




Data Management and Resource Sharing

Rigor & Reproducibility Workshop
14 May 2026

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1

Data Management and Resource Sharing



Topics

- History and Current NIH Policies
- Data Lifecycle (Data Management)
 - Data Quality & Integrity
- Case Study—*Time permitting*



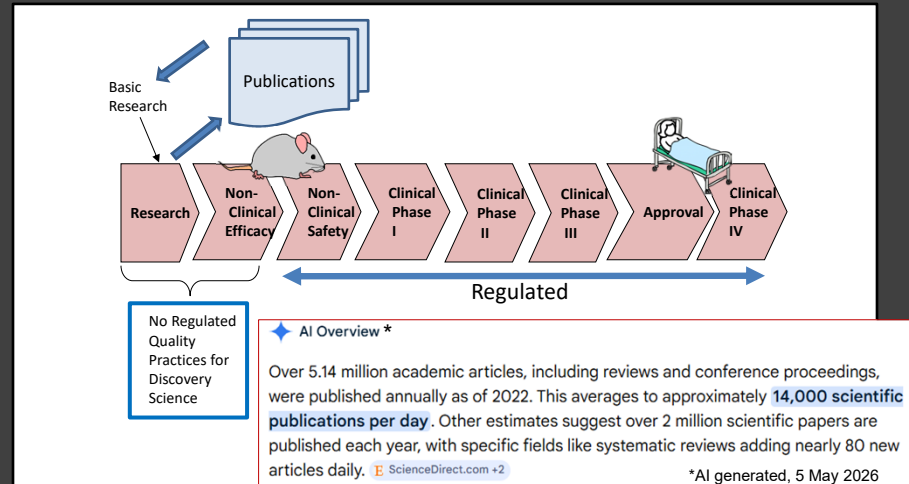
 References (links) provided on slides



2

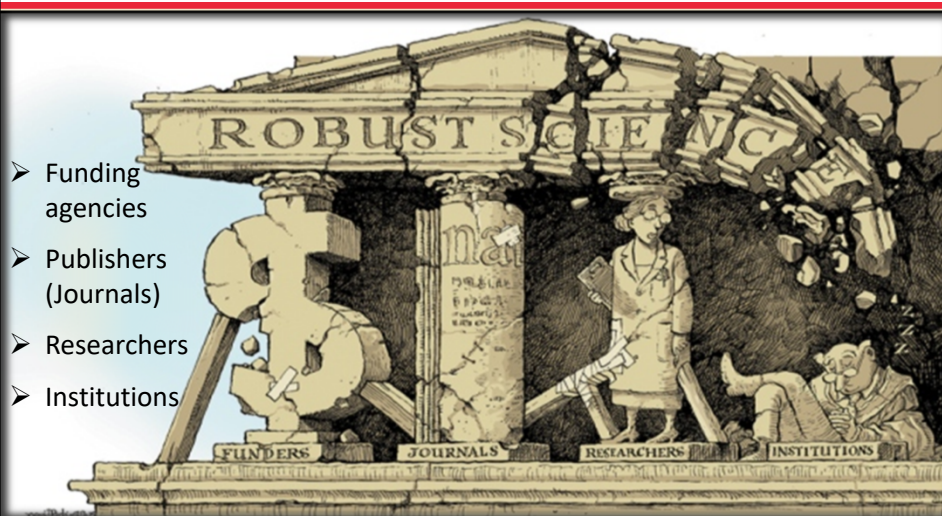
2

Product Development Pathway



3

Stakeholders of Robust Science



- Funding agencies
- Publishers (Journals)
- Researchers
- Institutions

<https://www.nature.com/news/robust-research-institutions-must-do-their-part-for-reproducibility-1.18259>

4

Scientific Advancement

- Funding agencies
- Publishers
- Researchers
- Institutions

*“Two of the cornerstones of science advancement are **rigor in designing and performing** scientific research and the ability to **reproduce** biomedical research findings.”*

~ NIH Central Resource for Grants and Funding Information



[Enhancing Reproducibility through Rigor and Transparency | grants.nih.gov](https://grants.nih.gov)

5

5

NIH Public Workshop (2014)

- Funding agencies
- Publishers
- Researchers
- Institutions

- **Sponsors:** NIH + *Nature Publishing Group* + *Science*
- **Issue:** Reproducibility, Rigor of research findings
- **Attendees:** Journal editors (>30 basic/preclinical science journals where NIH-funded investigators publish)
- **Goals:** Identify common opportunities in the scientific publishing arena to *enhance rigor and further support research that is reproducible, robust, and transparent*
- **Outcome:** **set of principles to facilitate these goals**, which a considerable number of journals have agreed to endorse



Marcia McNutt, Journals unite for reproducibility. *Science* 346, 679679(2014)

6

6

NIH Principles and Guidelines

- Funding agencies
- Publishers
- Researchers
- Institutions

Principles and Guidelines for Reporting Preclinical Research:

- Rigorous statistical analysis
- Transparency in reporting
- **Data and material sharing**
- Consider establishing best practice guidelines for:
 - Antibodies
 - Cell lines
 - Animals
- Endorsements (journals, associations, societies)
- Adapted Guidelines (to fit unique need)



[Principles and Guidelines for Reporting Preclinical Research | grants.nih.gov](https://grants.nih.gov/principles-and-guidelines-for-reporting-preclinical-research/)

7

7

Data and Material Sharing

- Funding agencies
- **Publishers**
- Researchers
- Institutions

- Require datasets be made available (where ethically appropriate) upon request
 - during manuscript review
 - upon publication
- Recommend datasets in public repositories, where available
- Encourage presentation of all other data values in machine readable format in the paper (or supplementary information)
- Encourage sharing of software



[Principles and Guidelines for Reporting Preclinical Research | grants.nih.gov](https://grants.nih.gov/principles-and-guidelines-for-reporting-preclinical-research/)

8

8

Data and Material Sharing

- Funding agencies
- Publishers
- Researchers
- Institutions

NOT-OD-21-013 Final NIH Policy for Data Management and Sharing (DMS)

Release Date: 29 October 2020

Effective Date: 25 January 2023

Section I, Purpose:

*“The National Institutes of Health (NIH) Policy for Data Management and Sharing...reinforces NIH’s longstanding commitment to making the results and outputs of NIH-funded research available to the public through effective and efficient data management and data sharing practices. **Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery** In addition, **NIH emphasizes the importance of good data management practices, which provide the foundation for effective data sharing and improve the reproducibility and reliability of research findings. NIH encourages data management and data sharing practices consistent with the FAIR data principles**”*



[NOT-OD-21-013: Final NIH Policy for Data Management and Sharing](#)

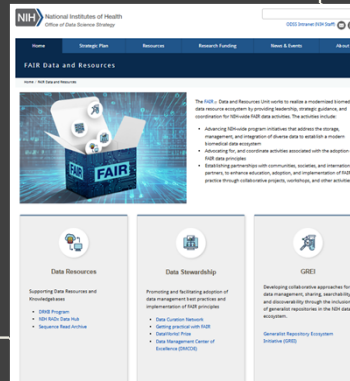
Data and Material Sharing

- Funding agencies
- Publishers
- Researchers
- Institutions

NIH encourages data management and data sharing practices consistent with the FAIR data principles.

- F** Findable
- A** Accessible
- I** Interoperable
- R** Re-usable

Data Engineers!



[FAIR Data and Resources | Data Science at NIH](#)

Data and Material Sharing

- Funding agencies
- Publishers
- Researchers
- Institutions

NIH encourages data management and data sharing practices consistent with the FAIR data principles.

- F** Findable
- A** Accessible
- I** Interoperable
- R** Re-usable

Data Engineers!



11

11

Policy Definition—Scientific Data

Scientific 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...

...**does not** include laboratory notebooks, preliminary analysis, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communication with colleagues, or physical objects, such as laboratory specimens.

But wait...



Note! Contracts and/or other applicable regulations may require retention of additional documents!



<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html#:~:text=For%20the%20purposes%20of%20the.used%20to%20support%20scholarly%20publications.>

12

12

Consortium Written Agreements

2024

“For foreign subrecipients, a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.”

Policy: NOT-OD-23-182 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html> effective January 1, 2024

Video Resource: <https://www.youtube.com/watch?v=mfHIV53-M3A>

Webinar On-Demand Video (Broadcast Oct. 17, 2023):
<https://grants.nih.gov/learning-center/nih-subaward-requirements>



13

13

Policy Definition—Metadata

Metadata = data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).



<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html#:~:text=For%20the%20purposes%20of%20the,used%20to%20support%20scholarly%20publications.>

14

14

Policy Definitions

Data Management = The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the **accessibility, reliability, and quality** of the scientific data for its users.

Data Sharing = The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example via an established repository.

Data Management and Sharing Plan (Plan) = A plan describing the data management, preservation, and sharing of **scientific data** and **accompanying metadata**.



<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html#:~:text=For%20the%20purposes%20of%20the,used%20to%20support%20scholarly%20publications.>


