

Who Owns Your Data?

Ann K. Adams. J.D.
Associate Vice President for Research
Northwestern University

Answer:
Your Institution
But Why?

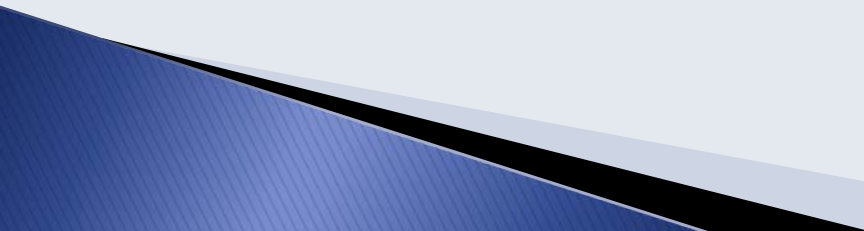
Basics for Discussion

Context: Federally sponsored research

Keep in mind universities likely apply the same policies/procedures regardless of funding

Definition: “Research Data”

There is no one standard definition of “research data,” but OMB provides a general framework; must consider specific, applicable federal regulations and sponsor requirements, institutional policy



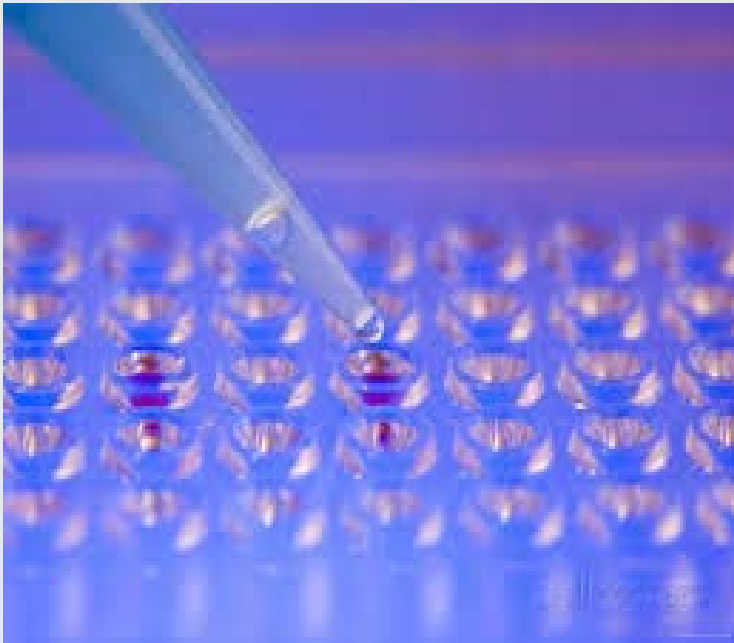
Definition of “Research Data” from the Uniform Guidance (2 CFR 200.315)

Recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following:

- Preliminary analyses
- Drafts of scientific papers
- Plan for future research
- Peer reviews
- Communications with colleagues



“Research Data” Also Excludes:



Physical objects (*e.g.*,
laboratory samples)

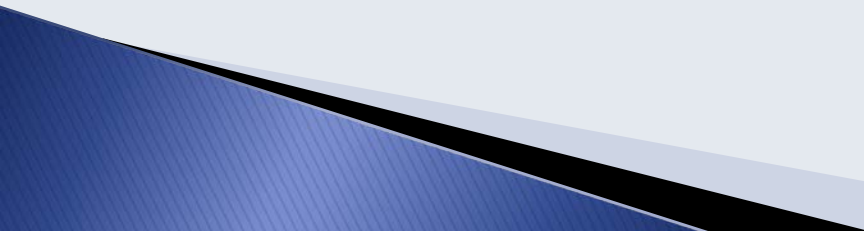
Trade secrets, commercial
information, materials
necessary to be held confidential

Personnel and medical information
and similar information

*Assume institutional ownership
and/or control over these items as
well*

Why Does the Institution Assert Ownership over Research Data?

Several reasons, including:

- To satisfy regulatory and oversight requirements as the recipient of federal funds
 - To ensure results can be shared in order to advance research and educational mission
 - To protect confidentiality for human research participants
- 

As recipients of federal (*i.e.*, taxpayer) funding, research institutions are under scrutiny and have numerous obligations to protect those funds

WASHINGTON, DC

★★★★★ THE WHITE HOUSE WASHINGTON ★★★★★

APRIL, 2014

YOUR FEDERAL TAXPAYER RECEIPT

UNDERSTAND HOW AND WHERE YOUR TAX DOLLARS ARE BEING SPENT

Enter your 2013 payments below or select an estimate from the drop down menu

Social Security Tax	Medicare Tax	Income Tax	CALCULATE YOUR RECEIPT
Enter Dollar Amount	Enter Dollar Amount	Enter Dollar Amount	

Don't have your tax information handy?

