No. 3

AUTM EDUCATIONAL SERIES:

Material Transfer Agreements

by Brian Leslie

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Association of University Technology Managers, Inc.

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Brian Leslie is associate intellectual property counsel for the Massachusetts Institute of Technology.

AUTHOR'S ACKNOWLEDGEMENT

A number of people and institutions contributed significantly to this monograph. Paul Sweeney (MIT) generously contributed an outline he prepared for a presentation on MTAs. Paul's outline was used as a starting point for Section 3 of this monograph and that section's organization and content benefit greatly from Paul's work. The Exhibits provided are forms used at MIT and developed over time by its legal staff. Many of the definitions and suggested contract language provided are taken from the Uniform Biological Materials Transfer Agreement (UBMTA), whose authors are too numerous to mention. Finally, the monograph was extensively reviewed and commented on by several extremely dedicated members of AUTM, especially Karen Hersey (MIT) and Joyce Brinton (Harvard). The contribution of their vast experience in these matters was invaluable.

The *AUTM Educational Series* publishes articles on important aspects of technology transfer. The information contained in these publications is intended as background educational material that may be of assistance to the technology transfer professional and the inventor; it is not, however, offered as legal advice and does not take the place of legal counsel.

Material Transfer Agreements

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EDITOR'S PREFACE

AUTM is pleased to continue its *Educational Series* with this third volume. The *Series* is designed to provide practical advice on the issues most often faced by technology transfer professionals and the investigators/inventors with whom they work. Future volumes are already being developed to focus on informative articles on topics of interest to technology transfer practitioners and inventors.

This is a timely publication for institutions that conduct biological research. The monograph is particularly concerned with transfer from for-profit to non-profit entities. Access to specialized research reagents, including DNA, RNA, and plasmids, is central to a successful university or foundation research program. With the maturation of the biotechnology industry, it has become clear that these materials sometimes represent great value. They may form part of a vital income-producing estate and can even be the entire basis for a company's activity or for a university laboratory's research. When these materials are transferred to the open university research community, the for-profit owner of the materials has costs and objectives that result in certain limitations on the recipient—limitations that may be uncomfortable. The purpose of this publication is to facilitate these transfers by raising the consciousness of technology transfer staff, their faculty researchers, and their corporate counterparts; to identify the most common issues and conflicts that non-profits perceive in accepting materials from for-profits; and to guide technology transfer professionals, administrators, staff, and researchers through the process of negotiating fair terms for both sides. The author sets forth an analysis of those issues that could complicate the exchange of valuable materials used in research, and he provides helpful advice on how to recognize and resolve these difficulties.

Evidently the exchange of materials has increased over the past few years, according to informal reports from AUTM members. Although most transfers are carried out with a minimum of negotiation and with balanced terms, there has been concern at the National Institutes of Health and among the non-profit recipients of materials

that the process needs to be smoother. AUTM offers this publication as one step toward more efficient exchange of materials that drive the engine of research and innovation.

We thank Mr. Leslie for this comprehensive work and encourage AUTM members and readers to submit original papers on topics of interest to professional technology managers for AUTM's publications. If you contemplate submitting a paper to the *AUTM Educational Series*, please contact the Managing Editor for content and review procedures.

Beatrice F. Bryan, *Series* Editor
August 1998

Material Transfer Agreements

Brian Leslie

1.0 INTRODUCTION

A Material Transfer Agreement ("MTA") is a contract that governs the transfer of one or more materials from the owner or authorized licensee to an institution for research purposes. Materials may include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, transgenic animals, pharmaceuticals, and other chemicals.

An MTA governs such issues as ownership of the transferred materials and of modifications and derivatives made by the recipient; limits on the use of the materials by the recipient institution; confidentiality of information related to the materials; and rights to inventions and research results.

MTAs are used to transfer materials between institutions from all sectors of the scientific community. Materials are transferred between for-profit institutions, between non-profit institutions, from non-profit to for-profit institutions, and from for-profit to non-profit institutions. As transfers of materials between for-profit institutions and from non-profit to for-profit institutions are typically conducted for strictly commercial purposes, these transfers are not addressed in this monograph.