Data Management & Sharing Plan – Template 2023

<p>OMB No. 0501-0001 and 0501-0002 (Rev. 07/2020) Approved Through 01/31/2025</p> <p>DATA MANAGEMENT AND SHARING PLAN</p> <p>Part of the proposed research in the application involves the generation of scientific data. The solicitation is subject to the NIH Policy for Data Management and Sharing and the submission of a Data Management and Sharing Plan. This research involves the generation and analysis of scientific data. The scientific data described in this application are subject to the NIH Policy for Data Management and Sharing. The Data Management and Sharing Plan (DMS Plan) must be submitted with the application and must describe the following information:</p> <p>1. Types and amount of scientific data expected to be generated in the project.</p> <p>2. When and how long the scientific data will be made available.</p> <p>3. Access, distribution, or reuse considerations.</p> <p>4. Oversight of data management and sharing.</p> <p>5. Access, distribution, or reuse considerations.</p> <p>6. Oversight of data management and sharing.</p>	<p>OMB No. 0501-0001 and 0501-0002 (Rev. 07/2020) Approved Through 01/31/2025</p> <p>1. Data Type</p> <p>2. Related Tools, Software and/or Code</p> <p>3. Standards</p>	
<p>Element 1: Data Type</p> <p>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.</p> <p>Element 2: Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and describe, 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 the project. If applicable, indicate that no consensus standards exist.</p> <p>Element 4: Data Preservation, Access, and Associated Timelines</p> <p>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.</p> <p>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.</p>	<p>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.</p> <p>Element 5: Access, Distribution, or Reuse Considerations</p> <p>A. Factors affecting subsequent access, distribution, or reuse of scientific data: Identify aspects that in drafting Plans, researchers must consider 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.</p> <p>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).</p>	<p>5. Access, Distribution, or Reuse Considerations</p> <p>6. Oversight of Data Management and Sharing</p>
<p>2026 Pilot DMS Plan Format Available for Immediate Use</p> <p>If you are just starting to prepare your DMS Plan, we recommend using the simplified 2026 Pilot DMS Plan format. The 2026 Pilot DMS Plan format is required for due dates on or after May 25, 2026. We will accept both the 2023 and 2026 formats for due dates prior to May 25, 2026.</p>		<p>16</p>



<https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page>

2026 Data Management & Sharing Form



OMB NO. PENDING

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 completion of a Data Management and Sharing Plan. If the proposed research in the application involves the generation of large-scale genomic data, the Genomic Data Sharing Policy also applies and must be addressed in this Plan. Refer to guidance on [Genomic Data Sharing](#) and [Genomic Data Management and Sharing](#). The GDS guidance is provided in the template below.

1. Will there be **maximum appropriate sharing of scientific data** underlying peer-reviewed publications and other findings resulting from the work supported by this award (including preprints, refereed papers reported at conferences, and other findings)?
Yes No
2. Will the scientific data underlying peer-reviewed publications be shared by the time of publication, or for other findings, by the end of the period of performance, which includes no-cost extensions?
Yes No
3. Will shared scientific data be made available for at least as long as required by applicable data repository policies and/or journal policies?
Yes No
4. If you answered "no" to elements 1, 2, or 3, or if you anticipate that sharing will be limited in some other way, please describe these limitations and the ethical, legal, or technical factors for them. Your response should specify a particular reason(s) for limiting sharing. (300 words maximum)
5. If scientific data derived from human research participants will be shared, will privacy, rights, and confidentiality of participants be protected as outlined in [HQT-OD-22-213](#)?
Yes No Not Applicable
6. In the table below, please list (300 words maximum):
 - a. Key types of scientific data anticipated to be generated during the project, including the species and modality, if known (e.g., "human genomic data," "rat functional magnetic resonance imaging data"). NIH recognizes that not all data types expected to be generated in the study will meet the definition of scientific data or can be anticipated in advance. If a data type does not appear on the list, it does not imply that that data type will not be shared if it is generated in the study.
 - b. The repository or an example of a repository where the scientific data may be managed and shared, if the scientific data is known at time of application. NIH expects the use of established repositories for preserving and sharing scientific data when they are available.


Expected Data Type	Established Repository or Example
7. For studies subject to the NIH Genomic Data Sharing Policy (GDS) (e.g., using NIH funds to generate large-scale human genomic data):
 - a. Will you share all large-scale human genomic and associated data in a NIH-designated repository according to the accelerated timeline expected in the GDS Policy?
Yes No Not Applicable
If "no," address in element 4.

OMB NO. PENDING


b. Do you anticipate that when sharing you will be able to meet the expectations of the Institutional Certification in the GDS Policy?
Yes No Not Applicable
If "no," address in element 4.



Limitations



Type and Repository Table



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[dms-blank-format-page-2026.docx](#)
[Writing a Data Management and Sharing Plan | Grants & Funding](#)

17

17

Data Management & Sharing Plan— Limitations

Examples of justifiable factors for limiting scientific data sharing include

- informed consent will not permit or will limit the scope or extent of sharing and future research use
- existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use
- privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm, and protective measures such as de-identification and [Certificates of Confidentiality](#) would be insufficient
- explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- restrictions imposed by existing or anticipated agreements (e.g., with third party funders, with partners, with repositories, with Health Insurance Portability and Accountability Act (HIPAA) covered entities that provide Protected Health Information under a data use agreement, through licensing limitations attached to materials needed to conduct the research)
- datasets cannot practically be digitized with reasonable efforts

Examples of reasons that would generally not be justifiable factors limiting scientific data sharing include

- data are considered to be too small
- data that researchers anticipate will not be widely used
- data are not thought to have a suitable repository





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[Writing a Data Management and Sharing Plan | Grants & Funding](#)

18

18

Data Management & Sharing Plan – Large Scale Genomic Data

Genomic Data Sharing Policy Overview

i This page provides information about NIH's scientific data management and sharing policies and repositories, previously available on the NIH Scientific Data Sharing Site. Please update any sharing.nih.gov bookmarks you may have to the new pages.

