2006 NIH Regional Seminar on

Program Funding & Grants Administration

Sharing Policies and the NIH - Caring about Sharing –

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Evolution of NIH Sharing

From pre-1980 to the Present

- PHS Grants Policy Statement - Pre-1980
- NIH Guide Supplement - May 1, 1980 – Hybridoma Sharing
- NIH Guide Notices - Mar 1984, Oct 1986, Oct 1987, Sept 1988 – Sharing of Unique Biological Materials
- PHS Grants Policy Statement - October 1, 1990 – Sharing of Unique Research Resources
- Developing Sponsored Research Agreements - November 8, 1994
  - History
  - Points to Consider: Universal, Special Consideration, & Others
- Biological Materials Policy - May 17, 1996
- NIH Intramural Research Program Guidelines for the Availability of Transgenic/Knockout Animals – March 1997
- NIH Research Tools Policy - December 23, 1999
  - History
  - 4 Principles & Guidelines
- NIH Data Sharing Policy – February 26, 2003
- NIH Model Organism Sharing Policy – May 7, 2004

PHS Grants Policy Statement Pre-1980

Publication

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

NIH Guide Supplement May 1, 1980

Policy Relating to Reporting and Distribution of Hybridomas Produced Under Grants and Contracts

"Current NIH policy on distribution of hybridomas and their products is to encourage its awardees to make such materials they develop readily and widely available for research purposes. The distribution of potentially patentable hybridomas, developed with NIH funding, may require additional guidelines in the future; these are now under consideration."

NIH Guide Notices Mar 1984, Oct 1986, Oct 1987, Sept 1988

Policy Related to Reporting and 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."

NIH Regional Seminar on Program Funding and Grants Administration

Data and Model Organisms Sharing Policies

What you need to know and do

Getting started: Read the policy statement

- The statement for the Data Sharing Policy is at: http://grants2.nih.gov/grants/policy/data_sharing/
- The statement for the Sharing of Model Organisms is at: http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html

Read the Guidance

- Data sharing: NIH Data Sharing Policy-Main Page: http://grants2.nih.gov/grants/policy/data_sharing/
- Model organisms: NIH Model Organisms Information – Main Page
- http://grants2.nih.gov/grants/policy/model_organism/

Read the FAQs

- The FAQs for the Data Sharing Policy are at: http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm
- The FAQs for the model organisms policy are at: http://grants2.nih.gov/grants/policy/model_organism/model_organisms_faqs.htm

Provide the least complicated plan possible!

Work with your program officer

- **Contact the program officer at the Institute from which you hope to receive funding**
- **The Program officer may urge you to involve your institutional technology transfer office**
- **The Program officer may consult with the Technology Development Coordinator (TDC) for his/her Institute if appropriate**

Where are the policy documents related to resource sharing (sharing data and/or model organisms) in the instructions to the SF 424 (R&R)?

- The resource sharing policies are found in instructions section III-I-E: Resource Sharing

For SF 424 (R&R) where do I insert my plan for sharing resources (data or model organisms)?

- Insert these as PDF documents in the PHS 398 Research Plan, in section 14 of the Research Plan Attachments.

What is the difference between sharing "research resources" and "data sharing?"

- **Unique research resources**: PUBLIC HEALTH SERVICE POLICY RELATING TO DISTRIBUTION OF UNIQUE RESEARCH RESOURCES PRODUCED WITH PHS FUNDING NIH GUIDE, Volume 25, Number 23, **July 12, 1996**

What are "unique research resources"?

- Categories : synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data.

What are data?

- Recorded factual material commonly accepted in the scientific community as necessary to document and support research findings.

Some specifics on the policies….

Model Organisms

Policy on the Sharing of Model Organisms

•all applications, all dollar amounts where the development of model organisms is anticipated

•include a description of a specific plan for sharing and distributing unique model organism research resources

OR state reasons why sharing is restricted or not possible.

What are Model Organisms?

- mammalian models, such as mouse and rat
- non-mammalian models, such as budding yeast, social amoebae, roundworm, Arabidopsis, fruit fly, zebrafish, and frog

BUT FOR THIS POLICY NOT:

- genetic variants of viruses, bacteria, and other prokaryotic organisms

Research resources to be shared

- 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 where:
  - mutations have been induced by chemicals, irradiation, transposons or transgenesis (e.g., knockouts and injection of DNA into blastocysts),
  - spontaneous mutations have occurred, and congenic or consomic strains.

