Many commenters were of the opinion that the thirty-day time limit for disclosure of research findings was too short. The final policy has been amended to state that a delay of 30-60 days is generally viewed as reasonable. This amendment is in accord with previous NIH guidance on sponsored research agreements, Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts, 59 FR 55674.

Comments were received in favor of adopting the Simple Letter Agreement as a free-standing, one page, uniform material transfer agreement. If used by the NIH intramural program and NIH grantees, commenters believe that the majority of transfers among and between not-for-profits and government laboratories would be greatly simplified. In response to specific comments, the Simple Letter Agreement has been significantly edited and updated. Recipients are encouraged to adopt the Simple Letter Agreement as their institution's model Material Transfer Agreement (MTA), and are expected to use the terms of the Simple Letter Agreement, or no more restrictive terms, for transfers of unpatented materials developed with NIH funding to other NIH grantees.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara McGarey, J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Fax: (301) 402-3257; E-mail: NIHOTT@od.nih.gov.

/s/
Maria C. Freire, Ph.D.
Director, Office of Technology Transfer
National Institutes of Health

Certified to be a true copy of the original document

SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Contracts

INTRODUCTION

The National Institutes of Health is dedicated to the advancement of health through science. As a public sponsor of biomedical research, NIH has a dual interest in accelerating scientific discovery and facilitating product development. In 1997, Dr. Harold Varmus, Director, NIH requested that a Working Group of the Advisory Committee to the Director look into problems encountered in the dissemination and use of unique research resources, the competing interests of intellectual property owners and research tool users, and possible NIH responses.[1] The Working Group found that intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. One of the recommendations of the Working Group was that NIH issue guidance to its funding recipients to help them achieve the appropriate balance. That guidance is provided in this two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation. A copy of the full Report of the Working Group, with more detailed background information, is available at the NIH web site, www.nih.gov/welcome/forum or from the NIH Office of the Director.

[1] The term "unique research resource" is used in its broadest sense to embrace the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines. The terms "research tools" and "materials" are used throughout this document interchangeably with "unique research resources." Databases and materials subject to copyright, such as software, are also research tools in many contexts. Although the information provided here may be applicable to such resources, the NIH recognizes that databases and software present unique questions which cannot be fully explored in this document.

PRINCIPLES

1. Ensure Academic Freedom and Publication

Academic research freedom based upon collaboration, and the scrutiny of research findings within the scientific community, are at the heart of the scientific enterprise. Institutions that receive NIH research funding through grants, cooperative agreements or contracts ("Recipients") have an obligation to preserve research freedom, safeguard appropriate authorship, and ensure timely disclosure of their scientists' research findings through, for example, publications and presentations at scientific meetings. Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant co-authorship or copyright to the provider of a material.

Reasonable restrictions on collaboration by academic researchers involved in sponsored research agreements with an industrial partner that avoid conflicting obligations to other industrial partners, are understood and accepted. Similarly, brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from a sponsor or the provider of a research tool is not inadvertently disclosed. However, excessive publication delays or requirements for editorial control, approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable.

2. Ensure Appropriate Implementation of the Bayh-Dole Act

When a Recipient's research work is funded by NIH, the activity is subject to various laws and regulations, including the Bayh-Dole Act (35 U.S.C. 200*et seq.*). Generally, Recipients are expected to maximize the use of their research findings by making them available to the research community and the public, and through their timely transfer to industry for commercialization.

The right of Recipients to retain title to inventions made with NIH funds comes with the corresponding obligations to promote utilization, commercialization, and public availability of these inventions. The Bayh-Dole Act encourages Recipients to patent and license subject inventions as one means of fulfilling these obligations. However, the use of patents and exclusive licenses is not the only, nor in some cases the most appropriate, means of implementing the Act. Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention.

In determining an intellectual property strategy for an NIH-funded invention useful primarily as a research tool, Recipients should analyze whether further research, development and private investment are needed to realize this primary usefulness. If it is not, the goals of the Act can be met through publication, deposit

in an appropriate databank or repository, widespread non-exclusive licensing or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to the goals of the Bayh-Dole Act. Where private sector involvement is desirable to assist with maintenance, reproduction, and/or distribution of the tool, or because further research and development are needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product. Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, can be consistent with the goals of the Bayh-Dole Act.

3. Minimize Administrative Impediments to Academic Research

Each iteration in a negotiation over the terms of a license agreement or materials transfer agreement delays the moment when a research tool may be put to use in the laboratory. Recipients should take every reasonable step to streamline the process of transferring their own research tools freely to other academic research institutions using either no formal agreement, a cover letter, the Simple Letter Agreement of the Uniform Biological Materials Transfer Agreement (UBMTA), or the UBMTA itself. The Appendix contains an updated free-standing version of the Simple Letter Agreement that is strongly encouraged for transfers of unpatented research materials among Recipients.

Where they have not already done so, Recipients should develop and implement clear policies which articulate acceptable conditions for acquiring resources, and refuse to yield on unacceptable conditions. NIH acknowledges the concern of some for-profit organizations that the concept of purely academic research may be diluted by the close ties of some not-for-profit organizations with for-profit entities, such as research sponsors and spin-off companies in which such organizations take equity. Of concern to would-be providers is the loss of control over a proprietary research tool that, once shared with a not-for-profit Recipient for academic research, results in commercialization gains to the providers' for-profit competitors. Recipients must be sensitive to this legitimate concern if for-profit organizations are expected to share tools freely.

For-profit organizations, in turn, must minimize the encumbrances they seek to impose upon not-for-profit organizations for the academic use of their tools. Reach-through royalty or product rights, unreasonable restraints on publication and academic freedom, and improper valuation of tools impede the scientific process whether imposed by a not-for-profit or for-profit provider of research tools. While these Principles are directly applicable only to recipients of NIH funding, it is hoped that other not-for-profit and for-profit organizations will adopt similar policies and refrain from seeking unreasonable restrictions or conditions when sharing materials.

4. Ensure Dissemination of Research Resources Developed with NIH Funds

Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout government, academia, and industry. Ideally, these new resources flow to others who advance science by conducting further research. Prompt access can be accomplished in a number of ways, depending on the type of resource that has been developed, whether it has broad or specific uses, and whether it is immediately useful or private sector investment is needed to realize its usefulness. The goal is widespread, timely distribution of tools for further discovery. When research tools are used only within one or a small number of institutions, there is a great risk that fruitful avenues of research will be neglected.

Unique research resources arising from NIH-funded research are to be made available to the scientific

research community. Recipients are expected to manage interactions with third parties that have the potential to restrict Recipients' ability to disseminate research tools developed with NIH funds.[2] For example, a Recipient might use NIH funds with funds from one or more third party sponsors, or acquire a research tool from a third party provider for use in an NIH-funded research project. Either situation may result in a Recipient incurring obligations to a third party that conflict with Recipient's obligations to the NIH. To avoid inconsistent obligations, Recipients are encouraged to share these Principles with potentia co-sponsors of research projects and third party providers of materials.

Recipients should also examine and, where appropriate, simplify the transfer of materials developed with NIH funds to for-profit institutions for internal use by those institutions. NIH endorses distinguishin internal use by for-profit institutions from the right to commercial development and sale or provision of services. In instances where the for-profit institution is seeking access for internal use purposes, Recipients are encouraged to transfer research tools developed with NIH funding to such institutions without seeking option rights or royalties on the final product.

---

[2] Research tools obtained or derived from human tissues constitute a special case. Certain restrictions on the use and further dissemination of such tools may be appropriate to ensure consistency with donor consent and human subjects protection. See 45 C.F.R. Part 46.

SUMMARY

Access to research tools is a prerequisite to continuing scientific advancement. Ensuring broad access while preserving opportunities for product development requires thoughtful, strategic implementation of the Bayh-Dole Act. The NIH urges Recipients to develop patent, license, and material sharing policies with this goal in mind, realizing both product development as well as the continuing availability of new research tools to the scientific community.

APPENDIX

GUIDELINES FOR IMPLEMENTATION

The following Guidelines provide specific information, strategies, and model language for patent and license professionals and sponsored research administrators at Recipient institutions to assist in implementing the Principles on Obtaining and Disseminating Biomedical Resources. Recipients are encouraged to use the strategies below, other strategies developed at their own institutions, or any other appropriate means of achieving the Principles.

Guidelines for Disseminating Research Resources Arising Out of NIH-Funded Research

Definition of Research Tools

- The definition of research tools is necessarily broad, and it is acknowledged that the same material can have different uses, being a research tool in some contexts and a product in others. In

determining how an NIH-funded resource that falls within the definition should be handled, Recipients should determine whether: 1) the primary usefulness of the resource is as a tool for discovery rather than an FDA-approved product or integral component of such a product; 2) the resource is a broad, enabling invention that will be useful to many scientists (or multiple companies in developing multiple products), rather than a project or product-specific resource; and 3) the resource is readily useable or distributable as a tool rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource. Recipients should ensure that their intellectual property strategy for resources fitting one or more of the above criteria enhances rather than restricts the ultimate availability of the resource. If Recipient believes private sector involvement is desirable to achieve this goal, Recipient should strategically license the invention under terms commensurate with the goal.

Use of Simple Letter Agreement

- Recipients are expected to ensure that unique research resources arising from NIH-funded research are made available to the scientific research community. The majority of transfers to not-for-profit entities should be implemented under terms no more restrictive than the UBMTA. In particular, Recipients are expected to use the Simple Letter Agreement provided below, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other Recipients for use in NIH-funded projects. If the materials are patented or licensed to an exclusive provider, other arrangements may be used, but commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate.

- Similarly, when for-profit entities are seeking access to NIH-funded tools for internal use purposes, Recipients should ensure that the tools are transferred with the fewest encumbrances possible. The Simple Letter Agreement may be expanded for use in transferring tools to for-profit entities, or simple internal use license agreements with execution or annual use fees may be appropriate.

- *Simple Letter Agreement for the Transfer of Materials*

  In response to the RECIPIENT's request for the MATERIAL [insert description] _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

  1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
  2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
  3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
  4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
  5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
  6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF