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How to
comply with NIH Policy on Data Management & Sharing Plans

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Image: © UB UniBE

Outline

- New National Institutes of Health Data Management and Sharing Policy
- Data Management and Sharing Plan (DMS) optional template
- Key Data Management and Sharing Plan (DMS) elements
- Research Data Management Support

New Data Management & Sharing Plan Policy

Starting from **January 25 2023**

Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of **scientific data**.

The DMS Policy applies to all research that generates scientific data, including:

- Research Projects
- Some Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

The DMS Policy does <u>not</u> apply to research and other activities that *do not* generate scientific data, including:

- Training (T)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resource (Gs)

https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/research-covered-under-the-data-management-sharing-policy#after

National Institutes of Health
FAIR Principles

- NIH encourages data management and sharing practices to be consistent with the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles.
- These principles make it easier for computers to process and analyze datasets, which is important when reusing or repurposing datasets for secondary research.
- To learn more, visit the GO FAIR initiative or read The NIH Strategic Plan for Data Science.

National Institutes of Health
Regulations on research data

- “NIH expects researchers to maximize the appropriate sharing of scientific data, taking into account factors such as legal, ethical, or technical issues that may limit the extent of data sharing and preservation.”
- DMP is part of an application.
- Although part of the official submission, when not considered during peer review the attachment is maintained as a separate “Data Management and Sharing (DMS) Plan” document in the grant folder viewable via the Status Information screen in eRA Commons. This document is viewable by authorized users and **is not part of the assembled e-Application**.

Data Management and Sharing Plan Assessment

- Applications selected for funding **will only be funded if the DMS Plan is complete and acceptable**.

- During peer review, reviewers **will not be asked to comment on the DMS Plan nor** will they factor the DMS Plan into the **Overall Impact score**, unless sharing data is integral to the project design and specified in the funding opportunity

Data Management and Sharing Plan

NIH Budgeting for DMS

Starting from 5 Oct 2023

DMS costs must be requested in the appropriate cost category:

- Personnel
- Equipment
- Supplies
- Other expenses

Specify estimated DMS cost details within the "Budget Justification" attachment of the R&R Budget Form or "Additional Narrative Justification" attachment of the PHS 398 Modular Budget Form, pursuant to the instructions.

Allowed costs

- Curating data
- Developing supporting documentation
- Formatting data
- De-identifying data
- Preparing metadata
- Local data management infrastructure
- Data deposit fees
- If the Data Management & Sharing (DMS) plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

NIH Budgeting for Data Management & Sharing Cost Estimation Tool

Data Management and Sharing Plan
Revisions

Pre-Award Plan Revisions:

- Applicants will be expected to communicate with their Program Officer and/or Grants Management Specialist to resolve any issues that prevent the funding IC from approving the DMS Plan.
- NIH Grants Policy Statement Section 2.5.1 Just-in-Time Procedures

Post-Award Plan Revisions:

- Plans may need to be updated or revised over the course of a project for a variety of reasons for example, if the type(s) of data generated change(s), a more appropriate data repository becomes available, or if the sharing timeline shifts.

Data Management & Sharing Plan

Format

Generation of scientific data → is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan.

Generation of large-scale genomic data → the Genomic Data Sharing Policy also applies and should be addressed in this Plan.

Text: in italics should be deleted. Do not include hypertext (e.g., hyperlinks and URLs) in the DMS Plan attachment.

Text length: The Plan is recommended not to exceed two pages

Template: There is no "form page" for the Data Management and Sharing Plan, while optional template exists with the **six key elements**.

Data Management & Sharing Plan Template

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

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.

