

June 10, 2021

#### **Moderator:**

**Jackie Bendall,** Director, Contracts & Grants Administration, COGR

#### **Panelists:**

**Sandi Caldrone,** Data Repository Outreach Specialist, Purdue University

**Gregory Farber,** Director, Office of Technology, Development and Coordination, National Institute of Mental Health, NIH

Lyric Jorgenson, Acting Assoc. Director for Science Policy and Acting Director of the Office of Science Policy, NIH





# NIH Policy for Data Management & Sharing

Council on Government Relations

Data Management and Sharing Working Group

June 10, 2021

#### Lyric Jorgenson, PhD

Acting NIH Associate Director for Science Policy Acting Director of the Office of Science Policy

sciencepolicy@mail.nih.gov



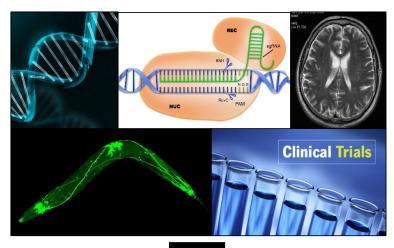
- Submission of Data Management & Sharing Plan for all NIH-funded research (how/where/when)
- Compliance with the ICO-approved Plan (may affect future funding)
- Effective January 25, 2023 (replaces 2003 Data Sharing Policy)
- Supplemental info available to assist
- Aims to foster data stewardship

## **Why Share Data**

Sparks New Research
Collaborations

Enhances Rigorous Study Design

Makes High-Value Datasets Available



Enables Unique Data
Combinations

Facilitates
Study Validation

Stimulates New Research Inquiries



#### **Maximizes Data Collection**

(reduces redundancy/maximizes participant contributions)

#### **Fosters Stewardship**

(provides transparency/accountability for taxpayer funds)

#### **Accelerates the Research Enterprise**

(for all the reasons stated above!)

## **An Iterative Policy Development Process**

- Sought public comment repeatedly
- Tribal Consultation<sup>3</sup>

\*Details provided in "NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing"

 Intersection with other government agencies & Secretary's Advisory Committee for Human Research Protections

2019: Solicited
MORE Community
Input
RFC: Draft Policy and

RFC: Draft Policy and Guidance

2016: Solicited Community Input

RFI: Strategies on Data Management, Sharing, and Citation 2018: Solicited
More Community
Input

RFI: Proposed Provisions for a Draft Policy

2023: Policy Effective Date

2020: Policy Release Date

## The Devil is in the Details...

- Scope: All NIH-supported research generating <u>scientific data</u>
  - 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 lab notebooks, preliminary analyses, peer reviews, physical objects

#### • Timelines:

- For when to share data, no later than <u>publication</u>
   or <u>end of award</u> (for unpublished data)
- For how long to share data, consider relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames



'Which brings us to my next point.'

## **Additional Expectations for Plans**

#### SHARING SHOULD BE ...

#### The default practice

- All scientific data should be managed; not all scientific data must be shared
- Maximize appropriate data sharing;
   Plans may justify exceptions (i.e., ethical, legal, technical factors)

#### Responsibly implemented

- · Plans should outline protection of privacy, rights, and confidentiality
- Existing laws, regulations, and policies continue to apply

#### Prospectively planned for

- During informed consent, including communicating how data will be used and shared
- Data submission, including whether access to data, even if de-identified, should be controlled

## Plan Submission and Review

#### **Extramural Grant Awards\***

#### **Plan Submission**

With application for funding in Budget
Justification section

#### **Plan Assessment**

Peer reviewers only comment on (not score) budget

NIH program staff assess Plans

Plans can be updated

#### **Plan Compliance**

Incorporated into Terms and Conditions

Monitored at regular reporting intervals – mechanisms and tools to support oversight under development

Compliance may factor into future funding decisions

<sup>\*</sup>Analogous requirements for contracts, OTAs, IRP



## Supplemental Info to the Policy: Allowable Costs

- Reasonable costs allowed in budget requests
  - Curating data/developing supporting documentation
  - Preserving/sharing data through repositories
  - Local data management considerations
- NOT considered data sharing 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)

