The meeting is closed to the public.

Dated: December 16, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice

AGENCY: National Institutes of Health (NIH), Public Health Service, DHHS.

SUMMARY: On May 25, 1999 the National Institutes of Health (NIH) published for public comment in the **Federal Register** a proposed policy entitled SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guideline for Recipients of NIH Research Grants and Contracts [64 FR 28205]. This policy is designed to provide recipients of NIH funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds and is intended to assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy. Comments on the Principles and Guidelines were requested by August 23, 1999. This Notice presents the final Principles and Guidelines together with NIH's response to the public comments received.

Background

The Present policy represents part of the overall implementation of recommendations made by the Advisory Committee to the Director (ACD) to Dr. Harlod Varmus, Director, NIH. Dr. Varmus requested that a Working Group of the ACD look into problems encountered in the dissemination and use of proprietary research tools, the competing interests of intellectual property owners and research users underlying these problems, and possible NIH responses. One of the recommendations in the Report was that NIH issue guidance to the recipients of NIH funding.

Purpose

The present policy is a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines providing specific information to patent and license professionals and sponsored research administrators for implementation. The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining. (1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools): and (2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help Recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements. It is also hoped that these Principles and Guidelines will be adopted by the wider research community so that all biomedical research and development can be synergistic and accelerated.

Comments and Agency Response

The National Institutes of Health (NIH) recognizes the importance of public involvement in the development of policy and sought widespread comment and participation by the various stakeholders in the biomedical research and development communities regarding the proposed policy. To this end, NIH sought comment not only from NIH grantees, but also from academic, not-for-profit, government, and private sector participants in biomedical research and development. In order to involve as many stakeholders as possible in the comment process, the proposed policy was advertised and comments solicited in a wide variety of venues. In addition to its publication on May 25, 1999, in the **Federal Register,** the proposed policy was made available on several different websites including the Federal Register Online, numerous NIH websites (Edison, NIH Office of Technology Transfer, NIH Office of Extramural Research and the NIH Director's Policy Forum), the Association of University Technology Managers (AUTM) website and Recombinant Capital's Signals Magazine. The proposed policy was also advertised on a variety of e-mail lists (including Techno-L) as well as in direct letters and e-mail to various stakeholders. In addition, the proposed policy was profiled in articles appearing in a variety of journals and magazines, including Science, Nature and Nature Biotechnology.

In response to the May 25 proposal, NIH received 45 letters, each of which contained one or more comments. Comments were received from academic institutions, scientific foundations, pharmaceutical companies, biotechnology companies (including providers of research instruments, biological reagents and genomic data), an industry trade association, professional societies, individual researchers and other individual commenters. Below is NIH's response to comments offered, organized by the section of the proposed policy to which they pertain.

Introduction

Several commenters suggested that sponsored research administrators be included within the target audience to which this policy is addressed. This suggestion has been adopted in the final policy.

Several commenters suggested that the policy is a de facto regulation and should either be promulgated in accordance with regulatory process or withdrawn. Several other commenters suggested that as a policy the Principles/Guidelines are not enforceable as law and that NIH should issue them as a regulation to ensure compliance. The NIH does not believe that a regulation, enforceable as law, is required at this time to facilitate sharing and access to research tools for its Recipients. Although the final policy is issued as a grants policy, to be incorporated into the NIH Grants Policy Statement, the NIH has not precluded the possibility of engaging in the regulatory process if widespread problems continue in access to NIH-funded research tools by NIH Recipients. In addition, on a case-by-case basis, the expectations set forth in the Principles and Guidelines may be imposed as specific requirements of NIH funding awards where the Recipient has failed to demonstrate sufficient progress in implementing the Principles and Guidelines.

Some commenters suggested that the policy should not be applicable to all projects that include NIH grant funds, but that NIH should set a minimum level of NIH funding that would trigger application of the policy. NIH has determined that the establishment of such a threshold would not be consistent with NIH's objective of ensuring that broad availability of research tools.

One commenter expressed concern that the proposed policy, if applied to recipients of Small Business Innovation Research (SBIR) grants, would place SBIR recipients under conflicting directives. The commenter suggests that because SBIR recipients are required, as a condition of their grant, to focus on the commercialization of technology, they would be unable to disseminate

research tools with the minimal intellectual property encumbrances advocated by the proposed policy. SBIR Recipients, like other NIH grantees, are subject to the dual obligations of disseminating unique research resources while promoting utilization, commercialization and public availability of their inventions. The NIH does not see a conflict between these obligations. The NIH invites its SBIR grantees to consult with their project officer in the event they encounter difficulty in the interpretation or implementation of this policy, either in general or with respect to particular unique research resources developed under their grant.