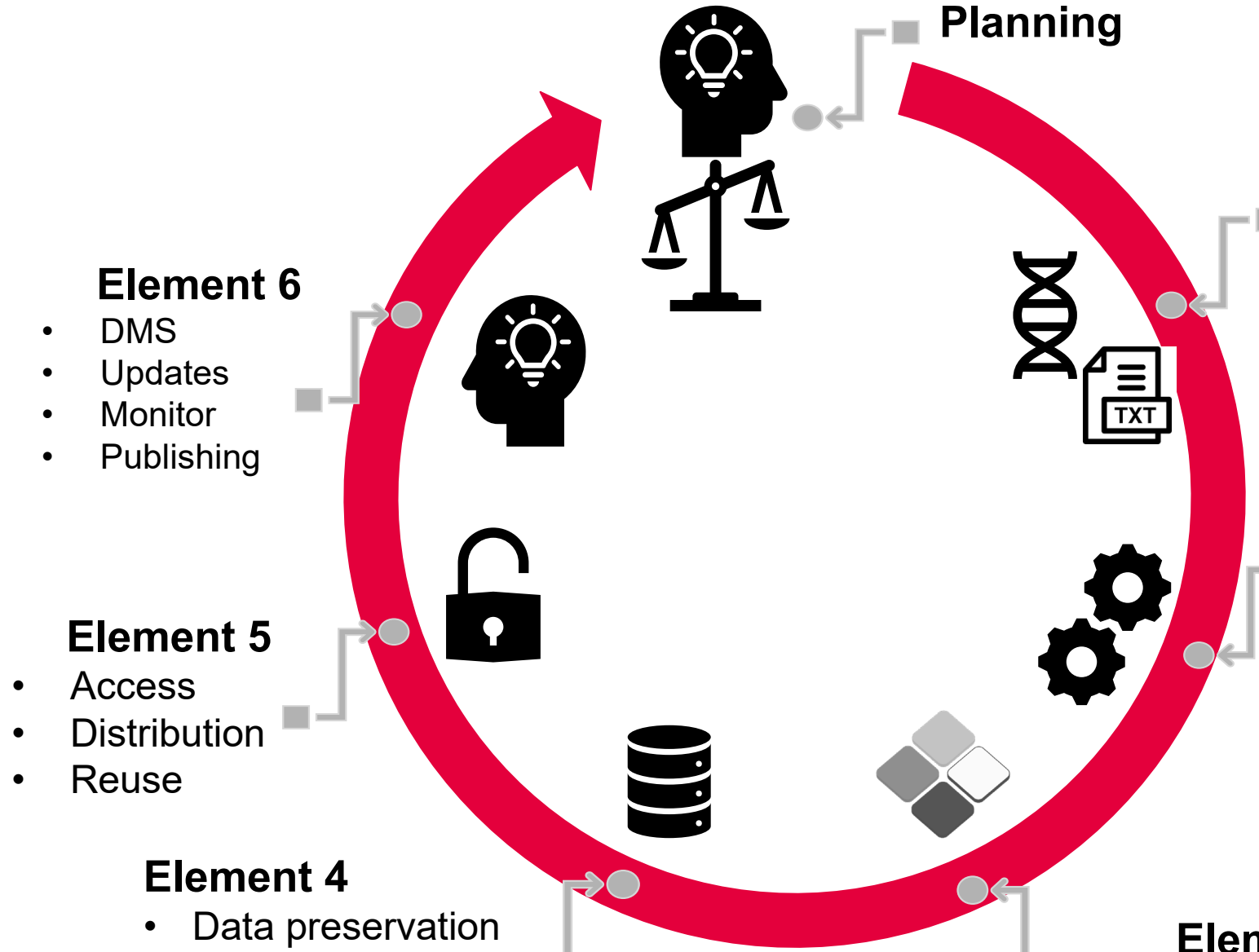
Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may 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.

optional DMS Plan format page



Planning

Element 1
- Data Type
- Format
- Data description
- Data size
- File convention
- Metadata & Documentation

