



RTC/CEC Monthly Conference Call

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Data Sharing Policies and Implementation

Facilitators: Greg Patts, BU RTC and Meredith Golden, Columbia RTC

Federal Data Sharing Requirement

OMB Circular A-110 (11/19/93, amended 9/30/99)

- ❖ Fed Gov't has right to obtain, reproduce, publish, or otherwise use data first produced under a federal grant
- ❖ Fed Gov't has right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes

Shelby Amendment (4/17/00)

- ❖ For institutes of higher education - applies only to data that is 1st produced in a project supported at least in part by fed funds and cited publicly and officially by a Fed agency such as in support of regs & administrative orders
- ❖ All data generated under an award is available to the public via FOIA

Agenda

- Overview of NIH Data Sharing Policy
- Relevance to the P42 RFA
- Discussion and potential action items

Data Sharing

NIH...believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals.

*Final NIH Statement on Sharing Research Data
Notice NOT-OD-03-032, 26 February 2003*

More on Data Sharing

Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data.

*Final NIH Statement on Sharing Research Data
Notice NOT-OD-03-032, 26 February 2003*

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH Data Sharing Policy

More specifically...

- ❖ Applicable to grant applications submitted on or after 10/1/03 for funds of \$500k or more in direct costs in any single year of the project period or as a special requirement of an FOA
- ❖ Data sharing plan expected and included in application and will be a condition of the award
- ❖ NIH will communicate its expectations with respect to data sharing and facilitate and encourage communication among the parties involved to promote sharing

NIH Data Sharing Methods

Data sharing can be accomplished through:

- ❖ ***Publishing**** - articles in scientific publications
- ❖ ***Researcher's efforts*** - investigator responds directly to data requests (either via CD-ROM or posting on a web site)
- ❖ ***Data enclave*** - controlled, secure environment in which eligible researchers can perform analyses using the data resources
- ❖ ***Data archive*** - place where machine-readable data are acquired, manipulated, documented and distributed
- ❖ ***Mixed mode*** - more than one version of a dataset, each providing a different level of access

*Some NIH documents state that only the sharing of final data sets meets the requirements of data sharing.

NIH Data Sharing Policy: What You
Need to Know for Successful Funding
[http://grants.nih.gov/grants/policy/data_sharing/
ata_sharing_brochure.pdf](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_brochure.pdf)

Data Sharing Agreements

- Purpose: put limitations on **who** can use your data and **how** your data can be used.
- For example, a recipient of data may agree to:
 - protect the privacy of subjects;
 - ensure data security at the recipient site;
 - not transfer the data to other users;
 - use the data only for research purposes;
 - have all research using the data approved by an IRB.
- Penalties for violating terms of the agreement are generally specified in these agreements.

NIH Data Sharing Plan

A brief paragraph after the research plan that *may* include the following:

- ❖ ***Schedule*** for data sharing (timely, no later than the acceptance for publication of the main findings from the final dataset; large studies can release data as it becomes available or are published)
- ❖ ***Format of final dataset***
- ❖ ***Documentation to be provided***- to prevent misuse, misinterpretation, or confusion (metadata)
- ❖ ***Analytical tools to be provided, if any***
- ❖ ***Need for data sharing agreement***- restricting users and/or use for research purposes only, to protect privacy of human subjects and proprietary information
- ❖ ***Restrictions on data due to local, State or Federal statutes***
- ❖ ***Mode of data sharing***- levels of access

Applicants may **request funds** in budget proposal for data sharing and archiving.

Data Sharing and Scoring

- ❖ Reviewers do not consider data sharing plan in determining scientific merit or priority score for applications

“Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).” (New RFA)

- ❖ Program staff responsible for assessing the appropriateness and adequacy of the data sharing plan
- ❖ Program staff concerns must be resolved before award made
- ❖ Program staff responsible for overseeing the data sharing policy

SRP Data Sharing in new P42 RFA

- ❖ Plan for Sharing Data. A data-sharing plan should be developed for the overall Center, if appropriate. For those including a data-sharing plan, ***the precise content will vary*** depending on the data being collected and how the investigator(s) is planning to share the data...
- ❖ ***Reviewers will comment*** on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).
- ❖ RTC Technology Transfer: ...each Center identifies opportunities and delineates mechanisms for the transfer of biomedical and non-biomedical technologies generated by the grantee into the hands of an end-user. This may be accomplished through ***...creating web-accessible data sharing systems to host information that may improve upon current risk assessments...***

NIH Online Data Sharing Resources

http://grants.nih.gov/grants/policy/data_sharing/

- ❖ Final NIH Statement on Sharing Research Data
- ❖ NIH Data Sharing Policy and Implementation Guidance
- ❖ Data Sharing Workbook
- ❖ NIH Data Sharing Brochure: *What you need to know for successful funding*
- ❖ Frequently Asked Questions about Data Sharing
- ❖ Many other data sharing documents and resources

Discussion

- ❖ Questions for NIEHS staff? Clarification of policy's implementation for the SRP?
- ❖ SRP experiences with data sharing?
- ❖ Unique issues when dealing with Tribal and international partners?
- ❖ Potential value of data sharing?
- ❖ Potential costs of data sharing?
- ❖ Disincentives for data sharing?
- ❖ Incentives for data sharing?
- ❖ Other ????

Possible Action Items

- ❖ Request NIEHS clarification of reasonable and appropriate data sharing plans
- ❖ Develop comprehensive list of currently shared SRP datasets and place list on SRP website
- ❖ Survey SRP PIs to determine obstacles/conflicts concerning data sharing
- ❖ Recommend to SRP potential incentives to encourage SRP centers to share data (e.g., add data sharing section to annual update and/or annual progress report)
- ❖ Encourage written statement of support by SRP center directors to promote data sharing
- ❖ Organize steering committee to advise on future data webinar topics for discussion
- ❖ Other???

Next steps?