Principles

1. Ensure Academic Freedom and Publication

Several commenters suggested that language be added to the guidelines to prohibit recipients from making coauthorship a condition of providing research tools. There appears to be general consensus within the research community that authorship is properly based upon significant intellectual contribution to the published paper. In most cases, simply making available research materials will not, in the absence of other contributions, justify coauthorship. (See *e.g.,* Responsible Science, Volume I: Ensuring the Integrity of the Research Process, Panel on Scientific Responsibility and the Conduct of Research, National Academy Press, 1992, p. 52). The final policy has been amended to reflect this view.

Several commenters expressed concern that the definition of ''Recipient'' in the proposed policy might not include individuals or entities receiving NIH funds through ''cooperative agreements.'' The policy is applicable to cooperative agreements and this has been clarified in the Principles and Guidelines.

2. Ensure Appropriate Implementation of the Bayh-Dole Act

Virtually all commenters requested clarification on how this policy would preserve incentives for the development and production of research tools that are ultimately sold as products to the research community. The policy has been clarified to ensure that where patent protection is necessary for development of a research tool as a potential product for sale and distribution to the research community. Recipients are not discouraged from seeking such protection, but should license the intellectual property in a manner that maximizes the potential for broad distribution of the research tool. The policy is not intended to require Recipient scientists to develop of maintain tools for widespread distribution, to discourage development of research tool products, nor to set or influence the price for research tools that are commercial products.

3. Minimize Administrative Impediments to Academic Research

One commenter suggested that reach-through rights should not be discouraged because they are sometimes helpful to Recipients by allowing them to obtain materials and equipment at reduced or nominal upfront cost. NIH is aware of this rationale for a Recipient agreeing to reach-through but finds that such practices contribute not only to specific restriction of access to subsequent tools arising out of the NIH-funded work, but also to the general proliferation of multiple ties and competing interests that is the source of the current access problems. NIH does not support the coupling of procurement with intellectual property rights and restrictions and expects Recipients to ensure that NIH-funded tools are not restricted as a result of such agreements. Therefore, Recipients should engage in such interactions on an infrequent, case-by-case, and highly controlled and monitored basis.

4. Ensure Dissemination of Research Resources Developed with NIH Funds

Numerous comments were received concerning the conditions under which research tools developed by recipients of NIH funds are to be transferred to for-profit entities. The comments received reflected the wide range of opinions present within the life sciences community on this point. On the one hand, some commenters urged that transfer of research tools to for-profit entities be carried out under the same terms as transfers to nonprofits/academic institutions. These commenters argue that because of the increasingly important role research tools play in the discovery and development of new therapeutic compounds, it is critical that these tools be made available to for-profit entities free of onerous contractual provisions. They argue that by adopting a transfer policy similar to that proposed for transfers to academic laboratories, NIH will ensure that the public will reap the benefit of its investment in government research in the form of new and improved pharmaceuticals. Other commenters opposed the general idea that the terms for transferring tools to for-profit entities should be identical to those for transfers of tools to academic and non-profit organizations. They argue that the fundamental differences in mission between for-profit entities and academic institutions justify different treatment with respect to the terms under which each obtains and uses tools.

In the final policy, the NIH has left considerable discretion to Recipients in determining how to achieve the principle of ensuring appropriate distribution of NIH-funded tools. As articulated by the policy, imposing reach-through royalty terms as a condition of use of a research tool is inconsistent with this principle. When transferring an NIH-funded research tool to a for-profit entity that intends to use the tool for its own internal purposes, Recipients are entitled to capture the value of their invention. Arrangements such as execution or annual fees are an appropriate way for Recipients to do so. Royalties on the sale of a final product that does not embody the tool, or other reach-through rights directed to a final product that does not embody the tool, discourage use of tools and are not appropriate in these circumstances. Royalties on the sale of final products are more appropriate to situations where a for-profit entity seeks to commercialize the tool, *e.g.,* by developing a marketable product or service, or incorporating the tool into a marketable product or service.

Appendix A Guidelines for Implementation

The final policy has been clarified with regard to NIH intent in attaching the more specific Guidelines to the general Principles. The Principles set forth the policy that NIH is issuing to its funding Recipients to assist them in fulfilling the dual obligations imposed by NIH grants policy with respect to the dissemination of unique research resources, and the Bayh-Dole Act with respect to utilization, commercialization and public availability of government funded inventions. These dual obligations must be thoughtfully managed. The Guidelines provide further information, model language, and suggested strategies for implementing the principles. The model language and strategies provided by the Guidelines are not intended as the sole means by which Recipients may implement the articulated Principles. It is the nature of advancing science and technology to present unique factual circumstances, and NIH expects that Recipients will determine the most appropriate means to achieve the Principles for unique technologies when the Guidelines do not provide a workable strategy.