# Supplemental Info to the Policy: Repository Selection

- Encourages use of established repositories
- Helps investigators identify appropriate data repositories
  - E.g., use of persistent unique identifiers, attached metadata, facilitates quality assurance
  - Refers to list of <u>NIH-supported Data</u> <u>Repositories</u>
- NIH ICs may designate specific data repository(ies)



## **Resources for Implementation**

#### What's Next?

- Engage in outreach to develop additional supplemental information (including tribal-specific considerations)
- Develop tools for estimating data management and sharing costs (informed by the <u>2020 NASEM report on forecasting costs</u> & <u>April 2021</u> NASEM workshop on the culture of data management & sharing)
- Develop approaches for incentivizing good data sharing practices
- Clarify interactions with other NIH-wide (e.g., GDS Policy) and ICO-specific data sharing policies
- Develop FAQs and other resources to aid policy implementation

**2-year implementation window!** 

## **Resources for Implementation**

#### What's Next?

- **Engage in outreach** to develop additional supplemental information (including tribal-specific considerations)
- **Develop tools** for estimating data management and sharing costs (informed by the 2020 NACLA report on foreclisting costs & April 2021 NASEM works to britte dilt in Galangia entire sharing)
- Develop approaches for incentivizing good data sharing practices
  Clarify interaction with partition See B Policy) and ICOspecific data sharing policies
- **Develop FAQs and other resources** to aid policy implementation

**~2-year implementation window!** 

# The NIMH Data Archive Cost Estimation Tool and Data Sharing Expectations

**Greg Farber** 

Director, Office of Technology Development and Coordination, National Institute of Mental Health

June 2021





#### **Overview**

- NIMH Data Archive
- NIMH Data Harmonization Activities
- NIMH and NIAAA Data Sharing Expectations
- Cost Estimation Tool





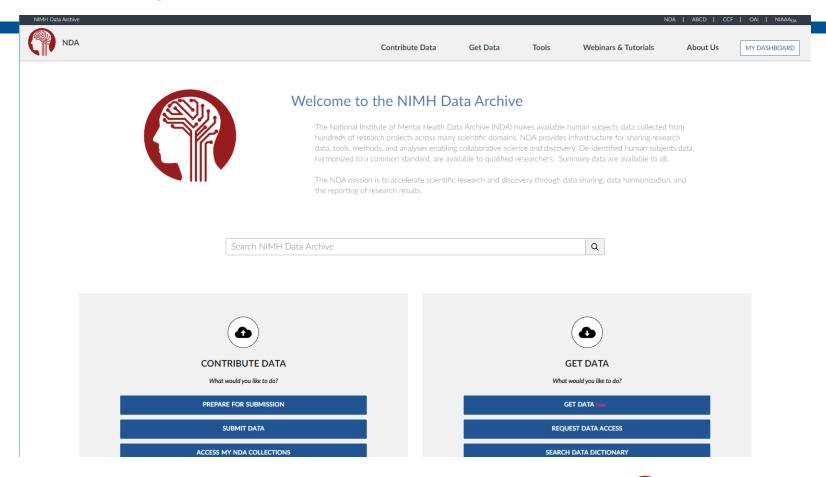
#### **NIMH Data Archive**

- NDA is a cloud-based data commons that (mostly) holds research data from human subjects
  - Federal data repository (<a href="https://nda.nih.gov">https://nda.nih.gov</a>)
  - Originally contained data from human subjects related to neuroscience research. We are now holding non-neuroscience data as a service to other NIH ICs. Most subjects have consented to broad data sharing.
  - Data are available to the research community through a not too difficult application process, although some data are freely available.
  - Summary data are available to everyone with a browser.
  - Web services are available for search, data dictionary, validation & submission, GUID generation (<a href="https://nda.nih.gov/tools/apis.html">https://nda.nih.gov/tools/apis.html</a>)
- Started in late 2006, and first data was received in 2008
- The data types include demographic data, clinical assessments, imaging data, and –omics data. There are no formal limits to the types of data that can be stored in NDA.





## **NDA Home Page**

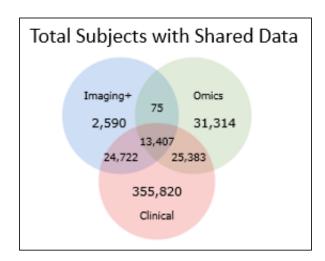






#### **NIMH Current Status**

- 500,000+ research participants in shared data
- 3,500+ approved users (access lapses after 12 months)
- 3.5 PB of imaging and omics data stored in the Amazon cloud
- 1,500+ collections (a data set associated with a grant award)
- 225+ studies (a data set associated with a publication and assigned a doi)
- 2,500+ different instruments in the NDA data dictionary.
- 300,000+ partially harmonized data elements

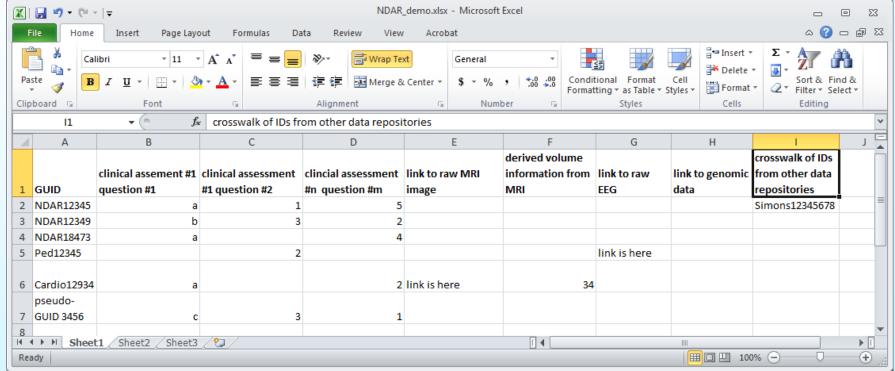






## NDA Structure – Rows and Columns are the Building Blocks

 It is best to think of NDA as a large (~300,000 data elements by ~530,000 people), sparse, two dimensional matrix.





					Data Element 9
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

Data from one collection







		Data Element	Data Element	Data	Data Element	Data Element	Data	Data Element	Data Element
GUIDS	1	2	3	4	5	6	7	8	9
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

Data from two collections, no common subjects







GUIDS	Data Element 2				Data Element 9
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

Data from two collections, no common subjects, but there are common data elements. Harmonization can be "interesting".







									Data
GUIDS	Element 1	Element 2	Element 3	Element 4	Element 5	Element 6	Element 7	Element 8	Element 9
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

Data from two collections and there are two common subjects (7 and 8). Potentially there are issues here related to the owners of the two collections accessing other data about a single research participant.







				Data		Data	Data		Data
	Element								
GUIDS	1	2	3	4	5	6	7	8	9
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

Data from one collection with additional derived information from a study added







## **NIMH Common Data Element Expectations**

- NIMH in consultation with the Wellcome Trust and other funders of mental health research, has identified a minimal list of data collection instruments that we will use to harmonize mental health data collection.
- All awards made after May 2021 will be expected to collect data using the common data elements.
- The goal of this effort is to facilitation harmonization of data collected in many different laboratories. Given the heterogeneity in our diagnostic categories, a common measurement framework is essential to make progress.
- A number of other mental health funders are imposing similar expectations on their awardees, and several journals are considering joining this effort.
- Full Details can be found at NOT-MH-20-067.





## One Repository for NIAAA and NIMH Data

#### NOT-MH-19-033 and NOT-AA-19-020

- Expects all applications to include a resource sharing plan that covers:
  - A summary of the data to be shared
  - The data standards/data dictionaries that will be used to collect the data
  - The schedule to validate the data against the standards/data dictionaries (NDA provides a useful validation tool that can be run without submitting data)
- Awardees will submit data (not share it with the research community) every 6
  months to allow the awardee to perform validation checks close to the time
  when data were measured.
  - Data are shared after original project ends or upon publication
- Reminds the research community that they need to fill out section C.5 "Other Products and Resource Sharing" in the RPPR.
- Enumerates key expectations in NDA Data Sharing Terms and Conditions, which are included in the Notice of Award
- Establishes NDA as the NIMH and NIAAA-designated human genomics data repository



