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Materials Transfer in Academia

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Questions and Answers

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Council on Governmental Relations

The Council on Governmental Relations (COGR) is an association of leading research-intensive universities. COGR's primary function consists in helping to develop policies and practices that fairly reflect the mutual interests and separate obligations of federal agencies and universities in federal research and training. COGR deals primarily with policies and technical issues involved in the administration of federally-sponsored programs at universities. It keeps under continuing review the problems potentially inherent in the development of federal policies, regulations, and other federal initiatives.

This brochure attempts to provide relevant information about the transfer of materials in academia. It does not claim to be a manual of university technology transfer, nor does it offer model policies. This brochure should not be taken as formal legal advice, and COGR cannot and does not warrant the legal sufficiency of the answers to the questions discussed in the brochure.

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Introduction

The transfer of materials and research tools is an essential aspect of scientific research. The types of materials exchanged are varied and are utilized in all areas of research including chemistry, biology, physics, computer science, and engineering but the vast majority of these transfers occur in the life sciences. Although this brochure will focus on transfers of biological materials, most of the concepts and issues discussed are relevant to all forms of material exchanges.

A transfer between provider and recipient may serve to facilitate the confirmation of research findings or may provide a unique material to further a new line of investigation. The open exchange of commonplace and nonproprietary materials between academic scientists usually occurs without risk or concern. When the material is of a unique or proprietary nature, the provider may wish to preserve its control of how the material is used and limit its further distribution. This is most common when the providing organization is a commercial, for-profit company.

A materials transfer agreement (MTA) is the contractual instrument used to define the terms and conditions for the exchange of materials. While MTAs are not funding agreements, many of the issues usually associated with a research contract can apply to these transfers and can have a dramatic impact on future research efforts. An MTA typically sets forth rights to use the materials

and may allocate rights that result from their use. Often MTAs address such issues as publication, involvement of students, limitations on the use of the materials, and the intellectual property rights of the provider and the recipient in the results of the research in which the materials are used.

Transfers from industry to academia are complicated due to the different objectives of the two parties. From the perspective of industry, no transfer can be made that will compromise the company's interest in a proprietary product. This may lead to MTA terms that substantially restrict use of the materials and give the company all rights to any new invention that results from their use. Academia, on the other hand, cannot compromise its objective to disseminate knowledge widely to the scientific community. Because of these differing objectives, universities often need to negotiate the MTA terms to ensure that they do not undermine the university's mission.

Given that money is rarely associated with these transfers, MTAs may be perceived by some to be inconsequential transactions. However, they are binding legal agreements that can impact a researcher's current and future research. Thus, it is important that researchers and administrators alike understand the issues and complexities involved in these transfers, especially given the large volume of MTAs that are being negotiated in the research community. While standard MTA

agreements (e.g., Uniform Biological Material Transfer Agreement (UBMTA) and the National Institutes of Health's (NIH) recommended Simple Letter Agreement) exist, MTAs with widely varying terms and conditions have proliferated, particularly between universities and industry.

We hope that that the "Twenty Questions and Answers" format of this brochure will assist the university administrator and/or the academic researcher in understanding some of the critical issues arising under these legal agreements and promote greater standardization of MTA terms and conditions.

University administrators and researchers should acquaint themselves with their institutions' policies and procedures governing material transfers and should obtain assistance from the appropriate university office to negotiate MTA terms and conditions. Because the MTA does not usually provide funding for the research utilizing the transferred materials, the MTA often needs to be reviewed jointly with any pre-existing funding agreements in order to ensure that the terms of these agreements do not conflict with one another. NIH's *Principles and Guidelines* (see Question 16 for more details) provides additional guidance to recipients of NIH funding with respect to transferring research materials and tools.

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Questions and Answers

1

Under what circumstances is an MTA needed?

The provider of material or data may feel an MTA is needed in the following circumstances:

- The material and/or information is proprietary;
- The material or information is being maintained as a trade secret;
- The material is infectious, hazardous or subject to special regulations;
- The provider is concerned about potential liability; and/or
- The provider wishes to obtain rights to the results of the research in which the material or information is to be used.