Select an Income Estimate ▼



NSF OIG Auditors Question Salaries, Other Costs Claimed by UWM

Former Northwestern Physician To Pay The United States \$475,000 To Settle Cancer Research Grant Fraud Claims

Emory University to Pay \$1.5 Million To Settle False Claims Act Investigation

Former Harvard professor Marc Hauser fabricated, manipulated data, US says


The University of South Florida Did Not Always Claim Costs in Accordance With Federal Regulations

In an Unusual Case, a Scientist is Charged With Falsifying HIV Data

Obligations of Federal Grantees

General Record Retention Requirement

Financial records, supporting documents, statistical records and “all other... records pertinent to a Federal award” must be kept for 3 years from the date the final expenditure report is submitted (2 CFR 200.333)



Obligations of Federal Grantees


Audits and Investigations

“The Federal awarding agency, Inspector General, the Comptrollers of the United States... must have the right of access to any documents, papers or other records... pertinent to the Federal award” (2 CFR 200.336(a))

Obligations of Federal Grantees

Research Misconduct Allegations

“[T]ake all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceedings, inventory the records and evidence, and sequester them in a secure manner” (42 CFR 93.305(a))



Obligations of Federal Grantees

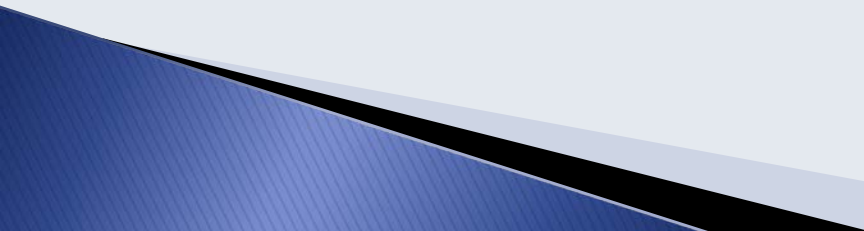
FOIA

In response to a FOIA request for research data relating to published research findings used to develop agency action, institution “must provide, within a reasonable time, the research data” (2 CFR 220. 315(e)(1))

Obligations of Federal Grantees

Human Subject Research


“[R]ecords relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by [federal authorities] at reasonable times and in a reasonable manner.” (45 CFR 46.115(d))




Other Grantee Obligations

- Litigation: Record retention holds imposed when litigation threatened or commenced to comply with procedural rules; also aid in litigation defense/prosecution
- Patent Prosecution: Reliance on primary research data (*e.g.*, lab notebooks) during patent prosecution to establish invention date, support patent application, etc.

Researchers Have Critical Roles as Data Stewards

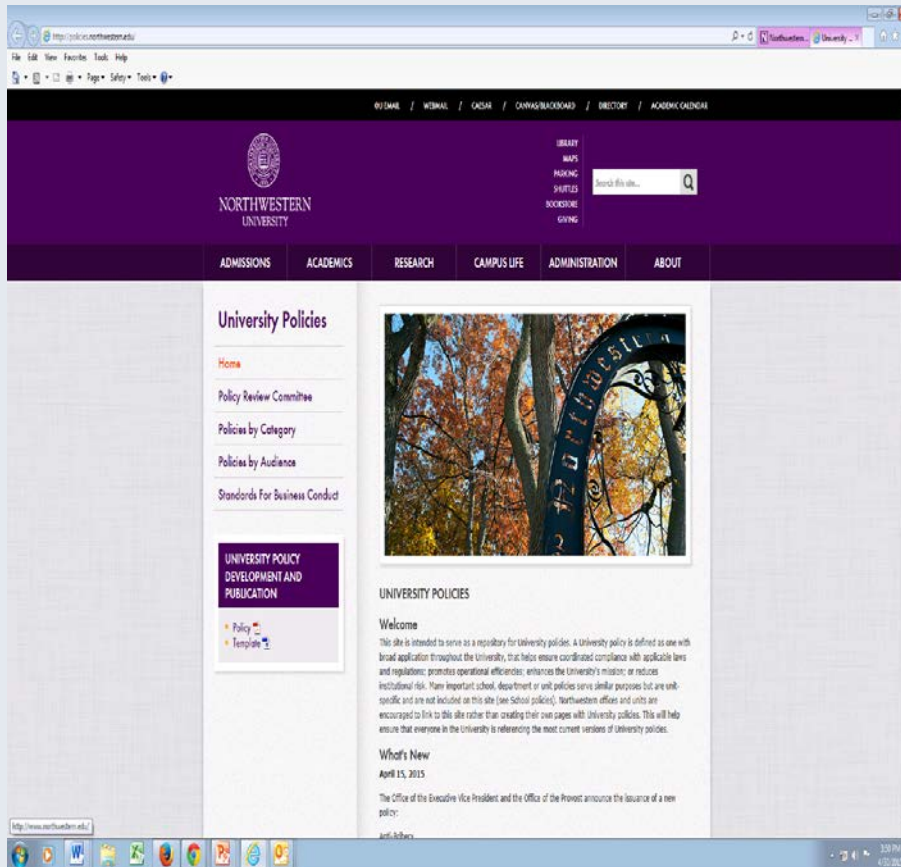
- Generally retain possession of data
 - Obligated to comply with federal and institutional retention requirements
 - Provide access to data as needed to institutional and/or regulatory officials
- 

