

NIH Regional Seminar on Program Funding
and Grants Administration – Salt Lake
City, Utah, March 5-7, 2007



NIH Data and Model Organism Sharing Policies

*J.P. Kim, J.D., M.B.A., M.Sc., M.A.L.S.
Director & Policy Officer,
Division of Extramural Inventions & Technology Resources (DEITR),
Office of Policy for Extramural Research Administration (OPERA),
Office of Extramural Research (OER),
National Institutes of Health (NIH),
U.S. Department of Health and Human Services (HHS)
Telephone: (301) 435-0679 / Fax: (301) 480-0272 / Email: jpkim@nih.gov
Websites: <http://inventions.nih.gov>; <http://iEdison.gov>*

- Basis of NIH Sharing -

Based on the NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it supports and conducts

So a basic precept....

The NIH expects that funded researchers will share resources, including models and data.

Selected NIH Sharing Policies

- *PHS Grants Policy Statement (GPS)*
- *NIH Guide Notices – Sharing of Unique Biological Materials (Sharing of Unique Research Resources in GPS)*
- *Biological Materials Policy - 1996*
- *NIH Intramural Research Program Guidelines for the Availability of Transgenic/Knockout Animals – 1997*
- *NIH Research Tools Policy - 1999*
– *Principles & Guidelines*
- *NIH Data Sharing Policy – 2003*
- *NIH Model Organism Sharing Policy – 2004*

PHS Grants Policy Statement

“Project directors and principal investigators are encouraged to make the results and accomplishments of their activities available to the public.”

NIH Guide Notices

Reporting & Distribution of Unique Biological Materials Produced with NIH Funding

“The purpose of this announcement is to emphasize the NIH policy that all unique biological materials developed with NIH funding be readily available to the scientific community after publication of the associated research findings or announcement at conferences. Restricted availability of these materials can impede the advancement of basic research and the delivery of medical care to the nation's sick.”

PHS Grants Policy Statement

Sharing of Unique Research Resources

"It is the policy of PHS to make available to the public the results and accomplishments of the activities that it funds. Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, when these resources are developed with PHS funds, it is incumbent upon investigators to make them readily available for research purposes to the scientific community and to publish the associated research findings."

Biological Materials Policy - 1996

May 17, 1996

<http://grants2.nih.gov/grants/guide/notice-files/not96-131.html>

This notice sets forth the National Institutes of Health (NIH) policy for allowing contractors and grantees (hereafter "Contractor") to license biological materials on which the contractor elects not to file a patent application and which are submitted to the NIH for review and possible election of government title under the Bayh-Dole Act.

**NIH Intramural Research Program
Guidelines for the Availability of
Transgenic/Knockout Animals - 1997**

Transgenic and gene "knockout" animals that have been developed using NIH intramural research funds and resources will be provided to other laboratories following publication of descriptions of the animals in the peer-reviewed literature. It is an obligation of NIH intramural scientists to make such animals widely available for research purposes. This can be achieved by making arrangements to send breeding pairs to a central repository such as the Induced Mutant Resource at the Jackson Laboratory. This would assure the availability of clean, genetically characterized animals within a year's time.

-NIH Research Tools Policy –

*“Sharing of Research Resources:
Principles and Guidelines for Recipients
of NIH Research Grants and Contracts on
Obtaining and Disseminating Biomedical
Research Resources”*

December 23, 1999

NIH Research Tools Policy

Principles and guidelines for recipients of NIH research grants and contracts for the sharing of biomedical research resources

What are research tools?

- Research tools, materials, and unique research resources are used interchangeably in the policy
- A resource with primary usefulness for scientific discovery vs. an FDA-approved product or integral component of such a product
- E.g., mabs, receptors, animal models, libraries, computer software and databases
- Broad access & availability needed
- Readily useable & distributable as a tool
- Useful lifecycle generally short
- Patented or unpatented

What is the policy?

- Principles
 - ensuring academic freedom and publication
 - minimizing administrative impediments
 - implementing Bayh-Dole Act
 - disseminating research resources
- Guidelines - Provide specific information, strategies, and model language for Recipient Institutions in obtaining and disseminating biomedical resources

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

2003 NIH Data Sharing Policy

"The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible."

NIH Policy on the Sharing of Model Organisms for Biomedical Research - May 7, 2004

"To further extant NIH resource sharing policies, all investigators submitting an NIH application or contract proposal beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR state appropriate reasons for why such sharing is restricted or not possible. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated."

Data and Model Organism Sharing Policies

Additional information for meeting expectations for sharing of resources, including data and model organisms

NIH 2004 Model Organism Sharing Policy Statement & Guidance

The NIH Model Organism Sharing Policy:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html> (07 May 2004)

NIH Model Organism Sharing Policy Information Page:
http://grants.nih.gov/grants/policy/model_organism/index.htm

Frequently Asked Questions (FAQs):
http://grants2.nih.gov/grants/policy/model_organism/model_organisms_faqs.htm

Model Organism Sharing Policy

- Covers **all** projects that produce or may produce model organisms, regardless of the amount of the budget
- Investigators submitting an NIH application (including competing renewals) are expected to include a concise plan addressing the timely distribution of organisms and resources, unless the proposed research will not generate new model organisms and related resources, OR state appropriate reasons for why such sharing is restricted or not possible.

What are “model organisms” to be shared under this policy?

- Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog.
- This only applies to non-human model organisms. Other than established cell lines, human specimens would require informed consent. This policy does not apply to human cells that are not commercially available.

What are “related resources” to be shared under this policy?

- Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. Genetically modified organisms are those in which mutations have been induced by chemicals, irradiation, transposons or transgenesis (e.g., knockouts and injection of DNA into blastocysts) or those in which spontaneous mutations have occurred.