#### **Post Award Expectations**

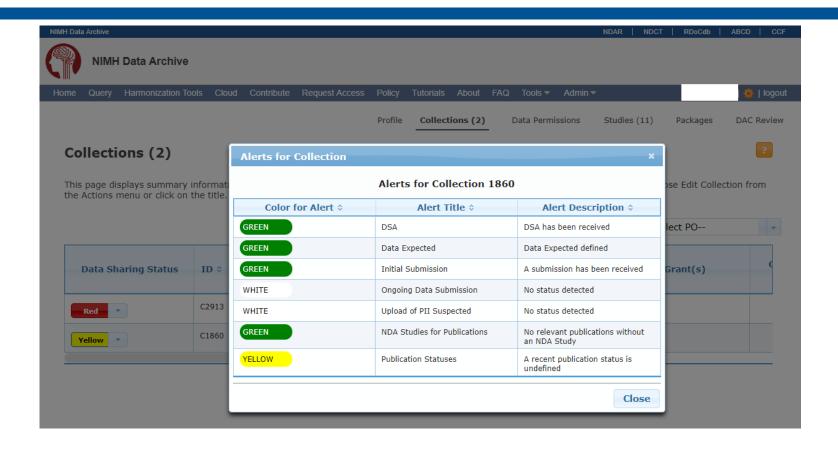
- 1) Pls can't ignore the NDA Getting Started with Data Sharing notifications that they receive shortly after their Notice of Award has been released. All new awardees get an e-mail letting them know that they have to:
  - Submit a data submission agreement
  - Define the data structures they are going to use to submit data
  - Suggesting (but not requiring) that they use the NDA Global Unique Identifier (GUID) to identify subjects
  - Craft informed consent language that is consistent with sharing broad data sharing with qualified researchers (similar to general research use for genomic data)
- 2) If an institutional official receives a copy of a letter after the initial award, it means that there is a problem with data sharing that is being escalated.







## **Real Time Metrics for Grants Compliance**







## **Costs for Data Sharing**

It is helpful to break down the costs related to data management and sharing into three phases.

- 1) Local data management that is needed as experiments are being conducted and the data are being analyzed.
  - Storage costs in the laboratory
  - Compute costs for the project
  - The infrastructure (hardware and software) may be laboratory based, department based, or institution based.
  - Charges to NIH can either be direct costs associated with the grant or as part of the institutional Facilities and Administrative costs.
  - It would be really interesting for NIH and for academic institutions to look at annual expenses for local data infrastructures as well as the (lack of) security for that infrastructure in comparison to what could be provided through commercial cloud based infrastructure.





## **Costs for Data Sharing**

It is helpful to break down the costs related to data management and sharing into three phases.

- 2) Data curation and documentation
  - These costs often only become apparent when a laboratory sends data to a
    particular data archive, when data are being analyzed, or when a paper is
    submitted to a journal.
  - There are useful technologies (such as Jupyter notebooks) to keep track of exactly how data were collected (and analyzed).
  - It is still true in many laboratories that the metadata containing experimental details aren't recorded appropriately because:
    - Experimental parameters don't change day to day in the laboratory (they think)
    - Lack of agreed upon standards in a community to describe a particular experiment
    - Data archives really help the community understand the magnitude of these problems and help the community reach consensus on the metadata that needs to be recorded.





## **Costs for Data Sharing**

It is helpful to break down the costs related to data management and sharing into three phases.

- 3) Data repository charges
  - Some repositories have a single up-front charge
  - Some repositories have baseline funding from an organization (institutional library, funding agency, non-profit) with deep pockets that makes the repository available to a research community
  - A few repositories allow free access to the research community (who donate most of the data) but charge industry to access the same data. This model is only open when the data are of clear value to an industry and the repository is mature enough to demonstrate that value.



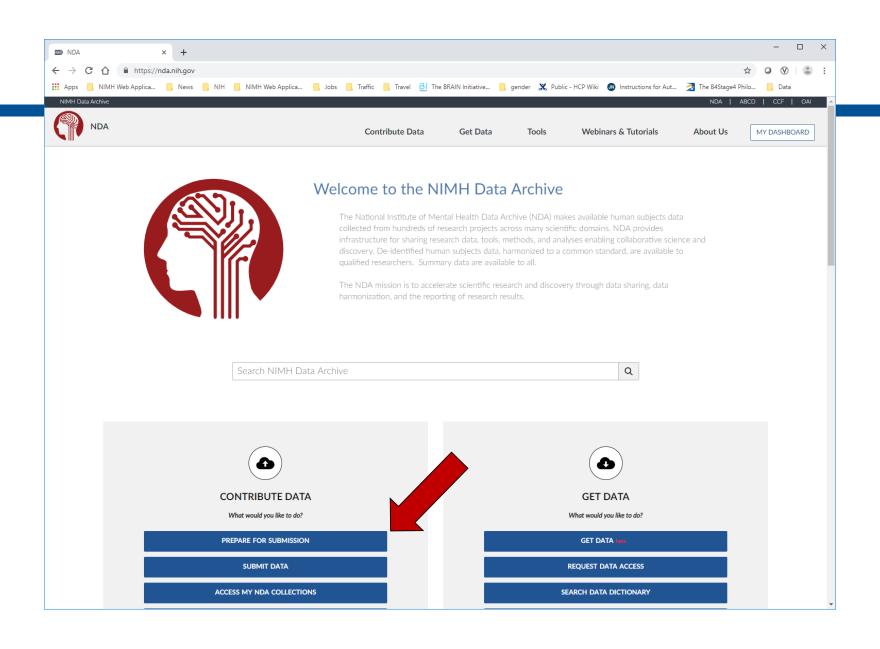


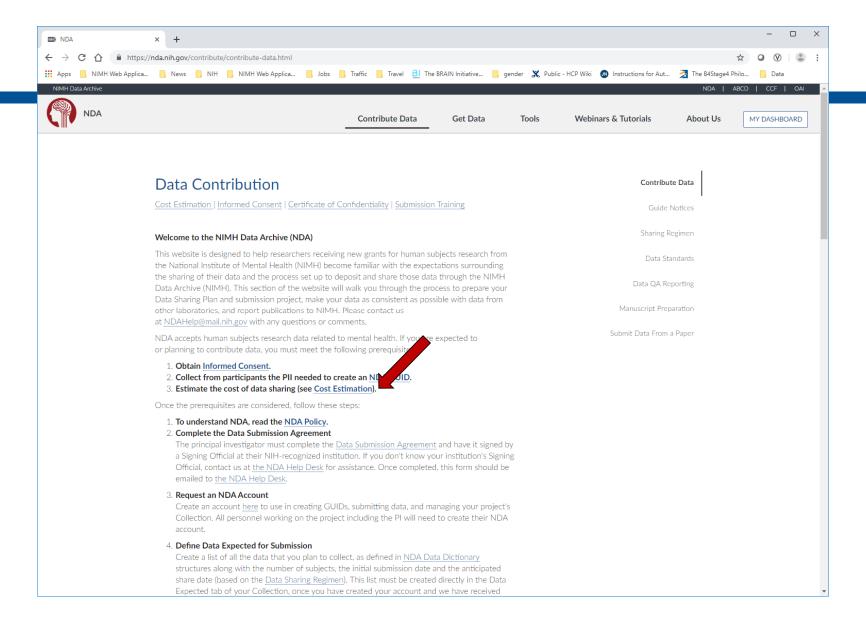
## NIMH Data Archive (NDA) Cost Estimator

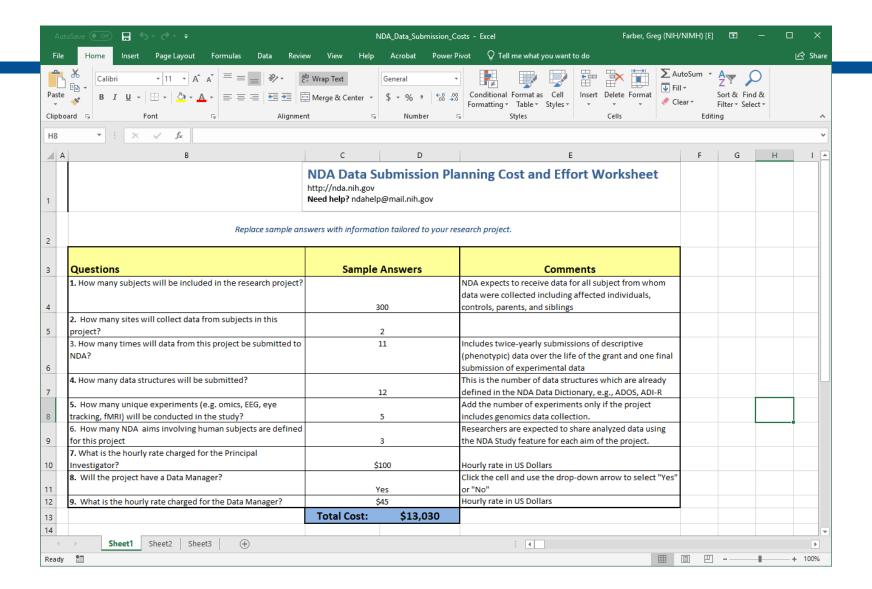
- This tool helps researchers estimate how much staff time and effort will be required to work with NDA staff to deposit their data (phase 2 in the previous slides).
- The tool does not currently help researchers think about the other costs associated with sharing data.