"Resources"

- materials and data necessary for the production and understanding of model organisms:
  - vectors
  - non-human embryonic stem cells
  - established cell lines
  - protocols for genetic and phenotypic screens, mutagenesis protocols
  - genetic and phenotypic data for all mutant strains

Model Organisms: Sample Sharing Plans

- Model plans are posted on the internet. Have a look!
- Language is provided that can be clipped and pasted into applications with the addition of appropriate information as fill in the blank.

  http://grants2.nih.gov/grants/policy/model_organism/

Model Organisms

Documents that are acceptable for the exchange of model organisms include, but are not limited to:

- Uniform Biological Materials Transfer Agreement (UBMTA)
- Material Transfer Agreement for Transfer of Organisms
- Simple Letter of Agreement (SLA)

What is the right time to share a model organism that is created with NIH funds?

"generally at least upon publication of the primary results" (FAQ 3)

What should be addressed in my sharing plan for my model organism?

Sharing plans may vary, depending on:

- the organism,
- the nature of the resources that will be shared,
- the extent to which intellectual property issues may be considered in sharing,
- your plans for distributing the resources.

(FAQ 40)

What's in an adequate plan?

Minimally the plan must include a mechanism to share:

- the model
- phenotypic data and genotypic data
- a repository or a mechanism by which investigators will send animal models to secondary users
- appropriate written agreements for transfer of the resource to secondary users

- The form in which you will provide the organisms (e.g., adults, embryos, sperm);
- Related research resources and data that you will provide;
- A reasonable time frame for periodic deposition of material and associated data;

- Whether you will share under your own auspices or use a repository, and, if a repository, which one;
- For vertebrate animals and for other species for which pathogens or contaminants are potentially serious problems, how you will maintain your strains to minimize the risks of infection or contamination.

How you will handle technology transfer and intellectual property issues, including:

- How the institution plans to make such organisms and resources widely available to the research community;

- **How the institution plans 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 reagents under the NIH award;**

- **A description of the mechanisms that will be used to distribute organisms and related research resources (e.g., material transfer agreements). Samples of model organisms sharing plans may also be found at http://grants.nih.gov/grants/policy/model_organism**

Review: 2 possibilities

- **For mechanisms other than special RFAs, whether or not there is a plan will not enter into the scoring of the application. The sharing plan itself may be discussed after the application is scored**
- **For special initiatives and research mechanisms, where specifically requested in the text of the announcement adequacy of the plan is a review criterion and it will figure into the score.**

2003 Data Sharing Policy

2003 Data Sharing Policy

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

Regardless of the dollar amount, NIH requests that data be shared

2003 Data Sharing Policy

- NIH guidelines do not include specific requirements for a data sharing plan
- NIH gives discretion to the Institutes and programs
- We offer a framework for your sharing plan

What's in an adequate sharing plan?

1. The mechanism for sharing

Direct transfer of data files

A web based platform

A physical location where qualified investigators may access data

A combination of mechanisms

Justification for why you cannot share

What's in an adequate sharing plan?

2. Criteria for access

Who may apply to use the data?

Who decides which qualified investigators can and cannot use the data?

What are the criteria for review of applications?

How will you report who does and does not have access?

What's in an adequate sharing plan?

3. What is the process for accessing data?

How do investigators apply?

How will applications be reviewed?

What is the timeline for review?

What's in an adequate sharing plan?

4. What is the process for providing data?

How will data be provided?

What documentation will be provided?

How will you answer questions and provide explanations regarding shared data?

What's in an adequate sharing plan?

5. For studies involving human subjects, what is the mechanism for informing subjects and Institutional Review Boards (IRBs) about the plan?

Subject confidentiality

HIPAA

Layered consent forms

What's in an adequate sharing plan?

6. How involved in the analysis proposed by qualified investigators will you be?

Avoid being too prescriptive. For example, "I must be included on all publications" would be too restrictive.

What's in an adequate sharing plan?

7. After the grant ends, how will you provide access to the data.

Contact person?

Website?

What's in an adequate sharing plan?

8. How will you track sharing requests over time?

Reports on your non-competitive renewals

Your final report

"Where do you want me to put my samples?"

- National repository
- Repository supported by your IC
- Other NIH approved site

Not sharing?

