Ferric Citrate

Ferrous Citrate

II. Current Monographs to which the Committee Proposes to Make Revisions

Calcium Citrate (reduce the lead limit and revise the fluoride limit test to an ion-selective electrode procedure)

Cellulose Gum (change the identification tests and heavy metals procedures)

Diatomaceous Earth (modify the description and the pH specification to include acid-washed powders)

Magnesium Phosphate, Tribasic (change the assay procedure, reduce the lead and heavy metals limits)

Nickel (revise the assay procedure for sponge nickel catalyst to provide sufficient complexing agent, dimethylglyoxime)

Sodium Erythorbate (add specification for loss on drying)

Sucrose (reduce lead limit)

Terpene Resin, Synthetic (delete the arsenic specification, revise the saponification value test)

III. Proposed New General Analytical Procedure

Total Unsaturation (replace method with one using Fourier transform infrared multivariate analysis)

Interested persons may, on or before July 9, 1999, submit to NAS written comments regarding the monographs and general analytical procedure listed in this notice. Timely submission will ensure that comments are considered for the second supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the second supplement, but will be considered for subsequent supplements or for a new edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs or the general analytical procedure listed in this notice are to be submitted to NAS (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. NAS will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–13092 Filed 5–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Request for Comments

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

ACTION: Notice.

Introduction: The National Institutes of Health (NIH) is seeking comments on a proposed policy entitled SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. This policy represents part of the overall implementation of recommendations made by the Advisory Committee to the Director (ACD) to Dr. Harold 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: This policy is a two-part document, consisting of Principles to set forth the fundamental concepts and Guidelines to provide specific information to patent and license professionals 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 (importing 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.

Request for Comments: NIH is seeking comment not only from NIH grantees, but from the full range of academic, not-for-profit, government, and private sector participants in biomedical research and development. Widespread comment and participation by varied stakeholders in the biomedical research and development enterprise is critical if these Principles, and their implementing Guidelines, are to be effective in guiding the interactions of NIH funding recipients with these sectors. 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.

The NIH welcomes public comment on the full text of the Principles and Guidelines, set forth below. Comments should be addressed to: Research Tool Guidelines Project, Ms. Barbara M. McGarey, J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325 Rockville, MD 20852–3804. Comments may also be sent by facsimile transmission to the Research Tool Guidelines Project, Ms. Barbara M. McGarey, at (301) 402–3257, or by e-mail to nihott@od.nih.gov.

DATES: Comments must be received by NIH on or before August 23, 1999.

Dated: May 18, 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

[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

Continued

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 assist them to achieve the appropriate balance. This two-part document, consisting of Principles to set forth the fundamental concepts and Guidelines to provide specific information to patent and license professionals for implementation, represents that guidance.

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.

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 or contracts (''Recipients'') have an obligation to preserve research freedom 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.

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 (Public Law 96–517). Generally, Recipients must 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.

Restrictive licensing, especially when coupled with indiscriminate use of the patent system, can be antithetical to the goals of the Bayh-Dole Act, such as where these are employed primarily for financial gain. Utilization, commercialization and public availability of technologies that are useful primarily as research tools rarely require patent protection; further research, development and private investment are not needed to realize their usefulness as research tools. In such cases, the goals of the Act can be met through publication, deposit in an appropriate databank or repository, widespread non-exclusive licensing for nominal or cost-recovery fees, or any other number of dissemination techniques.

In addition, commercialization and product development becomes more encumbered as the number of stakeholders laying claim to prospective revenues increases. Proprietary rights in research tools that do not require further development may function more as a tax on commercial development than as a source of rights to preserve the viability of end products and to motivate further investment. While such a tax may benefit the public by providing a financial return on the research investment, it may not always represent the appropriate valuation of a research tool and therefore serve as a disincentive to private sector use of the invention.

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.

Recipients should also examine and, where possible and 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. Recipients are encouraged to transfer research tools developed with NIH funding to for-profit institutions with the fewest encumbrances possible in instances where the for-profit institution is seeking access for internal use purposes. Examples of such internal uses are research, screening, and the use of methods or devices for product development.

Where they have not already done so, Recipients should develop and implement clear policies which articulate acceptable conditions for importing 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.

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.

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 conducting further research, advancing science and serving as the new standard which itself will be improved upon and ultimately replaced. This is accomplished by wide distribution on a nonexclusive basis, although wide distribution on reasonable terms by an exclusive distributor may meet these objectives as well. 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 must 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. For example, a Recipient might co-mingle NIH funds with funds from one or more third party sponsors, or import 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.

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 to patent and license professionals at Recipient institutions for implementing the Principles on Obtaining and Disseminating Biomedical Resources.

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

• Recipients must ensure that unique research resources arising from NIH funded research are made available to the scientific research community. Although some licensing of research tools to for-profit companies is necessary and appropriate, the majority of transfers, to both not-for-profit entities and 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 of the UBMTA (text below), or other comparable 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 such as a simple license agreement may be used, but commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate.

