2021

COGR

Council On Governmental Relations

Materials Transfer in Academia: 20 Questions and Answers

Released June 7, 2021

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INTRODUCTION

Council on Governmental Relations

The Council on Governmental Relations (COGR), established in 1948, is an association of almost 200 leading universities and research institutions and is nationally recognized as the technical expert on a wide range of research policy issues. For more information, please visit www.cogr.edu.

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. 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 approach is most common when the providing organization is a commercial, for-profit company or an academic provider who previously licensed the material to a for profit entity.

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 usually funded agreements, terms may include costs of preparation and shipping. Federal research sponsors may expect the materials to be listed as in-kind support with an associated dollar value and reported as other research support. Many of the challenges and concerns usually associated with a research contract can apply to material transfers and can impact 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, limitations on the use of the materials, and 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 often more complicated due to the different objectives of the two parties. From the perspective of industry, no transfer should be made that will compromise a company's interest in a proprietary product. This may lead to MTA terms that substantially restrict publication or 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 mission to disseminate knowledge widely to the scientific community. Because of these differing objectives, research institutions often need to negotiate the MTA terms to ensure that they do not undermine the organization's mission.

Given that money is rarely associated with these transfers, MTAs may be perceived by some to be inconsequential transactions. However, while there are usually many sources of funding, there is often only one source for critical research materials. Furthermore, MTAs are legally binding agreements that can significantly impact a researcher's current and future research or involve liability. 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 by 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 research institutions and industry.

We hope that that the "Twenty Questions and Answers" format of this brochure will assist the research 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.

Research administrators and researchers should acquaint themselves with their institution's policies and procedures governing material transfers and should obtain assistance from the appropriate institutional office to negotiate MTA terms and conditions. Because the MTA does not provide funding for the research utilizing the transferred materials, the MTA often needs to be reviewed jointly with any pre-existing funding agreements 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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In addition, COGR would like to acknowledge the members of the COGR Contracts & Intellectual Property Committee (now RSIP) who authored the original September 2003 publication of this paper:

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Question 1: *Under what circumstances is an MTA needed?*

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

- The material and/or associated information is proprietary
- The material or associated information is being maintained as confidential
- The material is infectious, hazardous or subject to special regulations
- The provider is concerned about potential liability
- The provider wishes to obtain rights to the results of the research in which the material or information is to be used, and/or
- The provider or recipient is located outside of the U.S. and the material will be subject to export control.

Question 2: *From the research institution perspective, what MTA terms frequently raise problems?*

Research Institutions 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 institution
- Create conflicting obligations (with other sources of funds or materials), and/or
- Impose reporting obligations that are more consistent with a sponsored research agreement.

Question 3: *How might an MTA's terms restrict academic freedom?*

For research institutions and academic researchers, the most problematic restriction on academic freedom is a contractual limitation on the ability to publish the results of research in a timely manner. A publication restriction is of particular significance because dissemination of information is an integral and required aspect of an institution's missions, policies, and often status

as a non-profit entity. Many agreements, especially those from for-profit providers, require the researcher to provide an advance copy of any manuscript or proposed public disclosure of results obtained with the material. The provider typically wants the right to remove its previously created proprietary information or to seek patent protection. Generally speaking, these requirements are not unreasonable provided they do 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.

A publication restriction is of particular significance because dissemination of information is an integral and required aspect of an institution's missions, policies, and often status as a non-profit entity.

Signing agreements with restrictions on the right to publish or the ability to conduct future research can have detrimental effects. As an example, consider the graduate or postdoctoral student whose research project is dependent on the use 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, research institutions typically have policies that prohibit these restrictions. Institutions frequently face the challenge of aligning these policies with limitations that industry seeks to impose.

Question 4: *Why is there concern about ownership rights in an MTA?*

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 they no longer have the right to use their own research results. Relinquishing ownership of inventions and copyrights can have potential repercussions beyond the loss of the right to use research results. The research institution has a duty to ensure that nothing precludes the broadest possible application of its research in the public interest. Failing to retain ownership of intellectual property makes it unlikely that the institution can meet this obligation. In addition, when federal funding is or may be involved, the institution must ensure it can meet its obligations under the Bayh-Dole Act [*PL 96- 517*]. In such cases, MTAs must acknowledge the rights of the federal government regarding inventions and copyrighted materials that may be made with the material.

Question 5: *What is meant by "reach-through rights" and when are they justified?*

Reach-through rights can mean different things. In exchange for the material, the recipient may be required to:

- grant the provider licenses or options to improvements or modifications of the material or to inventions made in the course of the research in which the material is used; or
- impose 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's position is that it is providing something of value and thus should get something in return. The issue for the research institution 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.

Question 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 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 usually appropriately 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.

Question 7: *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.

Such materials may rise to the level for protection as a patentable invention. Ownership of inventions, as opposed to physical materials, should be determined by U.S. patent law governing inventorship.

Question 8: *Is there ever an option for an institution to forego ownership rights?*

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

Although it is possible under limited circumstances to have some flexibility when it comes to ownership of inventions and copyrights, researchers 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 such an invention without the express approval of the funding agency except to, for example, another research institution or 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 significant impact on the future research of the researcher, since it may be necessary for the researcher to secure a license in order to subsequently use the invention or materials that they created. In most cases, the provider's concerns can be met through an appropriate license or option 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 manuscript may not be accepted for publication.

Question 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 even be prevented by state law from assuming this type of contractual limited liability.

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

There are numerous reasons that a providing institution and the providing researcher may want to ensure that an academic transfer is appropriately handled through an MTA. Issues including liability, academic credit, loss of control of the material, and access to information often arise and are examples that demonstrate the wisdom of using an MTA even with academic colleagues. In addition, in the rare instance where a dispute arises, a simple MTA can 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."

Question 11: *Can MTA agreements be expedited through standardization?*

Some progress has been made in standardization. NIH, working with institutional 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. Many research institutions are signatories to the UBMTA and are able to execute material transfers with a simple implementing letter that lists material, provider, and recipient. The list of current signatories to the UBMTA is found as of the date of publication at on the AUTM website.

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.

Question 12: *Who has the authority to sign MTA agreements?*

All agreements that bind the research institution, 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 signer 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, institutions may recommend (by policy of practice) that they also sign the agreement, not necessarily as a party to the agreement, but as an acknowledgement of their rights and responsibilities under the agreement.

Question 13: *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.

Question 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.

Question 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 reasonable 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.

Question 16: *What are the implications of NIH's "Principles and Guidelines..."?*

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 here as of the date of publication.

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 NIH-funded 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*. Current NIH guidance on resource sharing is available here.

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

Ethical guidelines for the use of human embryonic stem cells include the NIH *Guidelines for Research Using Human Pluripotent Stem Cells*, and the International Society for Stem Cell Research (ISSCR). Ethical use of materials within the laboratory begins with the Material Transfer Agreement. Whether being received from a repository or from a collaborating investigator, no human cell materials, and especially no human embryonic cell (hESC) line should ever enter the laboratory without the execution of an MTA or a legal equivalent.

Additionally, before any materials are received or research begins, it is necessary to obtain appropriate permissions from local organizations to proceed. It is standard for research and academic institutions to have an oversight committee in place to review and approve human embryonic stem cells research, commonly called SCRO (Stem Cell Research Oversight) or ESCRO (Embryo and Stem Cell Research Oversight) committees. Application should be made, and approval received prior to initiating the transfer of materials. Additional local ordinances may be in place in your region and should be evaluated and adhered to as applicable.

The NIH maintains and updates the NIH Human Embryonic Stem Cell Registry, a complete listing of cell lines that have been reviewed by the NIH and approved for use in US federally funded research. NIH-approved hESC lines have been evaluated and found to have been derived in a manner consistent with the core ethical principles outlined in the Common Rule (45 CFR Part 46 subpart A).

Question 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. It also may be helpful for the researcher to consult the research institution's biosafety office for advice. See also the discussion below regarding laws and regulations governing exports and the transfer of hazardous biological materials.

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

Before committing to a Material Transfer Agreement with a foreign party, the US provider should perform an assessment to determine whether there may be an export licensing requirement or other applicable sanctions, or restrictions associated with the foreign recipient. Many biological

pathogens (and associated genetic elements) are controlled for export under the Export Administration Regulations (EAR) administered by the Bureau of Industry and Security (BIS) of the US Department of Commerce (see 15 CFR Parts 730 to 774). Category 1 of the Commerce Control List includes Chemicals, "Microorganisms," and "Toxins" (See 15 CFR Part 774 Supplement 1). Materials that may be used in chemical and biological warfare might be subject to control under the International Traffic in Arms Regulations (ITAR) administered by the Directorate of Defense Trade Controls of the US Department of State Department (22 CFR Parts 120-130). The list of ITAR-regulated items can be found in the US Munitions List (22 CFR Part 121.1). In addition, certain foreign entities (including research institutions) may have specific prohibitions (see BIS Entity List) and certain countries have comprehensive sanctions that would restrict all exports, regardless of whether they are listed on the Commerce Control List or US Munitions List. An investigator planning to transfer materials outside the United States should work with the appropriate institutional staff to determine whether a license may be required. If a license is required, this could add additional months to the process before the material can be exported. 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).

Question 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.

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 regulate the possession, use, and transfer of the listed biological agents and toxins. The rules are extensive and significant, and, among other things, require registration certificates for entities; background checks for responsible institutional officials, investigators, and others who have access to the listed agents; and security plans, training, and substantial record-keeping. Additionally, institutional biosafety offices are a good resource if there are concerns related to the safety or permissibility of contemplated transfers.

Additional Resources

Bayh Dole Act: A Guide to the Law and Implementing Regulations (COGR, October 1999)
https://www.cogr.edu/bayh-dole-act-guide-law-and-implementing-regulations

MTA Challenges: COGR Meeting Presentation, Lisa Finkelstein, NIH, Steve Harsy, University of Wisconsin, Wendy Streitz, University of California (COGR, June 2012)
https://www.cogr.edu/cogr-meeting-presentations-june-7-and-8-2012

University Industry Research Relationships (COGR, August 2007)
https://www.cogr.edu/sites/default/files/University-Industry_Relations_brochure.pdf