2 From the University perspective, what MTA terms frequently raise problems?

Universities typically avoid terms that:

- Restrict academic freedom, such as restrictions on publication;
- Assert excessive rights of ownership in the research results;
- Ask for inappropriate indemnification by the university; and/or
- Create conflicting obligations (with other sources of funds or materials).

3 How do agreement terms restrict academic freedom?

The most problematic restriction on academic freedom is a limitation on the ability to publish the results of research in a timely manner. This is of particular significance because dissemination of information is an integral and required aspect of the institution's existence as a non-profit entity. Many agreements, especially those from for-profit providers, require the investigator to provide an advance copy of any manuscript or proposed public disclosure of results obtained with the material. Generally speaking, this requirement is not unreasonable provided it does not result in an excessive delay. However, more restrictive publication provisions may be unacceptable. For example, the provider may seek the right to approve publications, to have unrestricted pre-publication editorial rights, or to impose excessive publication delays. In addition, as discussed in greater detail below, granting the provider certain ownership rights in the results of the research may also limit the recipient's ability to publish, to continue research, or to utilize the fruits of research freely.

Signing agreements with restrictions on the right to publish or the ability to conduct future research can have catastrophic effects. As an example of the problems associated with such restrictions, consider the graduate or postdoctoral student whose research project is linked with the transfer of a material received under an MTA. If that MTA prevents or impedes their ability to publish — especially a

thesis or dissertation — or to use the research results to continue a line of inquiry, it may dramatically alter the course of their career. To ensure that providers cannot impose such limitations, universities typically have policies that prohibit these restrictions. Universities frequently face the challenge of aligning these policies with limitations that industry seeks to impose.

4

Why is there concern about ownership rights?

Some providers attempt to require that recipients and users of their materials relinquish all claims to ownership of any new materials created by the recipient or inventions made through the use of the provided materials. This requirement may apply regardless of whether creation of the new materials is dependent on the use of the provided materials. This not only represents a loss of intellectual property rights, but also may prevent the recipient from continuing a line of inquiry because he/she no longer has the right to use his/her research results. Relinquishing ownership of inventions and copyrights can have potential repercussions beyond the loss of the right to use research results. The university has a duty to ensure the broadest possible application of its research in the public interest. Failing to retain ownership of intellectual property makes it unlikely that the university can meet this obligation. In addition, when federal funding is or may be involved, the university must ensure it can meet its obligations under the Bayh-Dole Act [*PL 96-517*]. For this reason MTAs must acknowledge the rights of the federal government regarding inventions and copyrighted materials that may be made with the material.

What is meant by "reach-through rights" and when are they justified?

5

Reach-through rights can mean different things. In exchange for the material, the recipient must:

- grant the provider licenses or options to improvement or modifications of the material or to inventions made in the course of the research in which the material is used; or
- pay fees or royalties on products discovered through the use of the material even though the material is not part of the product or necessary to manufacture the product.

The first example is common in transfers of material from a for-profit to a non-profit; the company feels it is providing something of value and thus should get something in return. The issue for the university is whether the rights granted are reasonable under the circumstances.

The second example relies on the "but for" principle — but for the use of the provided materials, a development would not have been made and thus the provider feels entitled to share in the proceeds of the commercialization of the resulting development. In its *Principles and Guidelines* regarding research tools, NIH is clear that NIH-funded research tools should be provided to other non-profit entities without such reach-through rights. When transferring NIH-funded research tools to for-profit entities for their internal research use,

NIH encourages grantees to do so without seeking royalties on such "but for" products.

The NIH *Principles and Guidelines* offers examples of language regarding reach-through rights that could be included in MTAs and in sponsored research agreements with for-profit sponsors to accomplish the intent of the *Principles and Guidelines* as well as to meet the spirit of the Bayh-Dole Act.

6 What Are Some Desirable Definitions of Terms in Biological MTAs?

Material: Strictly speaking, the physical substance being transferred. However, providers may seek to include other items, including other forms of the material which may arise from modifications of the material made in the recipient laboratory (see below: Progeny, Unmodified Derivatives, and Modifications).

Progeny: Generally defined as the descendant copies of the material that are produced in the recipient laboratory as a result of replication (e.g., cell division, DNA copying). The implication is that progeny material is an essentially unchanged copy of the originally provided material, and thus is appropriately provider-owned.

Unmodified Derivatives: Usually means products of the originally transferred material (e.g., monoclonal antibodies secreted by a hybridoma cell line or parts of the original material), and these are also considered to be provider-owned. When the term "derivatives" is used in a contract, it should be clarified whether or not this term includes more than unmodified derivatives.

Modifications: Typically means modified derivatives (cf.: Unmodified Derivatives) of the original material (e.g., an original provider-owned DNA molecule or a fragment thereof newly embedded in a recipient-owned expression vector and using a recipient-owned promoter). Modifications with new utility that

include material from both the provider and the recipient may be inventions with ownership vesting solely with the recipient or in both the provider and the recipient as the specific facts indicate.

How is ownership of combination materials determined?

Equitable ownership of combination materials is determined in much the same way as ownership of any other physical property. For example, the owner of the expression vector with unique characteristics and the owner of the newly-cloned gene that is to be inserted into that vector are co-owners of the resulting engineered material. Similarly, when the owner of a catalyst collaborates with another party to produce a modified or specially processed form of the catalyst, joint-ownership may occur. It is common in such situations that the services of an experienced patent attorney will be utilized for an exact determination of the relative contributions of each party. Ownership of inventions, as opposed to physical materials, should be determined by U.S. patent law governing inventorship.

8 Is there an option for an institution to forego ownership rights?

Although it is possible under limited circumstances to have some flexibility when it comes to ownership of inventions and copyrights, investigators who are supported by awards from the federal government and their institutions are obligated to report inventions under the Bayh-Dole Act and its implementing regulations [*37 CFR 401*]. If title to inventions will not be claimed by the awardee institution, the government requires sufficient notice to be able to take title itself and file patents when warranted [*37 CFR 401.14(c) and (d)*]. Moreover, a non-profit organization may not assign title to an invention without the express approval of the funding agency except to an organization one of whose primary purposes is the management of inventions [*37 CFR 401.14(k)(1)]*. With respect to data or software first developed with government funding, the government obtains a royalty-free, non-exclusive, irrevocable, worldwide license to use, disclose, reproduce, prepare derivative works, and distribute copies for governmental purposes. Thus the institution cannot "give away" rights that it has previously agreed either to claim itself or grant to the federal government.

Even if permitted, waiving ownership to a third party may have a dramatic impact on the future research of the academic researcher, since it may be necessary for the researcher to secure a license in order to subsequently use the

invention or materials. In most cases the provider's concerns can be met through an appropriate license agreement, rather than the transfer of ownership. It also is important to recognize that journal publishers require that the author(s) make the materials described in their publications easily and reasonably available to other researchers in order for the published results to be verified. Without ownership and the ability to make the materials available to other researchers, a researcher's publication may not be accepted for publication.

9 What is indemnification, and what is the importance of limiting indemnification requirements?

Indemnification is the legal concept of assuming financial responsibility for certain acts and/or omissions arising under a contract. An MTA may require that the recipient institution indemnify the provider against any damage that may occur through use of the material. At a minimum, such liability should be limited to the recipient's own actions (i.e., any damage that may occur through the recipient's use of the material) and should exclude damages that result from the provider's negligence or unlawful actions. State institutions may be prevented by state law from even assuming this limited liability.

10 Why is it useful to use MTAs when materials are being sent to academic colleagues?

There are numerous issues that may be important to both the providing institution and the providing scientist that are appropriately handled through an MTA. Issues including liability, academic credit, loss of control of the material, and access to information have demonstrated the wisdom of using an MTA even with academic colleagues. In addition, in the rare instance where a dispute arises, a simple MTA can easily resolve a large percentage of disagreements. Occasionally, the material may be encumbered as the direct result of having arisen from sponsored research or having been exclusively licensed to another entity. An MTA is particularly important in these situations.

In any case, it is desirable that MTAs for transfers to academic colleagues be as unrestricted as possible. The use of the UBMTA or the NIH-recommended Simple Letter Agreement is highly recommended. For an excellent discussion of issues relating to data and materials sharing among researchers, see the report of the National Research Council of the National Academies on the "Sharing of Publication-related Data and Materials" at http://www.nap.edu/catalog/10613.html.