Simple Letter Agreement for Transfer of Non-Proprietary Biological Material

PROVIDER

Authorized Official: _____

Organization: _____

Address: _____

RECIPIENT

Authorized Official: _____

Organization: _____

Address: _____

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

1. The above BIOLOGICAL MATERIAL is the property of the provider and is made available as a service to the research community.

2. The BIOLOGICAL MATERIAL will be used for teaching and academic research purposes only.

3. The BIOLOGICAL MATERIAL will not be further distributed to others without the PROVIDER'S written consent. The RECIPIENT shall refer any request for the BIOLOGICAL MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the BIOLOGICAL MATERIAL available, under a separate Simple Letter Agreement, to other scientists (at least those at nonprofit organizations or government agencies) who wish to replicate the RECIPIENT SCIENTIST'S research.

4. The RECIPIENT agrees to acknowledge the source of the BIOLOGICAL MATERIAL in any publications reporting use of it.

5. Any BIOLOGICAL MATERIAL delivered pursuant to this simple letter 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 BIOLOGICAL MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the BIOLOGICAL MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

6. The RECIPIENT agrees to use the BIOLOGICAL MATERIAL in compliance with all applicable statutes and regulations, including, for example, those relating to research involving the use of human and animal subjects or recombinant DNA.

7. The BIOLOGICAL 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: [insert fee].

The RECIPIENT and the RECIPIENT SCIENTIST should sign both copies of this letter and return one signed copy to the PROVIDER SCIENTIST. The PROVIDER will then forward the BIOLOGICAL MATERIAL.

PROVIDER SCIENTIST

Organization: _____

Address: _____

Name: _____

Title: _____

Signature: _____

Date: _____

RECIPIENT SCIENTIST

Organization: _____

Address: _____

Name: _____

Title: _____

Signature: _____

Date: _____

RECIPIENT ORGANIZATION APPROVAL

Authorized Official: _____

Title: _____

Address: _____

Signature: _____

Date: _____

[Source: 60 FR 12771, March 8, 1995]

• Recipients must ensure that obligations to other sources of funding of projects in which NIH funds are co-mingled 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, which requires that unique research resources arising out of NIH-funded research be made widely available to third parties for further research. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely redistributed.''

''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 401, the PHS Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights:
* * *''

• Exclusive licenses for research tools should generally be avoided except in cases where the licensee undertakes to make the research tool widely available at moderate cost 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 Licensee to grant nonexclusive Research 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 above to the contrary, 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 and 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 Importing Research Resources for Use in NIH-Funded Research

• Agreements importing 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 thirty days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable.

• Under the Bayh-Dole Act and its implementing regulations, agreements importing 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 all modifications are unacceptable. 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 material, 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 material 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]

• Recipients are expected to avoid signing agreements to import 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 import 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, which requires that unique research resources arising out of NIH-funded research be made widely available to third parties for further research. Provider agrees that after publication, unpatented unique research resources arising out of this project may be freely redistributed.''

''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 401, the PHS Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights:
* * *''

• Agreements importing 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 license to new inventions arising directly from use of the material. These should be limited to circumstances where the material sought to be imported 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 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 37 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 contribution 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 importing NIH-funded materials from not-for-profit entities for use in NIH funded research will not provide commercialization option rights, royalty reach-through, or product reach-through rights back to the provider. Such materials should be imported under the 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 the 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 the sponsored funds do not interfere with NIH funding requirements such as open dissemination of research tools.

[FR Doc. 99–13044 Filed 5–24–99; 8:45 am]

BILLING CODE 4140–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Special Emphasis Panel I; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in June 1999.

A summary of the meetings and a roster of the members may be obtained from: Ms. Coral Sweeney, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–2998.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: June 28–30, 1999.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: June 28–29, 1999, 8:30 a.m.–5:00 p.m., June 30, 1999, 8:30 a.m.–adjournment.

Panel: Substance Abuse and Mental Health Services Administration Basic Action Grant–I, Hispanic Priority SM 99–007.

Contact: Raquel Crider, Room 17–89, Parklawn Building, Telephone: 301–443–5063 and FAX: 301–443–3437 or Amie Rogal, Room 17–89, Parklawn Building, Telephone: 301–443–8216 and FAX: 301–443–3437.

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: June 23–25, 1999.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: June 23–24, 1999, 8:30 a.m.–5:00 p.m.; June 25, 1999, 8:30 a.m.–adjournment.

Panel: Substance Abuse and Mental Health Services Administration Family Strengthening Coordinating Center SP 99–002.

Contact: Peggy Riccio, Room 17–89, Parklawn Building, Telephone: 301–443–9996 and FAX: 301–443–3437.

Dated: May 18, 1999.

Coral Sweeney,

Substance Abuse and Mental Health Services Administration.

[FR Doc. 99–13153 Filed 5–24–99; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Special Emphasis Panel I; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in June 1999.

A summary of the meeting and a roster of the members may be obtained from: Ms. Coral Sweeney, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–2998.

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Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: June 14–17, 1999.