How Problems Arise

- ✓ PI, postdoc or student leaves an institution and takes all the research data
 - ✓ Research misconduct allegation surfaces and institution cannot access the research data related to the allegations
 - ✓ Prime awardee sues a sub-awardee for non-performance and sub-awardee no longer has research data to demonstrate effort/results
 - ✓ Oversight agency conducts audit or investigation and research records are not available for review
- 

Steps to Take

#1 – Review Your Institutional Policies



Does your institution have a policy on data ownership?

Does your institution have a policy on record retention?

Sample Policies

Northwestern

Research Data: Ownership, Retention and Access

http://www.research.northwestern.edu/policies/documents/research_data.pdf

Retention of University Records

http://policies.northwestern.edu/docs/Retention_of_University_Records_030410.pdf

Stanford

Retention of and Access to Research Data

<https://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data>

#2 – Develop SOP for When Individuals Leave the Institution


For example, Northwestern policy allows PIs to take original data with:

- 1) Prior written approval of VPR
- 2) Written assurance from new institution that it will:
 - accept custodial responsibility
 - provide access if needed
- 3) Compliance with relevant confidentiality restrictions

Northwestern PI Check-Out List

Tip sheet for departments to help ensure proper steps are taken to address award close-out, data transfer, etc.

<http://www.research.northwestern.edu/ori/responsibleresearch/practical-resources.html>



#3 – Educate Yourself

ACCESS TO, SHARING AND
RETENTION OF RESEARCH DATA:

RIGHTS & RESPONSIBILITIES

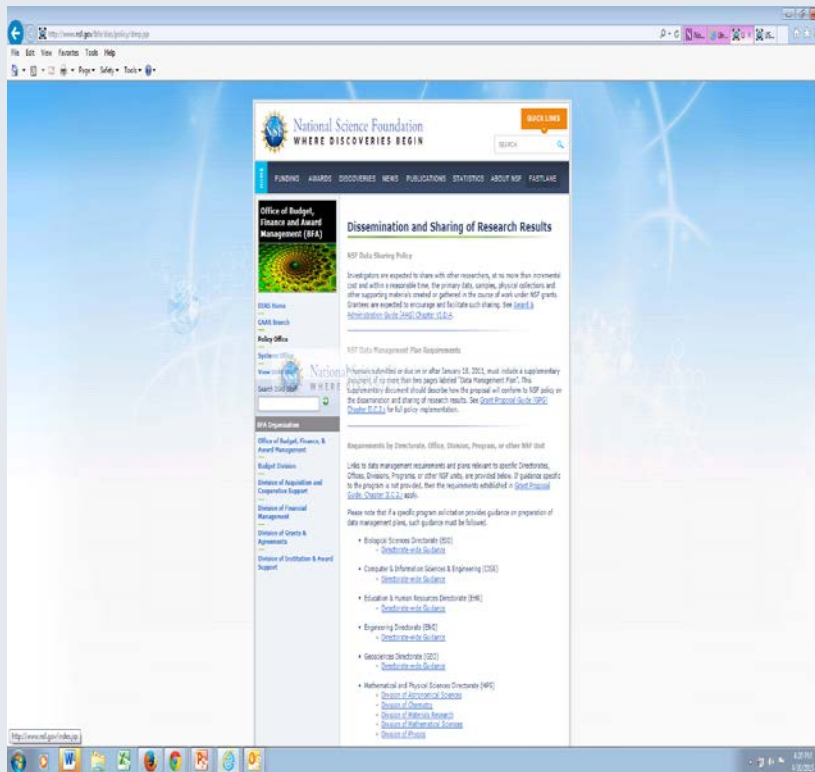
COUNCIL ON GOVERNMENTAL RELATIONS
OCTOBER 2011

4 Be Aware of Federal Government Public Access Policies



OSTP's "*Increasing Access to the Results of Federally Funded Research*," to increase public access to scientific publications and digital scientific data resulting from federally-funded research, consistent with long-standing federal policies encouraging data sharing and communication of research results

Today's Data, Tomorrow's Discoveries: Increasing Access to the Results of Research Funded by the National Science Foundation



“Investigators are expected to share with other researchers . . . the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing.”

https://www.nsf.gov/news/special_reports/public_access/

DoD Draft Data Access Plan



“[D]igitally formatted scientific data resulting from unclassified, publicly releasable research supported wholly or in part by DoD funding should be stored and publicly accessible to search, retrieve, and analyze to the extent feasible and consistent with applicable law and policy; agency mission; resource constraints; and U.S. national, homeland and economic security.”

http://www.dtic.mil/dtic/pdf/DoD_PublicAccessPlan_Feb2015.pdf

QUESTIONS?