- Provide written justification in the study protocol

How Program follows up on the two policies

After review: program officers may contact PIs to discuss the sharing plan

- PIs may expect to discuss their sharing plans with their program officers
- PIs may have terms and conditions applied to their award.

After review: program officers may contact PIs to discuss the sharing plan

- PIs may receive a formal letter containing the terms and conditions of award
- The Notice of Grant Award is issued noting the terms and conditions of award along with the signed sharing plan

Follow up: The annual progress report

- The annual progress report ["continuation" in the SF424 (R&R)] will be checked for follow through on the sharing plan.

  Additional information may be requested.

Follow up: The annual progress report

- With whom have you shared during the past year of your award?
- How many animals or how much data did you share? When did you share them?
- Were phenotypic and genotypic data shared along with the model organism?
- If you did not share with an investigator, why did you not share?

Reporting patents

- The non-competing renewal form (Form 2590, “Progress Report”) also asks for reporting of patents:

"f. Project-Generated Resources: If the research supported by this grant resulted in data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information available to be shared with other investigators, describe the resource and how it may be accessed."

Reporting patents

- Patents must be reported to NIH.
  http://grants2.nih.gov/grants/funding/phs398/phs398.html
- Patents should be reported through Edison within 60 days of the initial filing.
  https://s-edison.info.nih.gov/iaerl/

Special Cases

- What if you don’t know what will arise from the research that will be a sharable resource?
  - Under unusual circumstances, a PI may not know what will be sharable.
  - In this case, the award may have terms and conditions stating that the plan will be provided within a prescribed time after the award depending upon progress and the results that are obtained.

Good Luck!

My contact information

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PHS Grants Policy Statement October 1, 1990

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."

Federal Register, Vol. 59, No. 215, pp. 55674-55679 November 8, 1994

Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts

Provides Recipients with issues and points to consider in developing sponsored research agreements with commercial entities, where such agreements may include research activities which are fully or partially funded by NIH.

Points To Consider

"Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts"

Printed in The Federal Register, Vol. 59, No. 215, November 8, 1994, pp. 55674-55679

How did this develop?

- Culmination of various activities including: (i) review/analysis of 375 sponsored research agreements from 100 Recipients; (ii) meetings with industry, academia, and other government agencies; and (iii) a specially convened public forum involving subject matter experts from outside the NIH
- Provides considerations for developing sponsored research agreements with commercial entities when NIH funding is involved

The Considerations….

- Universal Points for Consideration
- Points for Special Consideration
- Other Points for Consideration by Nonprofit Recipients

Universal Points for Consideration

- Academic Freedom
  - Academic researchers should be free to select projects, collaborate with other scientists, determine the types of sponsored research activities which they wish to participate, and communicate their research findings at meetings and by publication and through other means
  - Academic researchers should be made aware of institutional agreements which may restrict their ability to pursue research and publish research results
  - Maintain independence to pursue own mission without undue influence or restraint by sponsor

Universal Points for Consideration

- Dissemination of Research Results
  - Timely dissemination of research findings
  - 30-60 day delay for filing a patent application generally workable
  - Sponsored research agreement which requires disclosure of NIH-funded inventions to an industrial sponsor prior to submission of the invention disclosure to NIH may be inconsistent with NIH grant or contract

Universal Points for Consideration

- Utilization
  - Development and commercialization of technology in an expedited and efficient manner
  - Avoid agreements allowing a sponsor to tie up development of technology to just decide whether to actively develop and commercialize or not
  - A 1st option to pursue licensing rights should be limited to 6 months after disclosure to sponsor. If sponsor fails to exercise option, a 2nd opportunity should generally not be retained to match other parties' offers for rights
  - Policies and procedures for due diligence requirements, performance benchmarks, & monitoring of licensees
  - Internal systems for required utilization reports

Universal Points for Consideration

- U.S. Manufacture
  - Term and condition of any license executed
  - Waiver possible but must be requested by funded institution after reasonable but unsuccessful efforts have been made to license or circumstances are such that domestic manufacture not commercially feasible

Universal Points for Consideration

- Notification Requirements and Records
  - Employee notification to Recipient institution
  - Sufficient written disclosure to NIH of invention
  - Written election to NIH of retention of title to invention
  - Adherence to time frames for initial filing of patent application
  - Execution/delivery of all instruments for to establish/confirm NIH rights throughout world in invention which Recipient has elected title

Universal Points for Consideration

- Notification Requirements and Records
  - Notifying NIH if Recipient decides not to continue patenting in any country
  - Conveyance of title to NIH when requested
  - Specifying NIH/government support on any patent applications and patents issuing there from
  - Timeline at: https://s-edison.info.nih.gov/iEdison/timeline.jsp
  - Invention Reporting and related Extramural Intellectual Property Policy: Division of Extramural Inventions & Technology Resources (DEITR), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER)

Points for Special Consideration

- Heightened sensitivity & scrutiny
  - If sponsor's financial support ≥ $5 million in any single year or $50 million over the total funding period
  - If sponsor's proportion of funding > 20% of Recipients total research funding
  - Sponsor's prospective licensing rights cover ALL technologies by a major group or component of the Recipient organization or a major proportion of the anticipated intellectual output of the research staff
  - Duration of proposed agreement > 5 years

Points for Special Consideration

- Scope of agreement
  - All or majority of technology exclusively licensed to one sponsor or other organizations are excluded from reasonable access to technology
  - Potential delays in commercialization if sponsor lacks interest or capability in developing all other technologies

Points for Special Consideration

- General funding versus the specific research project
  - Reasonable relationship between funds contributed and the rights granted to review and license resulting technology
  - If general funding is involved, potential limitations to a particular segment or percentage of inventions for a set period of time if such rights are required by sponsor

Points for Special Consideration

- Avoid any other unusual practice or stipulation that might generate public concern or undermine, rather then serve, the public interest

Other Points for Consideration by Nonprofit Recipients

- Rights generally cannot be assigned without NIH approval
- Share royalties collected on NIH funded inventions with inventors and, after payment of expenses, then utilize for support of scientific research and/or education
- Reasonable efforts to attract and license to small business firms

NIH Procedures for Handling Non-Election of Title to Patentable Biological Materials (Biological Materials Policy)

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

March 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.

Federal Register, Vol. 64, No. 246, pp. 72090-72096 December 23, 1999

Sharing of Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources ("NIH Research Tools Policy")

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?

- 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

Why the need for another policy statement?

- Scientists experiencing problems related to the dissemination and use of unique research resources
- Need to balance the competing interests of intellectual property owners and research tools users to address

Response to Need

- 1997, NIH Director requested that a Working Group of the Advisory Committee to the Director look into the problems

Recommendations

- Promote free dissemination of research tools without legal entanglements
- Further use of UBMTA
- Develop guidelines for extramural MTAs and licensing
- Review and strengthen current policies
- Establish "research tools forum"

Policy Development

- Reviewed NIH's longstanding policy on the sharing of unique research resources
- Reviewed NIH's Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts
- Developed policy based on earlier documents and discussions
- Requested additional comments from industry, academia, and others

The Result

The NIH Research Tools Policy

"Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts"

December 23, 1999

http://ott.od.nih.gov/NewPages/RTguide_final.html

http://ott.od.nih.gov/NewPages/64FR2090.pdf

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

Principle 1:

ENSURE ACADEMIC FREEDOM AND PUBLICATION

- Preserve academic research freedom
- Safeguard appropriate authorship
- Timely disclosure of results
- Applies to **all** funding recipients

Principle 2:

ENSURE APPROPRIATE IMPLEMENTATION OF BAYH-DOLE ACT

- Maximize utilization by research community
- Timely transfer to industry for commercialization
- Patent protection not always needed
- License to ensure widespread distribution of final tool product to public
- Avoid unnecessarily restrictive licensing practices

Principle 3:

MINIMIZE ADMINISTRATIVE IMPEDIMENTS TO RESEARCH

- Streamline academic transfers using Simple Letter Agreement (or equivalent)
- Implement clear tool acquisition policies
- Avoid encumbrances such as:
  - "reach through" or product rights
  - publication/academic freedom control
  - improper valuations

Principle 4:

- Share distribution principles with non-NIH research co-sponsors
- Simplify transfer to for-profits for internal use
- Limit exclusive licenses to appropriate fields of use
- Retain tool use & distribution rights

NIH Guide Notice NOT-OD-03-032: "Final NIH Statement on Sharing Research Data" - February 26, 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 October1, 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."

Further Discussions on NIH Data Sharing Policy and NIH Model Organism Sharing Policy

For further guidance on sharing policies and compliance therewith:

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