Learn what is expected of investigators and institutions under the NIH Genomic Data Sharing Policy.

On this page:

- [Applicability](#)
- [Planning, Submitting, and Accessing Genomic Data](#)

NIH expects the broad and responsible sharing of human as well as non-human genomic data resulting from NIH-funded research because the timely sharing of research results can accelerate discoveries that improve our ability to diagnose, treat, and prevent disease.



<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/overview>

19

19

Data Management & Sharing Plan – Progress Reports

May 9, 2024

Reporting Data Management and Sharing (DMS) Plan Activities in the Research Performance Progress Report (RPPR)

Notice Number:
NOT-OD-24-123

Key Dates

Release Date: _____ May 9, 2024

Related Announcements

- **September 23, 2024** - Reminder: Reporting Data Management and Sharing (DMS) Plan Activities in Research Performance Progress Reports (RPPRs) Submitted on or After October 1, 2024. See Notice [NOT-OD-24-175](#).
- **September 23, 2024** - Updated Processes for Requesting Revisions to an Approved Data Management and Sharing (DMS) Plan. See Notice [NOT-OD-24-176](#).
- **October 29, 2020** - Final NIH Policy for Data Management and Sharing. See Notice [NOT-OD-21-013](#).



[NOT-OD-24-123: Reporting Data Management and Sharing \(DMS\) Plan Activities in the Research Performance Progress Report \(RPPR\)](#)

20

20

Data Management & Sharing Plan – Progress Reports

Sept. 23, 2024

Reminder: Reporting Data Management and Sharing (DMS) Plan Activities in Research Performance Progress Reports (RPPRs) Submitted on or After October 1, 2024

Notice Number:
NOT-OD-24-175

Key Dates

Release Date: _____ September 23, 2024

Related Announcements

- September 23, 2024 - Updated Processes for Requesting Revisions to an Approved Data Management and Sharing (DMS) Plan. See Notice NOT-OD-24-176.
- May 9, 2024 - Reporting Data Management and Sharing (DMS) Plan Activities in the Research Performance Progress Report (RPPR). See Notice NOT-OD-24-123.
- October 29, 2020 - Final NIH Policy for Data Management and Sharing. See Notice NOT-OD-21-013.

Issued by
NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

The purpose of this Notice is to remind the research community of the requirement to address the NIH Data Management and Sharing Policy in Research Performance Progress Reports (RPPRs) submitted on or after October 1, 2024, and to provide additional details about the implementation of the RPPR instructions.

On October 1, 2024, NIH will issue new DMS questions that align with the [NIH Final Policy on Data Management and Sharing](#), asking recipients for updates on the status of data sharing, repositories, and unique identifiers for data that have been shared.

Overview of changes

NIH is adding several new questions about DMS activities to RPPRs submitted on or after October 1, 2024. This change was previously shared in a [May 2024 Guide Notice](#). For awards for which the NIH DMS Policy applies, recipients will be asked:

- Whether data has been generated to date and what type of data it is;
- Whether data has been shared for use by others;
- If data has been shared, in what repository and under what unique digital identifiers;
- If data has NOT been shared, what is the status of data sharing (e.g. being prepared for submission, submitted to repository, not yet expected to be shared); and
- If data has not been generated and/or shared as outlined in an approved DMS Plan, what corrective actions have or will be taken to comply with the approved Plan.

[NOT-OD-24-175: Reminder: Reporting Data Management and Sharing \(DMS\) Plan Activities in Research Performance Progress Reports \(RPPRs\) Submitted on or After October 1, 2024](#)

21

21

Data Management & Sharing Plan – Progress Reports

- Whether data has been generated to date and what type of data it is
- Whether data has been shared for use by others
- If data has been shared, in what repository and under what unique digital identifiers
- If data has NOT been shared, what is the status of data sharing
- If data has NOT been generated and/or shared as outlined in an approved DMS Plan, what *corrective actions* have or will be taken to comply with the approved Plan

Overview of changes

NIH is adding several new questions about DMS activities to RPPRs submitted on or after October 1, 2024. This change was previously shared in a [May 2024 Guide Notice](#). For awards for which the NIH DMS Policy applies, recipients will be asked:

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[NOT-OD-24-175: Reminder: Reporting Data Management and Sharing \(DMS\) Plan Activities in Research Performance Progress Reports \(RPPRs\) Submitted on or After October 1, 2024](#)

22

22

Data Management & Sharing Plan – Progress Report Instructions

Reminder: Reporting Data Management and Sharing (DMS) Plan Activities in Research Performance Progress Reports (RPPRs) Submitted on or After October 1, 2024

Notice Number:
NOT-OD-24-175

Key Dates

Release Date: September 23, 2024

For NIH recipients:

NIH recipients subject to the 2023 NIH Data Management and Sharing Policy must report activities related to their approved Data Management and Sharing (DMS) Plan in C.5.c. Data Management and Sharing. See NIH Grants Policy Statement 8.2.3.1 and the NIH Scientific Data Sharing website for additional information. These recipients must only report on activities related to a Resource Sharing Plan in C.5.b when applicable (i.e., sharing model organisms or research tools).