Several commenters suggested that research tools be better defined and that more examples be used to assist in determining whether the policy should be applied and if so, what licensing strategy is appropriate. For example, one commenter suggested that the policy draw a distinction between ''broad platform technologies'' and ''product-specific technologies'' when determining whether an exclusive license is appropriate. The final policy provides clarification of the criteria that Recipients might apply in determining how to handle a particular technology.

One commenter requested that the definition of research tools be expanded to include diagnostic genetic tests performed with ''home-brew'' reagents. The commenter suggested that the patenting and exclusive licensing of such tests is having a deleterious effect on clinical education, clinical research, and patient care. NIH declines to expand the definition of research tools to include diagnostic genetic tests. Where such tests are patented and licensed to for-profit entities, academic medical centers wishing to use such licensed tests in their clinical programs should negotiate terms of use with the commercial licensee.

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.

Dated: December 14, 1999.

Maria C. Freire,

Director, Office of Technology Transfer, National Institutes of Health.

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 potential 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 distinguishing 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.

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.

[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 CFR Part 46.

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 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 MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider Information and Authorized Signature

Provider Scientist: _____
Provider Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____
Certification of Authorized Official: This Simple Letter Agreement ____ has ____ has not [check one] been modified. If modified, the modification are attached.

_____
(Signature of Authorized Official) (Date)

Recipient Information and Authorized Signature

Recipient Scientist: _____
Recipient Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____
Signature of Authorized Official: _____
Date: _____
Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____
(Recipient Scientist) (Date)

Ensuring Consistent Obligations

Recipients must ensure that obligations to other sources of funding of projects in which NIH funds are used are consistent with the Bayh-Dole Act and NIH funding requirements. Unique research resources generated under such projects are expected to be made available to the research community. Recipients are encouraged to share these Guidelines with potential co-sponsors. Any agreements covering projects in which NIH funds will be used along with other funds are expected to contain language to address the issue of dissemination of unique research resources. Examples of possible language follow. The paragraphs are presented in a ''mix and match'' format:

''The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely distributed.''

''In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions that ensure that the research tool will be

available to the academic research community on reasonable terms.''

''Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials (or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider's independent intellectual property rights.''

''Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights: * * *''

Limiting Exclusive Licenses to Appropriate Field of Use

Exclusive licenses for research tools (where no further research and development is needed to realize the invention's usefulness as a tool) should generally be avoided except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available. When an exclusive license is necessary to promote investment in commercial applications of a subject invention that is also a research tool, the Recipient should ordinarily limit the exclusive license to the commercial field of use, retaining rights regarding use and distribution as a research tool. Examples of possible language include:

''Research License'' means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture, distribution, or provision of services, or in lieu of purchase, or for developing a directly related secondary product that can be sold. Licensor reserves the right to grant such nonexclusive Research Licenses directly or to require Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, Licensor shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of the materials.''

''Licensor reserves the right to provide the Biological Materials and to grant licenses under Patent Rights to not-for-profit and governmental institutions for their internal research and scholarly use.''

''Notwithstanding anything to the contrary in this agreement, Licensor shall retain a paid-up, nonexclusive, irrevocable license to practice, and to sublicense other not-for-profit research organizations to practice, the Patent Rights for internal research use.''

''The grant of rights provided herein is subject to the rights of the United States government pursuant to the Bayh-Dole Act and is limited by the right of the Licensor to use Patent Rights for its own research and educational purposes and to freely distribute Materials to not-for-profit entities for internal research purposes.''

''Licensor reserves the right to supply any or all of the Biological materials to academic research scientists, subject to limitation of use by such scientists for research purposes and restriction from further distribution.''

''Licensor reserves the right to practice under the Patent Rights and to use and distribute to third parties the Tangible Property for Licensor's own internal research purposes.''

Guidelines for Acquiring Research Resources for Use in NIH-Funded Research

Prompt Publication

Agreements to acquire materials for use in NIH-funded research are expected to address the timely dissemination of research results. Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results. A delay of 30–60 days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable.

Definition of Materials

Under the Bayh-Dole Act and its implementing regulations, agreements to acquire materials for use in NIH-funded projects cannot require that title to resulting inventions be assigned to the provider. For this reason, definitions of ''materials'' that include all derivatives or modifications are unacceptable. Other unacceptable variations include definitions of ''materials'' that include any improvements, or any other materials that could not have been made without the provided material. Conversely, it is important for providers of materials to be aware that a Recipient does not gain any ownership or interest in a provider's material by virtue of the Recipient using the material in an NIH-funded activity. Examples of acceptable definitions for ''materials'' include:

'' 'Materials' means the materials provided as specified in this document.''