Element 2
- Tools
- Software
- Code

Element 3
- Standards

Element 4
- Data preservation
- Access
- Timeline

Element 5
- Access
- Distribution
- Reuse

Element 6
- DMS
- Updates
- Monitor
- Publishing

Element 1
Data Type

SNP arrays

ChIP-Seq reads

DNA sequencing reads

Array CGH

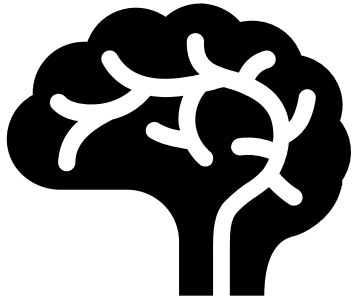
fMRI

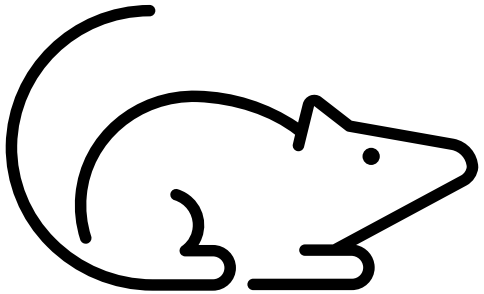
RNA-Seq reads

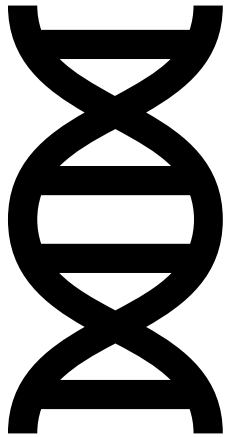
Element 1

Data Description

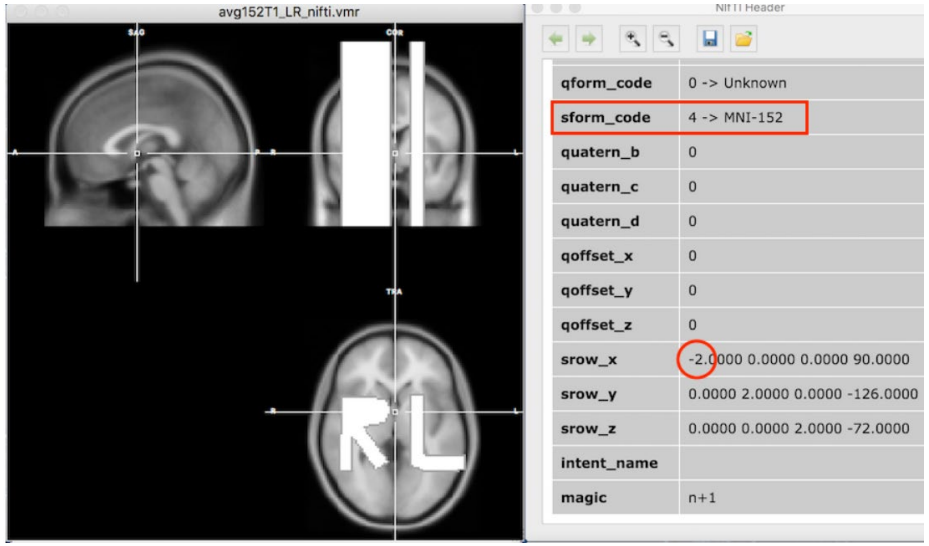
- Human data
- Genomic data
- Non-human data