The purpose of this notice is to remind the research community of the requirement to address the NIH Data Management and Sharing Policy in Research Performance Progress Reports (RPPRs) submitted on or after October 1, 2024, and to provide additional details about the implementation of the RPPR instructions.

On October 1, 2024, NIH will issue new DMS questions that align with the NIH Final Policy on Data Management and Sharing, asking recipients for updates on the status of data sharing, repositories, and unique identifiers for data that have been shared.

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- If data has not been generated and/or shared as outlined in an approved DMS Plan, what corrective actions have or will be taken to comply with the approved Plan.



[NIH and Other PHS Agency Research Performance Progress Report \(RPPR\) Instruction Guide](#)

Where Do We Begin?



Data Management and Resource Sharing



Topics

- History and Current NIH Policies
- **Data Lifecycle (Data Management)**
 - Data Quality & Integrity
- Case Study—*Time permitting*




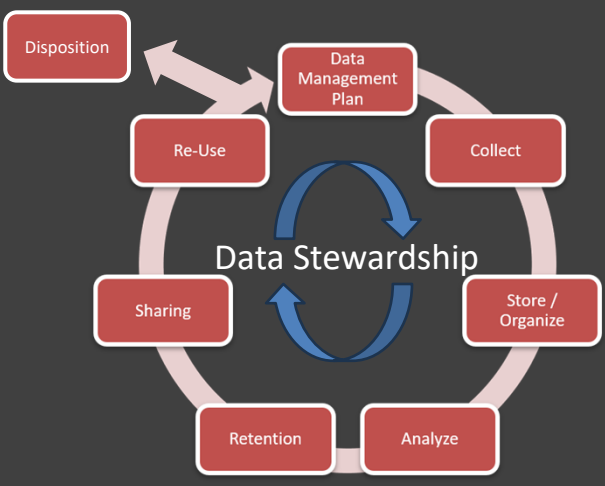
References provided on slides

25


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25

Data Lifecycle

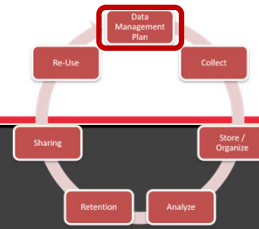



26

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26

Data Management



- Data is (are) a scholarly product
- Data are fragile and easily lost
- Growing research data requirements
- Good management helps prevent errors and increases the quality of your analysis
- Well-managed and accessible data allows others to validate and replicate findings
- **Research data management** facilitates sharing of research data and, when shared, data can lead to valuable discoveries by others outside of the original research team

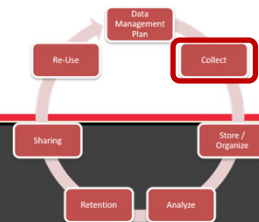
University of Pittsburgh Library System



27

27

Data Collection



- **Source (Raw) Data**
- Types (observational, derived, etc.)
- Format (text, numeric, modeling, images, etc.)
- Quantity
- Standards (e.g., HIPAA)
- Proprietary
- Owner / SME



28

28

Source Data (Original)

First capture of information



29

ALCOA Principles

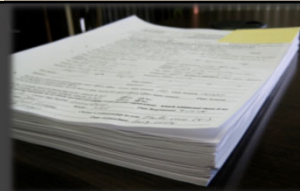
Applies to paper and/or electronic data

Data Quality

- Atributable
- Legible
- Contemporaneous
- Original
- Accurate

Data Integrity

- Complete, Consistent, Enduring, Readily Available



30

Data and Data Integrity

“Data are the foundation on which scientific, engineering, and medical knowledge is built.”