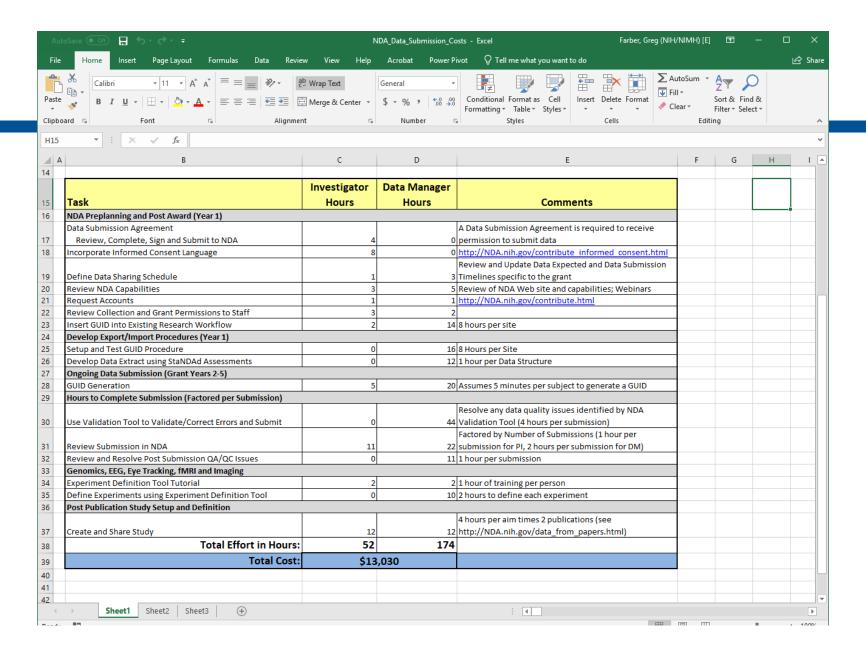












#### What isn't Included in the Estimator

- Time required to define new data dictionaries. This can be significant, but only needs to be done once. Defining a data dictionary involves significant work by NDA staff as well as the group depositing the new data dictionary.
- The cost estimates are for the researcher and do not include NDA staff effort. NDA pays those costs.





#### **NIH Executive Vacancy**

- Deputy Director, Office of Extramural Research
- Deputy to Mike Lauer
- The OER Deputy Director's role integrates a broad array of senior-level science administration, extramural research policy, and business functions of the OER, ensuring they are executed and supported through leadership of a sound strategic planning, business management, and communications.
- https://hr.nih.gov/jobs/executives
- Applications due June 30, 2021



# Purdue University Research Repository

research data management for Purdue

Sandi Caldrone
Data Repository Outreach
Specialist
scaldron@purdue.edu

## Purdue University

research culture deeply rooted in the midwest and focused on the persistent pursuit of the next giant leap

#### **History and Context**

- R1 land grant university in Indiana
- ranked #5 most innovative university in U,S. (US News and World Report 2021)
- ~45,000 students
- ~2,000 tenure track faculty

#### Research at Purdue

- 135+ research centers and institutes
- Discovery Park multidisciplinary groups and outside partners
- \$454 million in sponsored research (2018)

#### Our COVID year

- went virtual in March 2020
- 95% of research labs were back online by July 1, 2020
- 70% of employees working partially or fully remotely
- over 50% of students attended classes in person on a dedensified campus

#### CENTRALIZED RESOURCES FOR DATA-DRIVEN RESEARCH AT PURDUE

























More information: email rcac-help@purdue.edu or contact Preston Smith, director of research services and support, psmith@purdue.edu or 765-494-9729 EA/EOU



## PURR

Purdue

University

Research

Repository

founded 2011

#### Research Data Management for Purdue

The Purdue University Research Repository (PURR) provides an online, collaborative working space and data-sharing platform to support Purdue researchers and their collaborators.