Element 1
Data Format



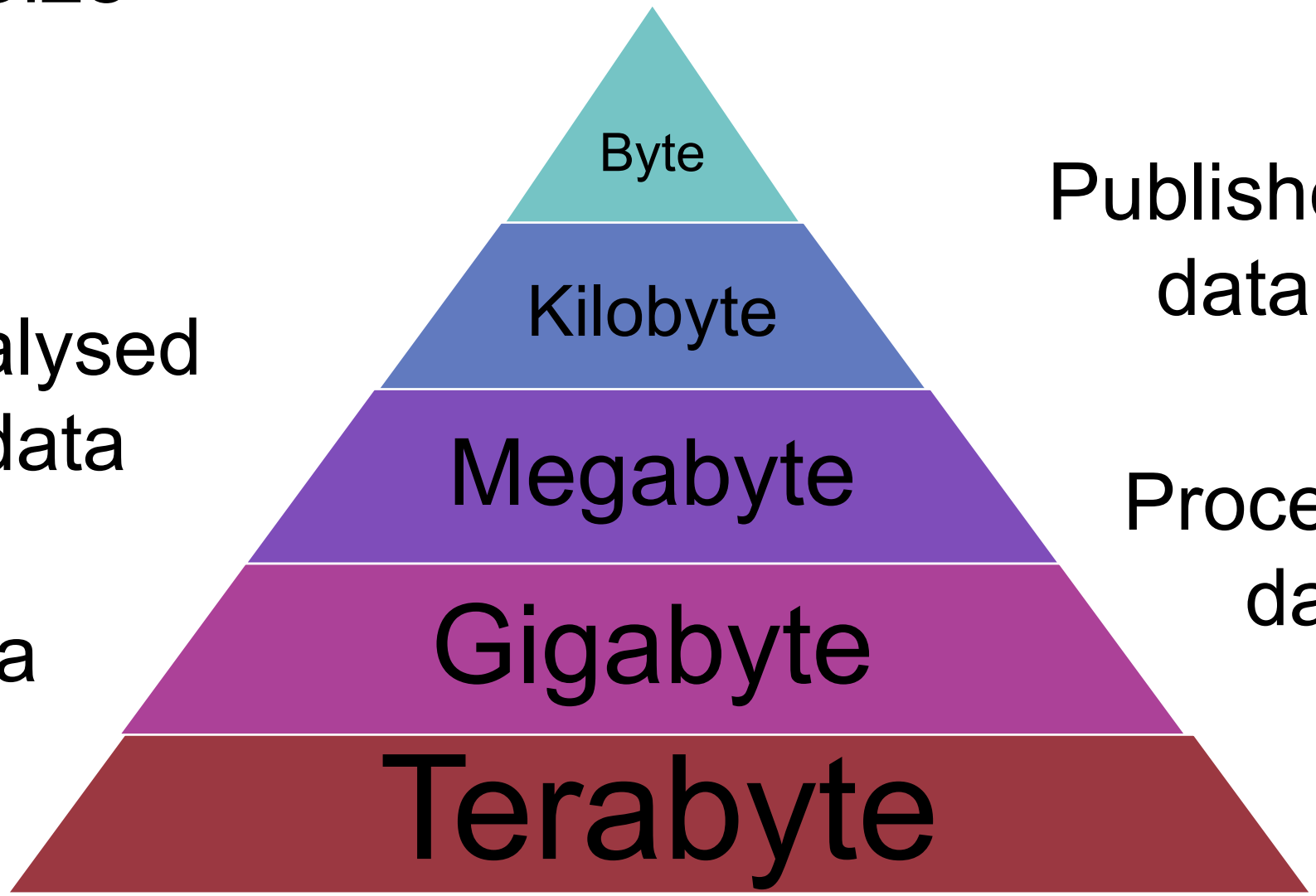
https://nifti.nimh.nih.gov/nifti-1/data

– . Cel

– .fastq

Element 1

Data Size



Published data

Analysed data

Processed data

Raw data

Element 1

Metadata and Documentation

- Naming conventions
- Metadata (for closed data)
- ReadMe files Readme_Template_EN.txt (3KB)
- Documentation (e.g., study protocols, data collection instruments)
- Codebooks (definition of variables)
- Data labels
- Laboratory Information Management System (LIMS, e.g., OpenBIS)
- Research Electronic Data Capture REDCap
- For clinical studies GCP-compliant secuTrial

REDCap Institutions 6328 Countries 151 Projects 1.6M Users 2.4M Articles 22.8k

secuTrial® for your clinical research

☑ Recommendation on research data documentation from the Open Science Team (PDF, 141KB)

Element 2

Related Tools, Software and/or Code

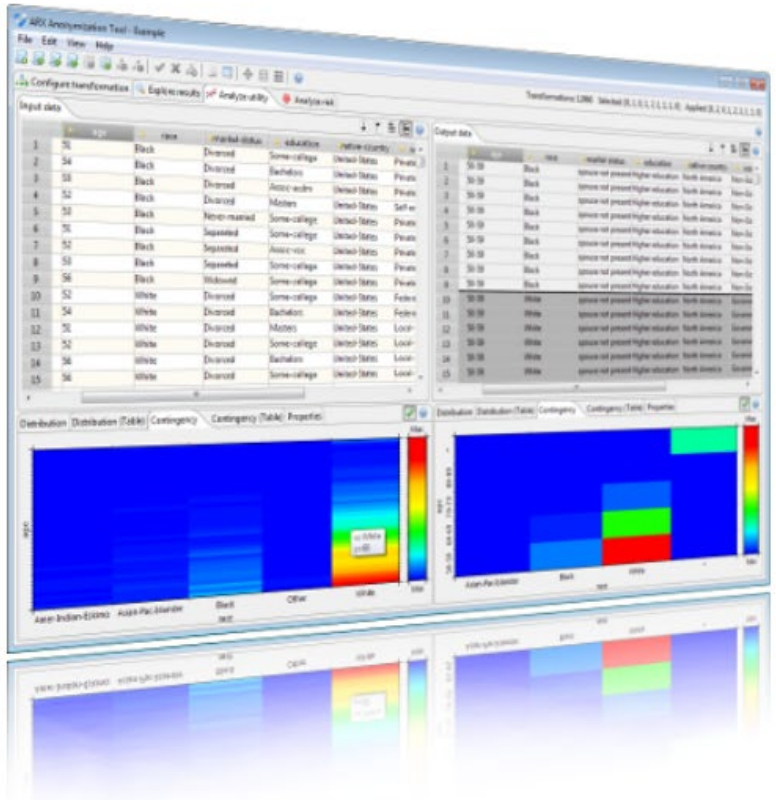
ARX

Data Anonymization Tool

ARX is a comprehensive open source software for anonymizing sensitive personal data. It supports a wide variety of (1) privacy and risk models, (2) methods for transforming data and (3) methods for analyzing the usefulness of output data.