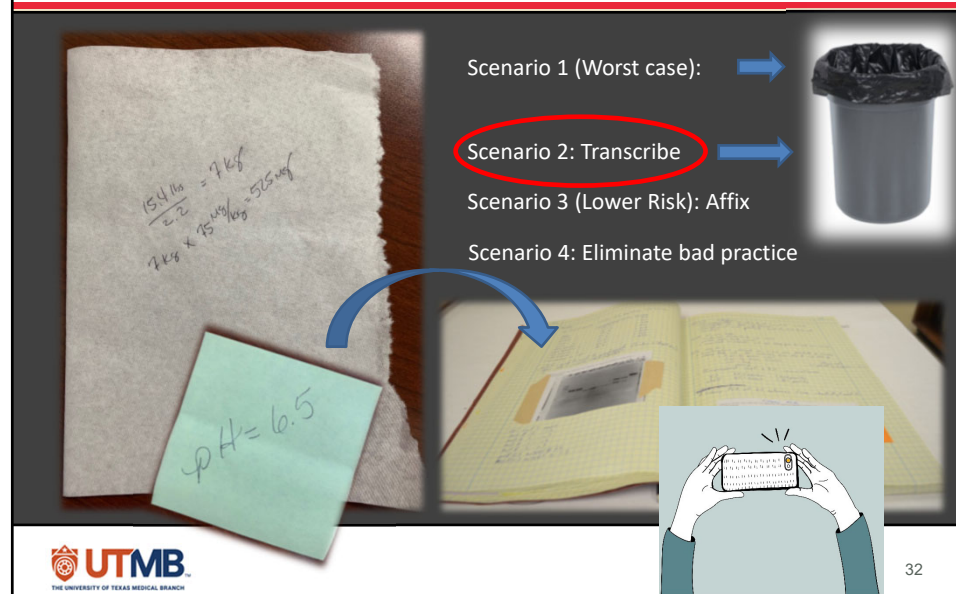
~Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age, National Academy of Science, National Academy of Engineering, and Institute of Medicine; Preface, 2009

“Data integrity is the degree to which data are complete, consistent, accurate, trustworthy and reliable and these characteristics of the data are maintained throughout the data life cycle...”

~OECD Advisory Document on GLP Data Integrity; 20 Sept. 2021

31

Data Risk - Non-enduring

Scenario 1 (Worst case): →

Scenario 2: Transcribe →

Scenario 3 (Lower Risk): Affix

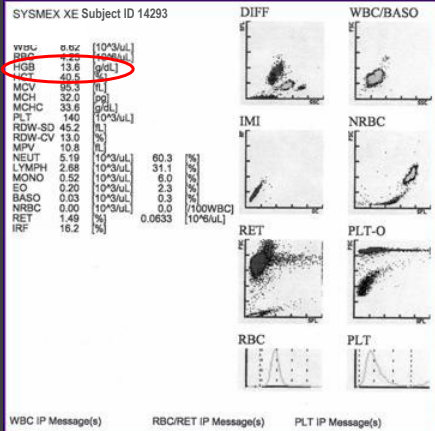
Scenario 4: Eliminate bad practice

32

Data Risk - Transcription Errors



Hemoglobin Value



Animal	HGB
12938	12.2
14039	8.9
14293	3.6
14980	13.8
15209	12.5
15490	9.5
15560	14.0

Source: Google Images



33

33

Data Risk - Illegible Data Entries



May 29, 2011

5/3/2026





34

34

Data Quality/Reproducibility Exercise

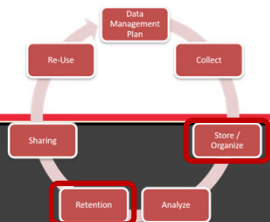
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35


35


Organization, Retention



Conditions

- Location (physical / electronic)
- Accessibility / Security (limited)
- Protection from Loss / Unauthorized Changes
- Change Control
- Move / Migration




36

36

Managing Electronic Data

- Audit Trails / Meta Data
- Security / Encryption
- Software Compatibility
- Back-up Frequency
- Program Updates
 - Automatic
 - Impact to significant digits
- Data Migration
- Windows PC vs. MAC
- Checksums

CR0216G XRD01 A347.xls

Project number File type:
 D = data
 G = graph
 L = letter
 P = proposal

CR0216L Kanare prelim stats02.doc


Project number Addressee Title

Documents library

Example.Study2018.031.0002

Name

- 1. Study Plan
- 2. Compliance Approvals
- 3. Project Management
- 4. Study Form Templates
- 5. Communication
- 6. Source Data
- 7. Data Tables
- 8. Statistics
- 9. Contributing Reports
- 10. Summary Report




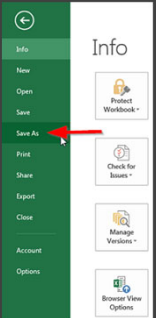
37

37

Risks to Electronic Data

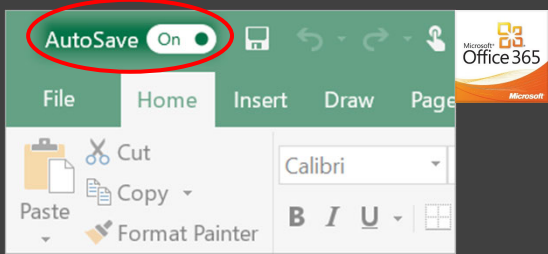
Overwriting of information






- Save
- Save As
- AutoSave

- Copy / Paste Errors





38

38

Electronic Laboratory Notebooks

Pros

- Project organization
- Collaboration
- Custom forms/fields to assure all data are captured
- Procedure Checklists
- Time standardization
- Auto reminders
- Searchable
- Audit trail
- Data exportable



Cons

- Cost
- Sustainability (\$)
- System administration
- Compatibility with other systems
- Software updates/data migration verification
- Discontinued (or support discontinued)



39

39

Lab Notebooks



Maintaining a laboratory notebook

Tips for undergraduates, but perhaps useful for anyone.