11 Can MTA agreements be expedited through standardization?

Some progress has been made in standardization. NIH, working with university representatives, developed the UBMTA and Simple Letter Agreement, both of which are suitable for transfers of materials among NIH-funded researchers and more generally for transfers between academic institutions. Over two hundred research institutions are signatories to the UBMTA and are able to execute material transfers with a simple implementing letter.

The UMBTA and the Simple Letter Agreement may not be appropriate when the material was made in an academic project supported by industry. In such cases, there may be obligations to the industry sponsor that are incompatible with those agreements. Unfortunately, standardization is unlikely for MTAs transferring materials from industry to academia since no one format is likely to address each company's vastly different policies, procedures, valuations, and objectives.

12 Who has the authority to sign MTA agreements?

All agreements that bind the university, including MTAs, must be signed by an officer of the institution having signatory authority. Agreements that are not signed by an authorized institutional official may not be valid and may make the signor personally responsible for any breach of the terms and obligations of the MTA. Additionally, since the researcher utilizing the materials is responsible for fulfilling most of the obligations under an MTA, it is recommended that he or she also sign the agreement, not necessarily as a party to the agreement, but as an acknowledgement of his or her duties under the agreement.

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Are MTA agreements ever enforced?

In the vast majority of transactions, the terms of the MTA will not need to be revisited and are merely the mechanism for obtaining the needed material. However, in those cases where a dispute arises or when the stakes are high, the terms of an MTA may be the subject of litigation. Even if no litigation occurs, the terms of the MTA will assist in adjudicating the dispute and properly apportioning credit and blame.

14 Is it reasonable to charge fees for the transfer of the material?

While the majority of material transfers occur without any associated fees, some MTAs do include a nominal charge to the recipient. This fee is generally calculated to offset the costs incurred by the provider in preparing and shipping the material (or animal) and may include, for example, the cost of materials, the extra labor required to make the material, and shipping and handling.

15 Are there other means of getting materials when the obstacle is time and effort?

There are two ways to handle a time and effort problem, neither involving an MTA:

- The materials may be suitable for deposit in a publicly-supported or user-fee-supported facility. For example, some cell lines may be accepted for maintenance and distribution by the American Type Culture Collection; or
- The right to make and distribute the materials at nominal cost may be licensed to a company that sells reagents to the research community. In this instance, the company becomes the provider, thus alleviating the researcher from the task of distribution.

What are the implications of NIH's "Principles and Guidelines..."?

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The "*Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*" defines expectations for NIH-funded recipients when exchanging biomedical research materials and tools; they are available at http://ott.od.nih.gov/NewPages/RTguide_final.html. Although originally issued as guidelines, they are now a condition of funding and arguably rise to the level of a contractual obligation. Under the *Principles and Guidelines*, scientists and institutions are expected to broadly disseminate tools that arise from NIH-funded research with as few encumbrances as possible. The *Principles and Guidelines* recognizes the difficult balance between NIH funding recipients' rights to disclose and publish their research findings, the right of the scientific community and public at large to access and share the research results, the right of providers to preserve proprietary rights to research tools, and the right of recipients to retain title to inventions made with NIH funds while assuring their utilization and commercialization for public benefit. The *Principles and Guidelines* implies a high level of diligence on the part of institutional officials both to educate and advise faculty and manage the process of disseminating and importing research tools. Institutions must carefully oversee interactions (such as industry-sponsored research agreements and exclusive licenses) that have the potential to restrict sharing and thereby contradict the *Principles and Guidelines*. It is also

worth noting that on May 28, 2003, the NIH published a draft policy on the sharing and distribution of mouse resources. The draft policy can be found at http://www.nih.gov/science/models/mouse/sharing/index.html. It encourages the timely sharing of mouse resources between researchers.

17 Are there special requirements for transferring human embryonic stem cells?

On August 9, 2001, President George W. Bush announced that federal funds may be used in research utilizing certain human embryonic stem (hES) cell lines, provided the cell lines are approved and meet certain established criteria. NIH created a Human Embryonic Stem Cell Registry that lists those stem cell lines meeting these eligibility criteria. As this is a recent and evolving topic, readers are advised to consult the NIH website http://www.nih.gov/news/stemcell/index.htm to obtain information about acquiring cells and the current policies and requirements.