The software has been used in a variety of contexts, including commercial big data analytics platforms, research projects, clinical trial data sharing and for training purposes.

ARX is able to handle large datasets on commodity hardware and it features an intuitive cross-platform graphical user interface. You can find further information here, or directly proceed to our downloads section.



Data Anonymization Tool · *ARX* is a comprehensive open-source software for anonymizing sensitive personal data https://arx.deidentifier.org/

Element 3
Standards

A common data element are developed that data

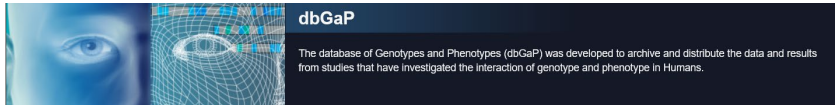
can be collected in the same way across multiple research studies

Common Data Elements: Standardizing Data Collection

Element 4

Data Preservation, Access, and Timelines

Database of Genotypes and Phenotypes (dbGaP)



NIH's central repository for human genomic and associated phenotypic data—even if the data will be submitted elsewhere

Certificate of Confidentiality – as an additional safeguard to prevent compelled disclosure of any personally identifiable information they may hold. NIH-funded studies are automatically covered under such a certificate.

Examples of Frequently Used Repositories for Human Genomic Data

AnVIL Shorts
Learn about AnVIL in our series of 2 minute videos!

ArrayExpress Functional genomics data

NIH National Heart, Lung, and Blood Institute

BioData CATALYST

Element 4

Data Preservation, Access, and Timelines

Secure Data Storage, Preservation and Support @ UniBE and Insel

- Information Security and Data Protection Analysis ISDP
- Information security management (ISO)
- Password-protected and controlled access
- IT-UniBE support helpdesk@id.unibe.ch
- Clinical Trial Unit (CTU) Research Data Management Support
- Data Protection Officer at the UniBE, Legal Service Office at UniBE
- Data Protection Insel Gruppe AG
- DLF Insel Research Governance Manager and research support

Element 4

Data Preservation, Access, and Timelines

Length of time to maintain and make data available

- No later than six months after the initial data submission begins
- At the time of acceptance of the first publication, whichever occurs first, without restrictions on publication or other dissemination.
- Grantee institutions are required to keep the data for **3 years following closeout of a grant or contract agreement.** Contracts may specify different time periods.

Section 8.4.2 of the NIH Grants Policy Statement

Element 4

Data Preservation, Access, and Timelines

NIH-supported Scientific Data Repositories*

Institute or Center	Repository Name	Repository Description	Open Data Submission	Data Submission Policy	Open Time Frame for Data Deposit
All		Keyword Filter			
CIT, NINDS	Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System	The Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system was developed to share data across the entire TBI research field and to facilitate collaboration between laboratories, as well as interconnectivity with other informatics platforms. Sharing data, methodologies, and associated tools, rather than summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches.	NO	How to submit	NO