Reasons to keep a laboratory notebook

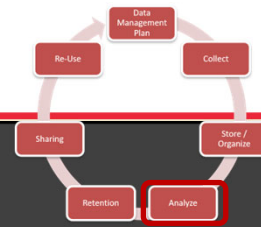
1. To provide yourself with a complete record of why experiments were initiated and how they were performed. You'll forget if you don't. Seriously: even in your youth your brain cells are senescing.
2. To give yourself a central, physical place to record your data, to note statistical outcomes, and to paste graphs that show results. Researchers who keep these items in separate places are unlikely to be productive scientists.
3. To encourage sound thinking. Keeping a notebook gives you a forum to talk to yourself — to ask questions, to record important thoughts about the experimental design, and to speculate on how your results might eventually be interpreted.
4. To provide information to a person who is interested in continuing your research project, even if you deem that possibility hilariously unlikely. And if you're doing important research and die an early, gruesome death, your colleagues might want to pick it up.
5. To get rich. Not everyone sets out with the goal of patenting a process or contraption, but you might stumble onto something actually important, and in such an event you must have a notebook that supports your claims.

<https://colinpurrington.com/tips/lab-notebooks/>

40

40

Data Analysis



- Implement methods to reduce transcription errors
- Prospectively define inclusion / exclusion criteria
- Develop prospective statistical plan (within the study plan) and analyze data in accordance with the plan
- Retain meta data and methods (protocols) that allow for study reconstruction
- Retain critical communication

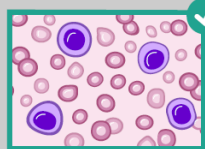
41

Image Manipulation

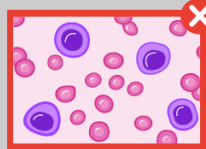
- Document all changes
- Retain unprocessed image
- Follow journal guidelines for permissible processing

COLOR ENHANCEMENTS

Changing the contrast, color, or brightness



Ensure that the meaning of the image stays the same and fine details are not removed.



Contrast and saturation were increased causing the background cells to disappear.

PICTURE IMPERFECT

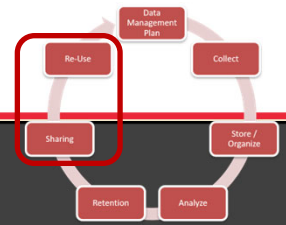
Did a top NIH official, neuroscientist Eliezer Masliah, doctor influential Alzheimer's and Parkinson's studies for decades?

By Charles Piller

- Western Blot Manipulation
- 1997 – 2023
- 132 Research Papers
- 18,000 Citations
- Prasinezumab in Phase I trials

42

Data Sharing



➤ Mechanisms & Format

- Online repositories
- Coding
- SharePoint / OneDrive
- Mixed media

➤ Limitations (e.g., HIPAA), Conditions / Exclusions

➤ Sharing Plan Timelines

"no later than the time of publication or the end of the award or support period, whichever comes first."

➤ Acknowledgements of source data

➤ Instructions



43

43

NIH ImmPort Data Upload Templates

Table Of Contents

1. adverseEvents.txt
2. assessments.txt
3. basic_study_design.txt
4. bioSamples.txt
5. controlSamples.txt
6. CyTOF_Derived_data.txt
7. ELISA_Results.txt
8. ELISPOT_Results.txt
9. experiments.txt
10. experimentSamples_CyTOF.txt
11. experimentSamples_ELISA.txt
12. experimentSamples_ELISPOT.txt
13. experimentSamples_Flow_Cytometry.txt
14. experimentSamples_Gene_Expression_Array.txt
15. experimentSamples_Genotyping_Array.txt
16. experimentSamples_HAI.txt
17. experimentSamples_HLA.txt
18. experimentSamples_Immunology_Histology.txt
19. experimentSamples_KIR.txt
20. experimentSamples_Mass_Spectrometry_Metabolomics.txt
21. experimentSamples_Mass_Spectrometry_Proteomics.txt
22. experimentSamples_MBAA.txt
23. experimentSamples_Neutralizing_Antibody_Titer.txt
24. experimentSamples_Other.txt
25. experimentSamples_QRT-PCR.txt
26. experimentSamples_RNA_Sequencing.txt
27. experimentSamples_Virus_Neutralization.txt
28. FCM_Derived_data.txt
29. HAI_Results.txt
30. HLA_Typing.txt
31. immuneExposure.txt
32. interventions.txt
33. KIR_Typing.txt
34. labTest_Results.txt
35. labTestPanels.txt
36. labTests.txt
37. Mass_Spectrometry_Metabolomic_Results.txt
38. Mass_Spectrometry_Proteomic_Results.txt
39. MBAA_Results.txt
40. PCR_Results.txt
41. protocols.txt
42. publicRepositories.txt
43. Reagent_Sets.txt
44. reagents_Array.txt
45. reagents_CyTOF.txt
46. reagents_ELISA.txt

