Resource Sharing Plan

Policy:
NIH Grants Policy Statement (rev. 10/1/2013)
Part II: Terms and Conditions of NIH Grant Awards
Section: 8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: http://grants.nih.gov/grants/intell-property.htm.

- **Data Sharing**
  NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. “Timely release and sharing” is defined as no later than the acceptance for publication of the main findings from the final data set. All investigator-initiated applications with direct costs of $500,000 or more (excluding consortium F&A costs) in any single year are expected to address data-sharing in their application. In some cases, FOAs may request data-sharing plans for applications that are less than $500,000 (excluding consortium F&A costs) in any single year.

  NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the HIPAA Privacy Rule (see Public Policy Requirements and Objectives—Confidentiality of Patient Records: Health Insurance Portability and Accountability). The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

- **Sharing Model Organism**

  All applications where the development of model organisms is anticipated are expected to include 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 why such sharing is restricted or not possible. 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. 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.

This expectation is for all applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Model Organism for Biomedical Research Web site at: http://www.nih.gov/science/models/.

- **Genome Wide Association Studies (GWAS)**

  NIH is interested in advancing GWAS to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.

  All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. For additional information see: http://gwas.nih.gov/.

Procedure

Preparation of resource sharing plans may be complex, and care should be taken to insure that institutional policies, local IRB rules, and local, state and federal laws and regulations are followed. In particular, investigators should carefully consider the following areas when developing data sharing plans:

- **Protecting the Rights and Privacy of Human Subjects:** Plans must comply with all applicable IRB rules and the federal Health Insurance Portability and Accountability Act (HIPAA) regulations pertaining to protected health information. When determining how best to make final research data available, Investigators must consider the need to protect against disclosure of personally identifiable data (or de-identify data when appropriate). Contact the Privacy Advocate in the BUMC IRB Office with any questions regarding HIPAA when preparing a data-sharing plan that involves to human research information

- **Meeting the Hospital's Intellectual Property and Third-Party Obligations:** Plans must comply with the Hospital's obligation under Bayh-Dole and the Technology Transfer Commercialization Act of 2000 to report to federal funding agencies on inventions resulting from federal funds, as well as with third-party obligations resulting from extramural sponsored research agreements or material transfer agreements. These laws also stipulate that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

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When developing a data sharing plan, investigators must allow adequate time for the BU Office of Technology Development (OTD) to review the intellectual property and/or proprietary information that must be protected prior to release of research data. The NIH Implementation Guidance recognizes the need to protect patentable and other proprietary data (including cases where co-funding is provided by the private sector) and acknowledges that reasonable delays in disclosure of research findings may be needed to accomplish this goal. Consult with the Director of the BU OTD if questions arise about intellectual property during the development of the data-sharing plan. All inventions must be disclosed to the BU OTD as soon as they have been invented, which means well in advance of starting to prepare a manuscript or abstract or making any public presentations.

The institution has prepared some sample language to assist Principal Investigators (PIs) in fulfilling their obligations as a recipient of federal funding (see below). PIs can adapt this script to reflect the types of research tools involved or what they expect to create if their application is funded.

Sample language:

Data Sharing Sample

Boston Medical Center is committed to the open and timely dissemination of research outcomes. Investigators in the proposed activity recognize that promising new methods, technologies, strategies and computer software [*revise as applicable to the nature of the research program*] may arise during the course of the research. The Investigators are aware of and agreed to abide by the principles for sharing research resources as described by NIH in "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources."

While the investigators expect that research tools will be freely shared with the research community, opportunities for technology transfer through commercialization will be explored as appropriate.

BUMC Office of Technology Development (OTD) manages intellectual property for both Boston University and Boston Medical Center. OTD serves faculty, staff and students by commercializing inventions, ideas and software developed at the Hospital to ensure that new knowledge benefits society.

OTD works with researchers to assess the commercial potential of new ideas. OTD's goals are to disseminate new ideas so the public can benefit from discoveries, and to generate revenues for research and education. When the best means of disseminating discoveries and new intellectual property is collaboration between the Hospital and commercial entities, OTD has a special role to play. It protects the rights of the inventors and the Hospital—and then typically works with industry, granting licenses so that a company will develop the discovery and bring it to the market. Revenues from licenses secured by OTD are shared with the inventor, the inventor's laboratory, and the inventor's academic division. Where opportunities arise for corporate sponsored research related to the NIH-funded research programs, the Hospital expects any agreements to conform to the principles described by NIH in the 1994 policy "Developing Sponsored Research Agreements: Consideration for Recipients of NIH Research Grants and Contracts."

Sharing of Model Organisms or Animal Models Sample 1:

Boston Medical Center is committed to the open dissemination of research results, information and research tools that facilitate research and further scientific progress. It is the expectation and goal of the Hospital that all "model organisms" (as defined by the NIH at www.nih.gov/science/models/) that are created during the course of NIH funded research grant projects, are shared with the research community. In accordance with these efforts Boston Medical Center will use as guidance the NIH Grant Policy on Sharing of Unique Research Resources and the NIH Policy on Sharing of Model Organisms for Biomedical Research, published May 7, 2004.

The guiding principles that the Hospital will follow to achieve the above stated goal are outlined below:

- The Hospital will work with and encourage its faculty to disclose newly created model organisms on a timely basis.

- The Hospital will facilitate the transfer of model organisms to researchers requesting access through its material transfer agreements or a Simple Letter Agreement (SLA) or a Uniform Biological Materials Transfer Agreement (UBMTA). Alternatively, the Hospital may, when appropriate, make the material available through the use of a repository or a commercial distributor. In all cases, arrangements will be made to ensure that the materials are made widely available to the non-profit research community.

- If the Hospital decides to patent the model organism, it will take steps to ensure that the protection of rights shall not interfere with the distribution of the organism to the scientific community.

- If the Hospital decides to patent and license the model organism, it will negotiate terms with licensees that promote widespread distribution of the organism. With respect to exclusive licenses, the agreements will include provisions for the return of rights to the Hospital should the licensor fail to commercialize the technology and offer it for public sale in a timely manner. The

Hospital will also make every effort to reserve rights to the licensed material to the Hospital and other non-profit institutions.

- The Hospital will draw upon the expertise within Hospital's Office of Technology Development (OTD), the office of General Counsel and other appropriate offices within the institution when developing individual model organism sharing plans with its principal investigators.

- If third party patents or contract obligations exist, the Hospital will seek to minimize any possible restrictions affecting the availability of model organisms.

- **Sharing of Model Organisms or Animal Models Sample 2:**

  Following the characterization and peer-reviewed publication of [ORGANISM], [ORGANISM] will be freely distributed to investigators at academic institutions wanting [ORGANISM] for non-commercial research.

  [If organism is covered by AAALAC, insert the following paragraph:]

  > Individual requests for shipment of [ORGANISM] generated by this program project funding to AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care International)-accredited institutions will be honored. The recipient investigators would provide written assurance and evidence that the animals will be used solely in accord with their local IACAC review; [ORGANISM] will not be further distributed by the recipient without consent of the PI; and [ORGANISM] will not be used for commercial purposes.

  Requests for [ORGANISM] from for-profit corporations to use [ORGANISM] commercially may be negotiated by the Hospital's patent management organization, the Office of Technology Development. All royalty income shall be subject to distribution pursuant to the Hospital's policies and procedures on royalty income. The Hospital will report any invention disclosure submitted to it to the appropriate federal agency.

  "Other Research Resources" generated with funds from this grant may include DNA constructs, etc. These resources, as available, would also be freely distributed upon request to qualified academic investigators for non-commercial research.

  My institution and I will adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the "Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts" issued in December, 1999.http://www.ott.nih.gov/policy/rt_guide_final.html. Specifically, material transfers to non-profit institutions would be made with no more restrictive terms than in the Simple Letter Agreement or the UBMTA and without reach through requirements. Should any intellectual property arise which requires a patent, we would ensure that the technology remains widely available to the research community in accordance with the NIH Principles and Guidelines document.

- **Sharing of Model Organisms or Animal Models Sample 3:**

  "As this project may result in the development of unique model organism research resources, and to make such resources available to the research community in a timely manner to further research, development, and application, Boston University (BU) and Boston Medical Center (BMC) agree to utilize their current material transfer agreement (MTA) capabilities and intellectual property (IP) protection through BU's Office of Technology Development. Because this office subscribes to the federal standard, either a Simple Letter Agreement (SLA) or a Uniform Biological Materials Transfer Agreement (UBMTA) is used to transfer materials to other subscribing institutes. For institutions that do not subscribe to the federal standard, BU has developed a template MTA, containing terms similar to those in the SLA/UBMTA documents, with conditions included to protect any current or pending BU IP rights. BU can also share these resources through an appropriate license if more formal protection of its IP interests is required. Any reach-through requirements on transferred materials will be addressed within the terms and conditions of BU's MTAs, which follow general U.S. Patent Law

principles to govern potential inventorship rights, with ownership following inventorship, and also include general guidelines on good-faith discussions between BU and the recipient of the resources on handling potential subsequent commercial license situations when BU IP is involved. BU will encourage its investigators to reference any developed resources in its publications, presentations and on its internal web postings so that other researchers are aware that such resources are available."

- **If not possible to share Sample:**

  "Although it is anticipated that this project will result in the development of unique model organism research resources, BMC's ability to share such resources is restricted or not possible because _____."

In Conclusion

When preparing a data sharing plan (or resource sharing plan), review and follow closely the NIH Implementation Guidance for Data Sharing section entitled "What to Include in an NIH Application." Sections of the grant application which may be involved in a data/resource sharing plan are 1) the Data/Resource Sharing Plan itself which should follow immediately after the Research Plan Section and which will not count towards the application page limit 2) the Budget and Budget Justification as funds may be requested for implementation of the Data/Resource Sharing Plan itself 3) the Background and Significance Section if support is being sought for a large data sharing database, or 4) the Human Subjects Section in order to address issues of confidentiality of data and privacy matters.

NIH has indicated that if an application contains a resource sharing plan, it expects the plan to be implemented and may take various forms of action to protect the government's interest in the case of non-compliance. Therefore, care should be taken to ensure that data-sharing and resource sharing plans are fully enacted if a grant is awarded, and that all plans closely follow the applicable Hospital policies, local IRB rules, local, state and federal laws and regulations and intellectual and third party obligations.