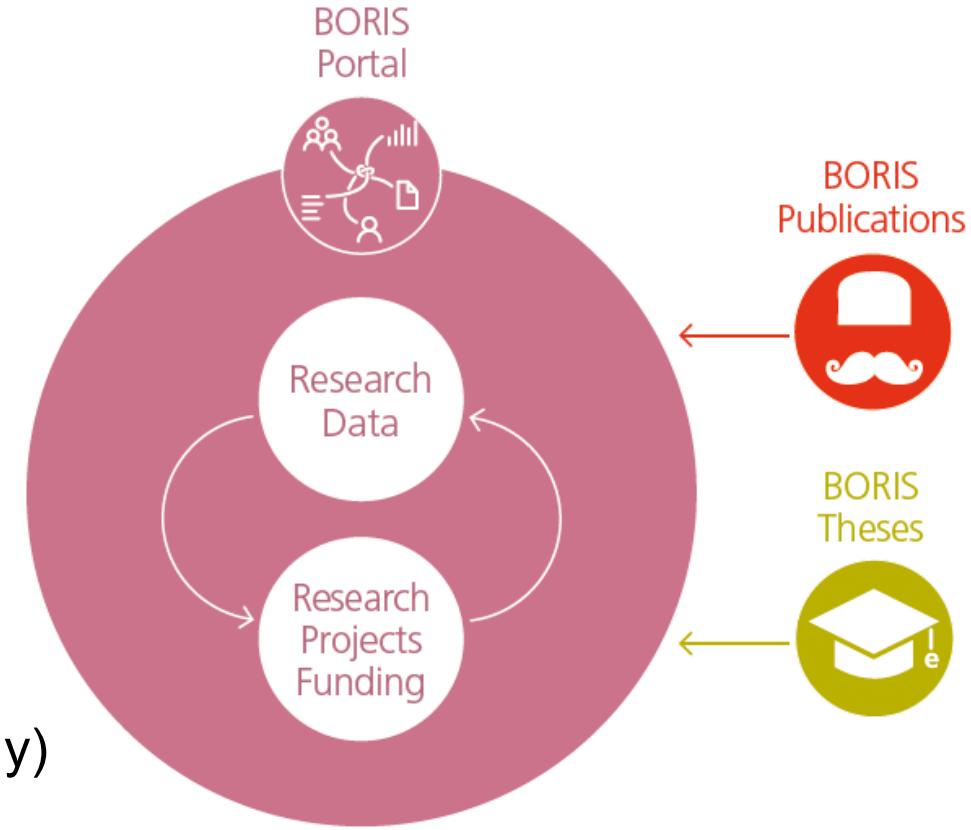
Selecting a Data Repository, Digital Object Identifier (DOI)

https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data

Element 4
Data Preservation, Access, and Timelines

BORIS Portal Research Data Repository

- Institutional research data repository @ UniBE
- Digital Object Identifier (DOI)
- Metadata description (Dublin Core)
- Metadata stored under (CC0) and permanently
- Data documentation upload
- Managing data access
- Licenses
- Policy for long-term preservation (**10 years**)
- For clinical studies permitted (anonymized data only)



https://boris-portal.unibe

Element 5

Access, Distribution, or Reuse Considerations

Maximise the appropriate sharing of scientific data

Justify any applicable factors or data use limitations

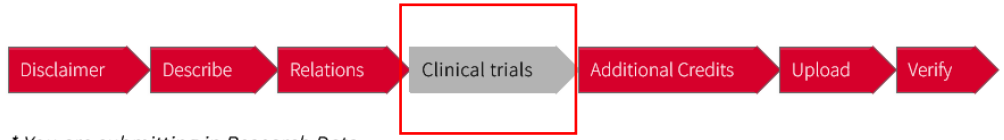
Consider:

- Informed Consent
- Privacy and confidentiality protections,
- and any other considerations that may limit the extent of data sharing

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 5

Access, Distribution, or Reuse Considerations



Element 5

Access, Distribution, or Reuse Considerations

Managing data access:

Open — Open access to dataset.

Embargoed — Enter date after which dataset will be released.

Restricted — Upload dataset and grant access on request.

Closed — No data upload, but meta-data can be entered to verify existence of dataset.

Data Transfer and Use Agreement

- recommended for data that cannot be shared openly
- individually define re-use conditions for dataset
- share DTA along with data for others to download and sign

Element 6

Oversight of Data Management and Sharing

Responsible Persons (title, roles) for Data Management and Sharing Plan to:

- Monitor and
- updates through the project life cycle

NIH Data Management Plan

Sample Plans

Sample Plan A:

Clinical and/or MRI data from human research participants

Sample Plan B:

Genomic data from human research participants

Sample Plan C:

