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ＮＩＨのマテリアルに関するガイドライン

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ＮＩＨのマテリアルに関するガイドライン

１．概要

このガイドラインは、"PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF ＮＩＨ RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES"との名称で1999年12月23日に発行された。このガイドラインは、ＮＩＨの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・取得を図るための適切な条件についての指針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している。

２．内容

２－１　対象

「Research Resource」という用語を使用しているが、これは研究者が実験室で使用するツール全てを意味するものである。例えば、細胞株、単クローン抗体、試薬、動物モデル、成長要因、結合化学およびDNAライブラリ、クローンおよびクローニング・ツール（PCR（ポリメラーゼ連鎖反応法）など）、メソッド、実験室機器および機械などを含む。これは、「Research Tool」や「Material」と同じ意味で使われている。

２－２　原則

（１）　学問の自由および公開の保証

ＮＩＨからの研究資金を受けている受給者は、研究の自由を維持し、著作を適切に保護し、研究者が出版物または科学学会の発表などを通して自身の研究結果を適時に開示することを保証する義務を負う。

（２）バイ・ドール法の適切な実施の保証

受給者が発明に対する権利を取得する場合、当該発明の活用、商業化および一般への開放を促進する義務を伴う。バイ・ドール法は受給者に対し、上記の義務を履行する方法の１つとして、助成の対象となる発明につき特許権およびライセンスを取得することを促している。ただし、特許権および排他的ライセンスを利用することは、バイ・ドール法を実施する唯一の方法ではなく、場合によっては最も適切ではないこともある。対象発明が主に研究ツールとして有用な場合、不適切なライセンス慣行は、発明の活用、商業化および一般への開放を促進するというより、むしろそれを妨げる。

そこで、主に研究ツールとして活用するために知的財産権に関する戦略を決定する場合、受給者は、研究、開発および民間投資が有用性を実現するためにさらに必要か否かを評価すべきである。否定的な結論が出た場合、バイ・ドール法の目標は、公開、適切なデータバンク等での保管、広範囲の被排他的ライセンス付与または他の普及方法を通して達成することが可能である。ただし、営利目的のスポンサーに対しては排他的な内部使用に限るなど、当該発明のライセンスを制限的に許諾することは、バイ・ドール法の目標に反する。

（3）学術的研究に対する行政干渉の最小化

移転契約時協議を繰り返して研究ツールの使用時期を遅延させることを防ぐために手続きを簡略化して、略式契約やカバーレター、統一バイオ材料移転契約（UBMTA）のシンプル・レター契約やUBMTAを利用して、合理的な手段を講ずるべき。受給者は、リソースを取得する際に、受け入れられる条件、受け入れられない条件はそれに従うことを拒否する明確な方針を作成し実施すべきである。

営利団体は、自身のツールを非営利団体が学問的に利用する場合に非営利団体に対して課す負担を最小限にしなければならない。

（4）研究リソースの普及の保証

ＮＩＨの助成研究から生まれた研究リソースは、科学界に解放すべきである。

受給者は、ＮＩＨ資金に基づき開発した材料を営利的機関に対してその社内使用のために移転することを検討し、適切な場合には、それを簡略化する。ＮＩＨは、営利的機関による社内利用を商業開発およびサービスの販売・提供から区別することを勧めている。営利的機関がその社内利用の目的で利用を求めている場合、受給者は当該機関に対して、ＮＩＨ資金に基づき開発した研究ツールをオプション権または最終製品に対するロイヤルティを要求せずに移転することが望ましい。

2－3 ガイドライン（ＮＩＨの助成研究から生まれた研究リソースの普及のため）

（1）研究ツール定義

研究リソースの取扱いを決定する際に、受給者は、次の事項について検討を行い、いずれかに該当するリソースについての自身の知的財産権戦略は、当該リソースの最終的利用可能性を制限せず、むしろそれを高めるものであることを保証すべきである。

- リソースの主な有用性は、FDA承認製品または当該製品の不可欠な構成部分ではなく、発見のためのツールであるか
- リソースは、広範囲にわたり、プロジェクトまたは製品の特定のリソースというより、多くの研究者（または複数の製品を開発する複数の会社）に有用な発明を可能にするものか
- リソースの開発または配布のために最も適切な方法として民間セクターが関与することが必要である状況というよりむしろ、リソースは、ツールとしてすぐに実用化でき、配布することができるものであるか

（2）シンプル・レター契約の利用

非営利団体への移転は、UBMTA と同程度の制限条件に基づき行うべき。特に、受給者は、シンプル・レター契約または同程度の制限的条件に基づく他の文書を利用し、ＮＩＨ資金に基づき開発したツールで特許を受けていないものを他の受給者がＮＩＨ助成プログラムに利用する場合に当該受給者に対し移転することを容易にすることが望ましいとされる。

材料の特許権またはライセンスがプロバイダに排他的に帰属する場合、他の契約を利用する

ことができるが、商品化に関するオプション権、リーチスルーのロイヤルティまたはリーチスルーの製品権をプロバイダに戻すことは適切ではない。

営利団体がその内部使用のためにＮＩＨ助成ツールの利用を求めている場合、受給者は、可能な限り最小の負担にてツールを移転することを保証するべきである。ツールの営利団体への譲渡の際にシンプル・レター契約をさらに拡張することができ、または内部使用の簡単なライセンス契約の締結もしくは年間使用料を徴収するライセンス契約が適当である。

（3）義務が両立することの保証

受給者は、ＮＩＨ資金が使用されているプロジェクトにおいて他の基金から受給している場合にはその基金に対する義務がバイ・ドール法およびＮＩＨ資金の要件と矛盾しないことを保証しなければならない。

（4）排他的ライセンスを適切な使用分野に限定

研究ツール（発明のツールとしての有用性を実現するために研究および開発が更に必要とされない場合）に関する排他的ライセンスは、原則として差し控えるべき。ライセンシーが制限のない配布を通して研究ツールを広く研究者に利用させる義務を負う場合またはライセンサーが研究ツールを広く利用させる権利を有する場合はこの限りでない。研究ツールでもある助成対象発明の商品化に対する投資を促進するために排他的ライセンスが必要となる場合、受給者は、研究ツールとしての使用および配布に関する権利を留保して、通常は排他的ライセンスを商業的使用分野に制限すべきである。

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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 Guidelines 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. 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:

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*.

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 rants 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 as 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 or 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.