NIH has negotiated materials transfer agreements for its intramural investigators with some hES cell providers. Academic investigators must arrange access to the hES cells directly through the supplying company or laboratory. NIH has asked approved hES cell providers to make cells available in accordance with the NIH *Principles and Guidelines*, and NIH recipients are advised to consider these guidelines when acquiring cells. NIH regulations on research with hES cells when utilizing federal funds can be found in the NIH *Guidelines for Research Using Human Pluripotent Stem Cells* http://www.nih.gov/news/stemcell/stemcellguidelines.htm.

18 Are there special requirements for transferring "special" biological material?

Yes. For example, the Convention on Biological Diversity of 1992 is principally concerned with the conservation of diverse ecological systems. However, it also contains certain provisions relating to the commercialization of genetic materials obtained from developing countries. This is an area that is still evolving, and not many institutions or countries have either experience or mechanisms in place to handle such arrangements. Researchers should call on the resources of their technology transfer offices, and for the immediate future, it will probably be useful to have the technology transfer professionals consult experienced colleagues for assistance in this area.

Additionally, the importation of some biological materials into the U.S. requires USDA permits. If the proper documentation does not accompany packages, the materials may be quarantined or otherwise delayed, and they may suffer damage in the process. It is better to determine early whether permits will be needed. USDA forms, if needed, are available on-line at <http://www.aphis.usda.gov/forms>. It also may be helpful for the researcher to consult the university's biosafety office for advice. See also the discussion below regarding laws and regulations governing exports and the transfer of hazardous biological materials.

19 Is an export license needed to transfer materials outside the United States?

Under U.S. export control laws, automatic licenses can apply to most biological materials. In some cases, however, a license may be required from the Bureau of Export Administration of the Department of Commerce or from the U.S. Department of State. There are, for instance, controls on the export of materials that could possibly be used in chemical or biological weapons. Examples given of such materials include human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens. The Export Administration Regulations (EAR) administered by the Commerce Department are at *15 CFR Parts 768-799*. The section covering the scope of materials covered is *15 CFR Part 742 Supplement No. 1(12)*. The International Traffic in Arms Regulations administered by the State Department are at *22 CFR Parts 120-130*. The list of regulated items is in *22 CFR Part 121*. An investigator planning to transfer materials which are controlled by the EAR or the ITAR outside the United States should work with the appropriate institutional staff person to obtain the required license. There are civil and criminal penalties for violating either the EAR or ITAR. Please also note that some highly hazardous biological materials may require multiple permits (e.g., for export from the U.S., and for import into another country).

20 Are there special regulations regarding the transfer of toxic biological agents?

Yes, there are laws and regulations covering possession, use, and transfer of certain biological agents and toxins that have the potential to pose a severe threat to public health and safety. Agents that pose a threat to human health (the so-called select agents) were initially regulated by the federal government in the Antiterrorism and Effective Death Penalty Act of 1996 [*PL 104-132*], which placed restrictions on the transfer of these agents and imposed record-keeping requirements on institutions that shipped or received them. The USA PATRIOT Act of 2001 [*PL 107-156*] restricted certain categories of individuals from possessing select agents and imposed criminal penalties. The Public Health Security and Bioterrorism Response Act of 2002 [*PL 107-188*] expanded these laws to include biological agents and toxins that affect plants and animals and regulated entities such as universities that use the listed agents in research.

The Centers for Disease Control and Prevention (CDC) of the U. S. Department of Health and Human Services and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture have issued Interim Final Rules governing the possession, use, and transfer of the listed biological agents and toxins to implement these laws. The effective date for the rules was February 7, 2003, although for institutions who were lawfully working with the select agents prior to that time, certain

provisions and requirements are phased in, with full compliance for both rules required by November 12, 2003. Both the CDC and APHIS websites include a set of Questions and Answers, which are amended periodically to respond to questions and comments about the Interim Rules from the research community. The rules are extensive and significant, and, among other things, require registration certificates for entities; background checks for responsible university officials, investigators, and others who have access to the listed agents; and security plans, training, and substantial record-keeping. Upon full implementation in November, 2003, these rules will supersede the previous regulations controlling transfer of the select agents. Transfer of the so-called overlap agents, those that are both human and animal pathogens, appear to require both notification of CDC and an APHIS permit. The COGR website will be periodically updated with information about the implementation of and issues arising under these new regulations.

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