What do “resources” include for purposes of this policy?

The term “resources” includes materials and data necessary for the production and understanding of model organisms, such as vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

What resources are not under this policy?

- Although genetic variants of viruses, bacteria, and other prokaryotic organisms should be made widely available pursuant to NIH policy, at this time NIH is not expecting the submission of a sharing plan from investigators who intend to develop non-eukaryotic organisms.

What's an adequate plan for sharing under the 2004 NIH Model Organism Policy?

Sharing plans may vary, depending on various factors, including:

- The particular resources/organisms;
- The nature of the resources that will be shared;
- The extent to which intellectual property issues may be considered in sharing, and
- The specific **approaches** and **mechanisms** for distributing the resources.

Examples of mechanisms that may be used:

- Repositories or under the researchers' own auspices
- If using a Material Transfer Agreement (MTA), terms should generally be no more restrictive than those in the Uniform Biological Material Transfer Agreement (UBMTA) (<http://www3.niaid.nih.gov/about/organization/odoffice/s/omo/otd/UBMTA.htm>), the Simple Letter Agreement (SLA) (http://www.nhlbi.nih.gov/tt/docs/sla_mta.htm), or the Material Transfer Agreement for the Transfer of Organisms (MTA-TO) (http://ttb.nci.nih.gov/forms/MTA_TO_NIH_Model_09_2004_Final.doc)

What's an adequate plan?

Refer to Samples of Previous Accepted Plans:
A Simple Plan:
http://grants2.nih.gov/grants/policy/model_organism/model_organ_simple_plan.doc
A Plan for Sharing Mice:
http://grants2.nih.gov/grants/policy/model_organism/model_organ_mouse_plan.doc
A Complex Plan:
http://grants2.nih.gov/grants/policy/model_organism/model_organ_complex_plan.doc

When in doubt....

Confer with your own Institution's Office of Sponsored Research or its office that handles technology transfer matters (e.g., TTO, Office of General Counsel (OGC))

NIH 2003 Data Sharing Policy Statement & Guidance Documents

The NIH Data Sharing Policy:
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html> (26 Feb 2003)

NIH Data Sharing Policy Information Page:
http://grants2.nih.gov/grants/policy/data_sharing/

NIH Data Sharing Policy & Implementation Guidance:
http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

Frequently Asked Questions (FAQs):
http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm

2003 NIH Data Sharing Policy

- Applies to applications seeking **\$500,000 or more** in direct costs in any year of the project period.
- Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.

What are data to be shared?

- Recorded factual material commonly accepted in the scientific community as necessary to document and support research findings.
- Data from human subjects (e.g., surveys, clinical studies) also can be shared if the identity and privacy of research participants can be protected.

What are data to be shared?

- Potentially all kinds of data are candidates for sharing, but unique data are especially important. By "unique data", we mean data that cannot be readily replicated. Examples of studies producing unique data include: large surveys that are too expensive to replicate; studies of unique populations, such as centenarians; studies conducted at unique times, such as a natural disaster; studies of rare phenomena, such as rare metabolic diseases.

What are not "data" for purposes of the 2003 policy?

- Data does not mean summary statistics or tables; rather, it means the data on which summary statistics and tables are based. This does not include laboratory notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

What's an adequate plan for sharing under the 2003 NIH Data Sharing Policy?

Data sharing plans may vary, depending on the data being collected and how to share the data, and may wish to include:

- Expected schedule for data sharing;
- Format of the final dataset;
- Documentation to be provided, such as (i) whether any analytic tools will also be provided or (ii) whether a data-sharing agreement will be required; and
- Mode of data sharing (e.g., under their own auspices by mailing a disk, posting data on their personal website, or through a data archive or enclave).

Additional considerations for data sharing plans:

- Mechanism for sharing
- Policies and procedures for accessing data and for providing data
- For studies involving human research participants, appropriate mechanism for informing subjects and Institutional Review Boards (IRBs) about the sharing plan
- Access to the data after the grant ends
- Tracking of sharing requests over time
- Samples/data deposited in a repository

What's an adequate plan?

- NIH guidelines do not include specific requirements for a data sharing plan
- NIH gives discretion to the Institutes and programs
- A workbook of approaches of successful data sharing at http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf
- Examples of Data Sharing Plans at http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#ex

When in doubt....

Confer with your own Institution's Office of Sponsored Research or its office that handles technology transfer matters (e.g., TTO, Office of General Counsel (OGC))

A Few More Considerations for both the MOSP and DSP:

- The institution would need to make certain that any rights or obligations to third parties are consistent with the terms and conditions of the NIH award to ensure appropriate dissemination of model organisms or resources under the NIH award

A Few More Considerations for both the MOSP and DSP:

- Investigators should be encouraged to develop their sharing plans in concert with the investigator's own institutional sponsored research program office, general counsel's office, or other office that handles technology transfer matters for that institution

**To comply with these policies,
applicant and their research
institutions should:**

- Read the policy statements, guidance, and FAQs, including the sample plans
- Read the specific Funding Opportunity Announcement (FOA)
- Discuss the programmatic goals with Program staff
- Involve the institution's experienced personnel in development of the sharing plans

**For further guidance on sharing
policies and compliance therewith:**

*J.P. Kim, J.D., M.B.A., M.Sc., M.A.L.S.
Director & Policy Officer,
Division of Extramural Inventions & Technology Resources (DEITR),
Office of Policy for Extramural Research Administration (OPERA),
Office of Extramural Research (OER),
National Institutes of Health (NIH),
6705 Rockledge Drive, Suite 310, MSC 7980
Bethesda, Maryland 20892-7980
Telephone: (301) 435-0679
Email: jpkim@nih.gov
Websites: <http://inventions.nih.gov>; <http://iEdison.gov>*
