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: [insert fee]_____

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 modifications 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*

- 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 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 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 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]

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 37 C.F.R. 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 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 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 conditions on the use of the sponsored funds do not interfere with the open dissemination of research tools.

December 1999

保健福祉省

国立衛生研究所

生物医学研究リソース取得・普及に関する
NIH 研究助成契約の助成金受給者ための原則およびガイドライン
最終報告書

機関名：国立衛生研究所（NIH）、公衆衛生総局、保健福祉省（DHHS）

概略：1999 年 5 月 25 日、国立衛生研究所（以下 NIH という。）は、一般からの意見を求めるために、「生物医学的研究リソースの共有」と題した、NIH 研究契約の助成金受給者に関する方針案を連邦官報に発表した（連邦官報 64 巻 28205）。本方針は、ＮＩＨ資金受給者に対して連邦政府資金を利用して開発された独自の研究リソースの普及・取得に関する適切な条件についてのガイドラインを提供するものであり、かつ、受給者がバイ・ドール法やＮＩＨ資金方針に基づく義務を守ることができるよう支援することを目的とする。本原則およびガイドラインに対する（一般からの）意見は、1999 年 8 月 23 日までに提出するよう求められた。本報告書は、最終原則およびガイドライン、ならびに、一般からの意見に対する NIH の回答を記載している。

背景

本方針は、所長の諮問委員会（ACD）から NIH 所長、Dr. Harold Varmus に対してなされた勧告の総合的な実施計画の一部を表している。Dr. Varmus は、ACD の作業グループが財産的価値を有する研究ツールの普及・利用に際し生じる問題、およびそれらの問題に内在する知的財産権所有者と研究ユーザの利害の対立ならびに NIH としての回答案を検討するよう要請した。報告書中の勧告の 1 つが、NIH はＮＩＨ資金の受給者に対してガイドラインを発行すべきというものであった。

目的

方針は 2 部構成であり、基本概念を記載した原則部分と特許権・ライセンス専門家や委託研究管理者に対する実施のための情報を提供するガイドライン部分から分かれている。