'' 'Materials' means the materials provided as specified in this document. Materials may also include Unmodified Derivatives of the materials provided, defined as substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original materials, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.''

'' 'Materials' means the materials provided as specified in this document. Materials may also include Progeny and Unmodified Derivatives of the materials provided. Progeny is an unmodified descendant from the original material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.''

'' 'Materials' means the materials being transferred as specified in this document. Materials shall not include: (a) Modifications, or (b) other substances created by the recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives. Progeny is an unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original Material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original Material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.'' [Source: Uniform Biological Materials Transfer Agreement; terms defined therein]

Ensuring Consistent Obligations

Recipients are expected to avoid signing agreements to acquire research tools that are likely to restrict Recipients' ability to promote broad dissemination of additional tools that may arise from the research. This might occur when an agreement gives a provider an exclusive license option to any new intellectual property arising out of the project. A new transgenic mouse developed during the project could fall under this license option and become unavailable to third party scientists as a result. Examples of agreements to examine include material transfer agreements (MTAs), memoranda of understanding (MOU), research or collaboration agreements, and sponsored research agreements. Recipients should consider adopting standard language to place in such agreements to address this issue. The following are examples of possible language to include in MTAs, sponsored research agreements, and other agreements that either acquire materials from or co-mingle funds with non-government sources. The paragraphs are presented in a ''mix and match'' format:

''The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that after publication, unpatented unique research resources arising out of this project may be freely distributed.''

''In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions which insure that the research tool will be available to the academic research community on reasonable terms.''

''Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials (or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider's independent intellectual property rights.''

''Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights: * * *''

Grantbacks and Option Rights

• Agreements to acquire materials from for-profit entities for use in NIH-funded research may provide a grant back of non-exclusive, royalty-free rights to the provider to use improvements and new uses of the material that, if patented, would infringe any patent claims held by the provider. They may also provide an option for an exclusive or non-exclusive commercialization license to new inventions arising directly from use of the material. These should be limited to circumstances where the material sought to be acquired is unique, such as a patented proprietary material, and not reasonably available from any other source. A non-exclusive ''grant-back'' might be used, for example, to protect a for-profit entity that provides a proprietary compound from being blocked from using new uses or improvements of that compound discovered during the NIH-funded project. In providing license options, Recipients must ensure that licenses granted to providers under such options are consistent with Bayh-Dole requirements, including the preference for U.S. industry requirements and reservation of government rights under 47 CFR part 401.

• In determining the scope of license or option rights that are granted in advance to a provider of materials, Recipient should balance the relative value of the provider's contributions against the value of the rights granted, cost of the research, and importance of the research results. The rights granted to providers should be limited to inventions that have been made directly through the use of the materials provided. In addition, Recipients should reserve the right to negotiate license terms that will ensure: (1) continuing availability to the research community if the new invention is a unique research resource; (2) that the provider has the technical and financial capability and commitment to bring all potential applications to the marketplace in a timely manner; and (3) that if an exclusive license is granted, the provider will provide a commercial development plan and agree to benchmarks and milestones for any fields of use granted.

• It is expected that agreements to acquire NIH-funded materials from not-for-profit entities for use in NIH-funded research will not include commercialization option rights, royalty reach-through, or product reach-through rights back to the provider. Such materials should be acquired under the Simple Letter Agreement or UBMTA, or, if the materials are patented,a simple license agreement that does not request reach-through to either future products or royalties. If the providing not-for-profit organization is constrained in sharing the material due to a pre-existing sponsored research agreement or license, NIH expects that not-for-profit provider to negotiate a suitable resolution with the private research sponsor or licensee. The co-mingling of NIH and sponsored research funds is allowed, however, Recipient is responsible for ensuring that conditions on the use of the sponsored funds do not interfere with the open dissemination of research tools.

[FR Doc. 99–33292 Filed12–22–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Center for Substance Abuse Prevention (CSAP) National Advisory Council in January 2000.

The meeting will be open. The agenda will include presentations and updates on CSAP's programs, the SAMHSA Administrator's Report, a CSAP budget update, and discussions of administrative matters and announcements. If anyone needs special accommodations for persons with disabilities, please notify the contact listed below.

A summary of this meeting, a roster of committee members, and substantive program information may be obtained from the contact listed below.

Committee Name: Center for Substance Abuse Prevention National Advisory Council

Meeting Dates: January 10, 2000, 9 a.m.–5 p.m. (Open)

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20841.

Contact: Yuth Nimit, Ph.D., 5600 Fishers Lane, Rockwall II Building, Suite 901, Rockville, Maryland 20857, Telephone: (301) 443–8455.

Dated: December 17, 1999.

Sandra Stephens,

Acting Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 99–33306 Filed 12–22–99; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4432–N–51]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, room 7266, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR Part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled