Contact Nina at nexner@vcu.edu