Genomic data from a non-human source

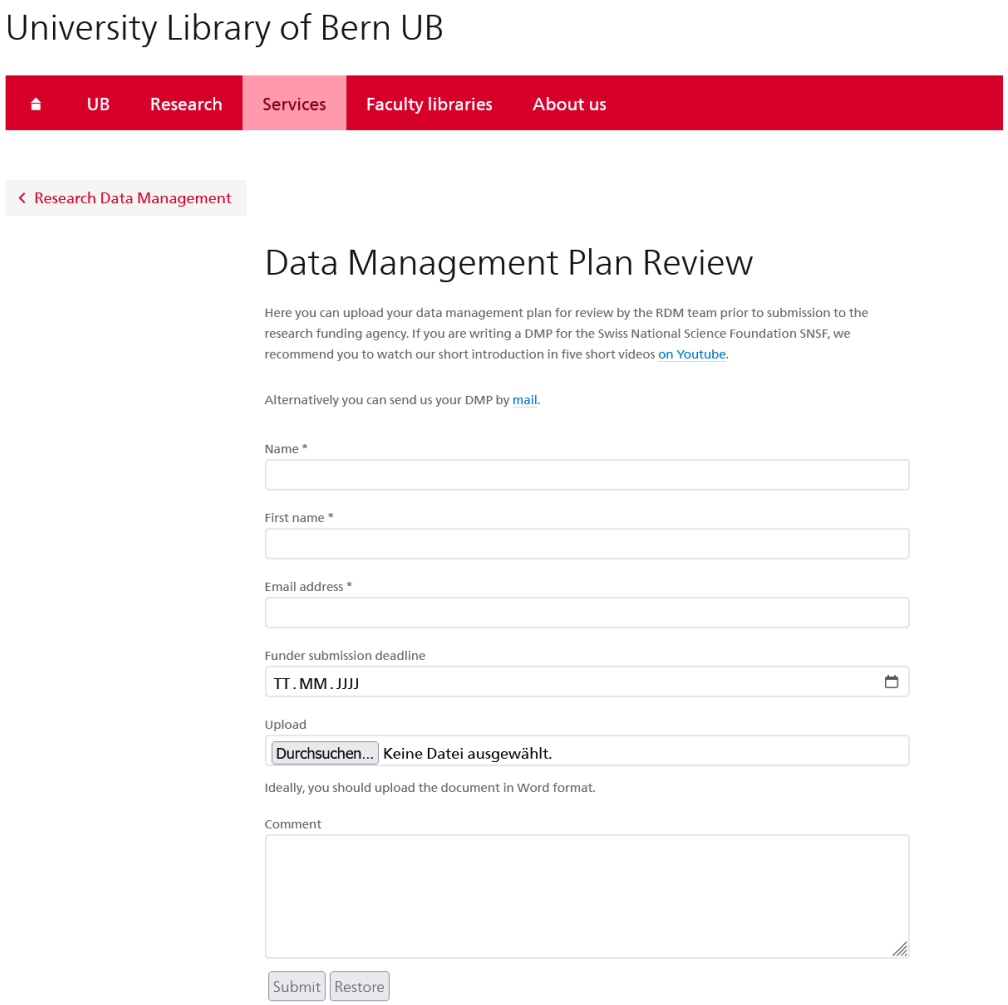
Sample Plan D:

Secondary data analysis

More examples (Link)

Open Science Research DMP Support

Data Management and Sharing Plan Review



Data Management Plan review online or via email openscience@unibe.ch

Feedback within 1-3 working days

Research Data Management Support
Training Sessions and Workshops

“How to” training series in research data management:

- How to write and update a Data Management Plan
- How to manage research data ethically
- How to efficiently document research data
- How to store research data during the project
- How to license research data
- How to publish your research data in 5 easy steps

BORIS Portal

- Research Data and Projects

Research Data Management Support

Training Sessions and Workshops

Open Science, Open Access & Open Research Data workshops:

- Open Science: Open Research Data
- NIH: New Data Management and Sharing Policy
- Ethics and responsibility in Open Science
- How to finance your OA publication
- How to comply with SNSF Open Access and Open Research Data requirements

Image: © UB UniBE

Transferable Skills Program for (Post)Docs

- Introduction to research data management (ECTS 1)

Bern Data Talks
Preparing Data for Publication

21 NOVEMBER

17:15 - 18:00 UHR

EVENT
OPEN SCIENCE

Bern Data Talks - Preparing Data for Publication

- Prof. Dr. Tobias Hodel
University of Bern, Digital Humanities

- Prof. Dr. Stefan Brönnimann
University of Bern, Institute of Geography

- Thilo Hirsch
Bern University of Applied Sciences, Bern University of the Arts

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- Funder's news
- Training sessions and courses
- Developments in Open Access and Research Data

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Research Data Management Support
Survey

We would like to learn about your wishes and needs in order to optimize our training and consulting services.
Thank you for participating in this short and anonymous survey!

t1p.de/RDMsurvey

Contact

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Research Data Management Support

Domain: Medicine, Vetsuisse, Insel Hospital