Full spectrum support from planning to publication



PLAN

Meet funders' data requirements with our



COLLABORATE

Your own file sharing space and update feed



**PUBLISH** 

Publish your data, get a DO

## PURR Origins

key institutional partners and motivations for founding PURR in 2011

#### Libraries

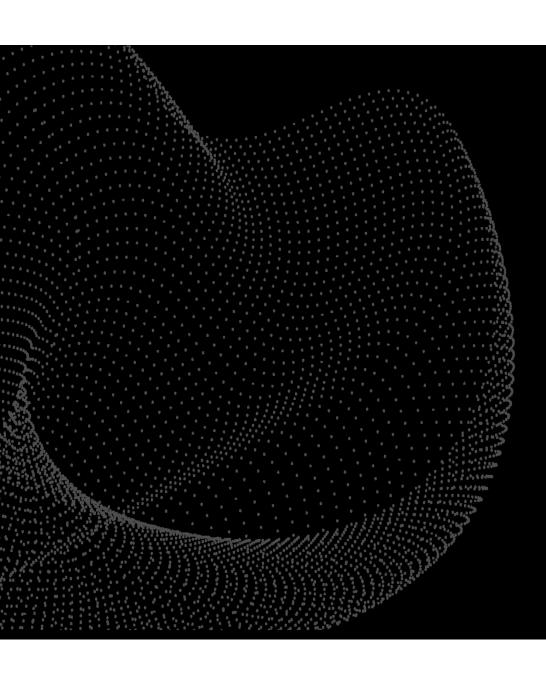
long-term stewardship and access to data as a part of the scholarly record, library and information science expertise

#### Research Office

more competitive proposals and compliance with funder requirements

#### IT

research computing expertise, e.g., storage engineering, HPC



# How PURR works for researchers

## The Research Data Lifecyle in PURR

**PLAN** 

expertise

review DMP best practices, and consult with experts

COLLABORATE

private space

use secure, online storage space to share files with collaborators

**PUBLISH** 

public space

meet funder requirements for open access and receive a DOI

ARCHIVE

preservation

PURR partners with the MetaArchive preservation network

**IMPACT** 

tracking

automatic counts of views and downloads, plus citation tracking



Home

Datasets

**Projects** 

Help

Michael Witt ▼

#### Michael Witt: Dashboard

Dashboard

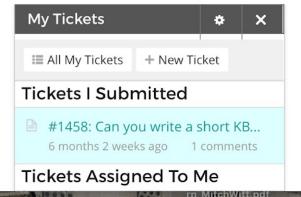
My Groups My Projects

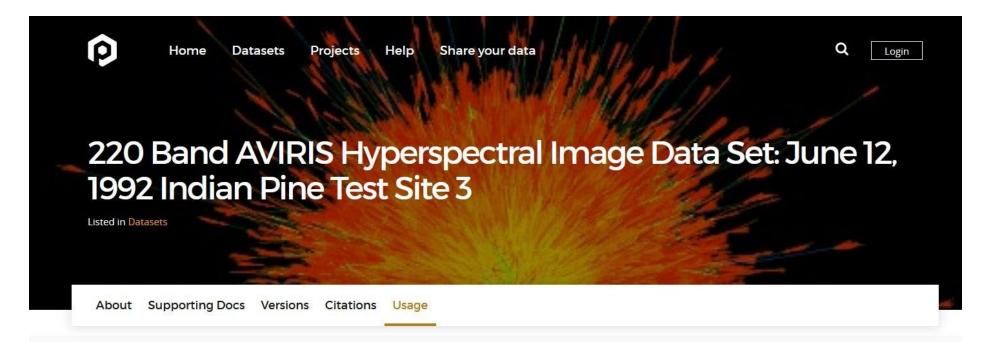
My Impact

Add Modules









By Marion F. Baumgardner<sup>1</sup>, <u>Larry L. Biehl</u><sup>1</sup>, David A. Landgrebe<sup>1</sup>

Purdue University

This publication includes the AVIRIS hyperspectral image data for Indian Pine Test Site 3 along with the reference data for this site including observation notes and photos for the fields within the approximately 2 mile by 2 mile area.