47. reagents_ELISPOT.txt
48. reagents_Flow_Cytometry.txt
49. reagents_HAI.txt
50. reagents_HLA_Typing.txt
51. reagents_KIR_Typing.txt
52. reagents_MBAA.txt
53. reagents_Neutralizing_Antibody_Titer.txt
54. reagents_Other.txt
55. reagents_PCR.txt
56. reagents_Sequencing.txt
57. reagents_Virus_Neutralization.txt
58. RNA_SEQ_Results.txt
59. standardCurves.txt
60. study_design_edit.txt
61. subjectAnimals.txt
62. subjectHumans.txt
63. treatments.txt
64. Virus_Neutralization_Results.txt



- Study Design
- Protocols (procedures)
- Public Repositories
- BioSamples
- Control Samples
- Experiment samples
- Lab Tests
- PCR Results
- Reagent sets
- Reagent Sequencing
- Standard Curves
- Treatments

Data Engineers!



<https://import.niaid.nih.gov/home>

<https://import.org/shared/home>

44

44

DMS Costs



Allowable Costs

Reasonable, allowable costs may be included in NIH budget requests for:

- ✔ Curating data
- ✔ Developing supporting documentation
- ✔ Formatting data according to accepted community standards, or for transmission to and storage at a selected repository for long-term preservation and access
- ✔ De-identifying data
- ✔ Preparing metadata to foster discoverability, interpretation, and reuse
- ✔ Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (for example, before deposit into an established repository).
- ✔ Preserving and sharing data through established repositories, such as data deposit fees. If the Data Management & Sharing (DMS) plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

[Budgeting for Data Management & Sharing | Grants & Funding](#)



Data Management and Resource Sharing



Closing Thoughts...


- 53 landmark studies
- 6 confirmed (11%)
 - Controls
 - Reagents
 - Investigator bias
 - Described complete data set



<https://www.nature.com/articles/483531a>



Data Management and Resource Sharing

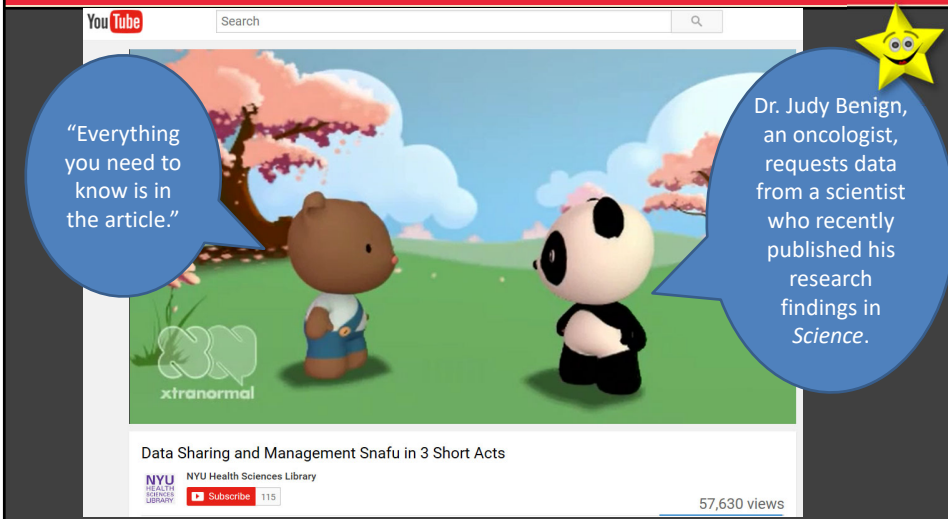


- Be organized!
- Advocate data stewardship throughout the data lifecycle
- Implement the ALCOA principles
- Verify requirements in RFP / Contract
- Understand that a Data Management and Sharing Plan is a Term and Condition of the Notice of Award (NIH)

47

47

Why is Data Management and Resource Sharing Important?



“Everything you need to know is in the article.”


Dr. Judy Benign, an oncologist, requests data from a scientist who recently published his research findings in *Science*.

Data Sharing and Management Snafu in 3 Short Acts

NYU Health Sciences Library

57,630 views

<https://www.youtube.com/watch?v=N2zK3sAtr-4>

 **UTMB**
THE UNIVERSITY OF TEXAS MEDICAL BRANCH

48

48

Data Management and Resource Sharing



Topics

- History and Current NIH Policies
- Data Lifecycle (Data Management)
 - Data Quality & Integrity
- **Case Study—Time permitting**



References provided on slides


49




49

Case Study—Data Sharing

Identify options (i.e., conditions and/or limitations) for sharing data from a study with 500 human subjects being screened for sexually transmitted diseases.



50



50

Case Study—Data Sharing

*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.



Grants.nih.gov

51

51



thank you!



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52

52