Download Bundle (1 GB)

Version **1.0** - published on 30 Sep 2015 doi:10.4231/R7RX991C - cite this

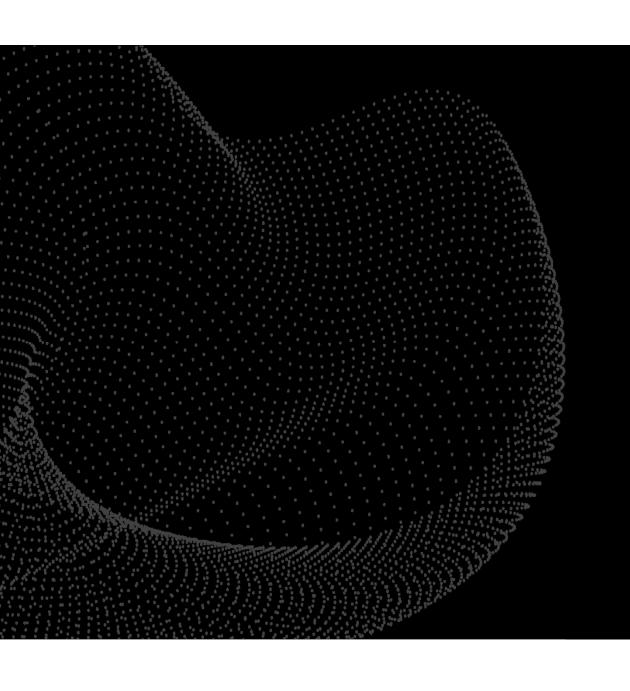
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101 citation(s)

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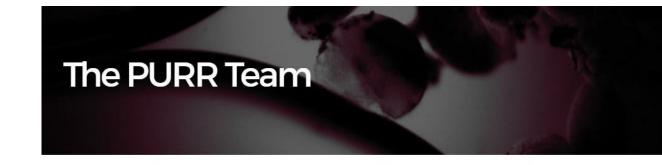


How PURR works behind the scenes

# Daily Operations

#### LIBRARIES RESEARCH DATA

- data curation
- user support
- development and maintenance custom functionality
- education and outreach



#### **PURR Staff**



Sandi Caldrone
Data Repository
Outreach Specialist
Purdue University
Libraries



Michael Witt
PURR Director
Associate Professor
Purdue University
Libraries



Jerry Kuang
Digital Library
Software Developer
Purdue University
Libraries



Standa Pejša Data Curator Purdue University Libraries

### **Tech Partners**

supporting PURR staff as we support users

**HUBzero** 

open source platform for science gateways providing core functionality, technical support Campus and Libraries IT

project file storage infrastructure, and some hosting for custom webpages

MetaArchive

digital preservation cooperative using the LOCKSS platform

#### Collaboration

#### with the research office

Interaction and information sharing between PURR and the research office are built into both automatic processes and human-driven workflows

#### **Proposal Writing**

 PURR provides DMP training, boilerplate language, and templates

#### **Grant Award**

- Research office alerts PURR when a grant that mentioned PURR in the DMP is approved
- PURR and liaison librarian reach out to PI

#### **Project Creation**

- PURR project creation process has guardrails for sensitive data
- · PURR sends automatic alerts to research office
- Grant funded projects receive more storage
- Research office verifies grant info triggering the storage upgrade

## How do our partnerships add up?

PURR BY THE NUMBERS

457

676

4,610

1,241

DATA MGMT PLANS **GRANT AWARDS** 

REGISTERED RESEARCHERS PUBLISHED DATASETS



purr.purdue.edu purr@purdue.edu Q & A



## Next Session: Discussion Hour: Costing Hot Topics Discussion @ 5 pm EDT

Visit us at www.cogr.edu

## Thank You



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