Many materials are transferred between non-profits. Both parties to such transfers have similar missions, including bringing the benefits of their research to the public. Nevertheless, negotiating MTAs between non-profits can still be problematic. Beginning in the Fall of 1990, AUTM and the National Institutes of Health collaborated to develop formats to simplify the transfer of biological materials among non-profit institutions. This collaboration culminated in the creation of the

Uniform Biological Material Transfer Agreement, or UBMTA, for the transfer of proprietary materials. A Simple Letter Agreement was created for the transfer of non-proprietary materials. The UBMTA and Simple Letter Agreement may be used for most transfers between non-profit institutions. These agreements protect the interests of both parties, while still remaining faithful to the non-profits' desire for free exchange of information and ideas. For more information on the UBMTA, refer to the *AUTM Technology Transfer Practice Manual*, Part IX, Chapter 2, or the AUTM website.

AUTM recommends that the UBMTA and the Simple Letter Agreement be used for as many material transfers between non-profits as possible. When these agreements are not sufficient because of special circumstances, AUTM encourages the provider institution to avoid imposing conditions on another non-profit that the provider would find difficult to accept itself.

More difficult issues arise when negotiating material transfers from for-profit institutions to non-profit institutions. For-profit corporations have a duty to their stockholders to maximize economic gain. They often seek to maximize the rights they obtain when they allow an institution to use their materials. This can conflict in a dramatic way with the non-profit's mission to disseminate research results for the greatest public benefit. Negotiating an MTA with a for-profit can be especially arduous for this reason. Non-profit institutions must carefully consider what rights they are willing to grant to for-profit materials providers. They must balance these rights with the rights granted to research sponsors, and they must always discharge their duty to transfer the benefits of their research to the public.

MTAs are typically only a few pages in length. However, they can represent a substantial undertaking for a technology transfer office, if only in processing and record-keeping. The number of these agreements is growing as is their complexity. Increasing amounts of time are devoted to their negotiation. Academic investigators are concerned about delays and about the damage to their research that these delays can cause. Individuals negotiating MTAs on behalf of academic institutions face a dilemma—they must facilitate the research enterprise, but they must not compromise the institution's academic principles or its financial health.

This monograph provides general guidance to non-profit institutions negotiating MTAs for the transfer of materials from for-profit

corporations. It should also help technology transfer personnel explain MTA-related issues to administrators and researchers. It reviews common terms and conditions in MTAs from the perspective of a non-profit research institution. It discusses general considerations such as the nature of the transferred material and the policies of the recipient institution. Finally, it reviews policies and procedures that may be implemented to avoid conflicts between MTAs and an institution's other contractual obligations.

2.0 DEFINITIONS

Certain terms have special significance when discussing MTAs. An MTA may define these terms in a specific way. If an MTA does not define these terms, they can be subject to varying interpretations that have a significant impact on the agreement. In order to provide clarity to this overview, the following terms are briefly discussed.

COMMERCIAL PURPOSES: Commercial Purposes can be a difficult term to define when dealing with research at non-profits. It may be defined broadly to include research that is funded by commercial enterprises or research in which commercial enterprises have rights. It may be defined narrowly to include research only when its funding would be taxable income under the tax laws. The UBMTA defines Commercial Purposes as follows:

> The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

DERIVATIVES: This term may be very broadly defined to mean any substance (or possibly any process or other product) that was derived from use of the Material. Under this broad definition, if a Material is used to make a product, and that product is utilized in another process to make a second product, and so on through a large number of steps,

the final product might still be seen as a Derivative of the Material, no matter how many processes and additional reactants separate it from the Material. A more restrictive definition of Derivatives would be substances derived *directly* from the Material. That is to say, the Material was used in a process or reaction that resulted in the Derivative. See also the discussion of Unmodified Derivatives below.

MATERIAL: The Material may simply be defined as the substance being transferred, or it may include additional substances, such as Progeny, Modifications, and Derivatives. The UBMTA defines Material as follows:

> ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL 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.

The definition of Material for any given MTA is significant and is discussed in more detail in subsequent sections.

MODIFICATIONS: This term may be defined to mean any substance created by modifying the Material. The UBMTA uses a more restrictive definition. It defines Modifications as substances created by the Recipient that contain/incorporate the Material. Thus, if a recipient receives a plasmid and inserts it into a cell, the UBMTA would define the cell containing the plasmid as a Modification.

NON-PROFIT ORGANIZATION(S): The UBMTA defines non-profits as follows:

> A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

Foreign academic and research organizations are sometimes concerned that this definition may not include them. Such organizations may wish to refer to applicable laws from their own country. Alternatively, they

may wish to expand the definition to include all universities, teaching hospitals, research institutes, and/or government research laboratories, regardless of designation under the U.S. tax code.

ORIGINAL MATERIAL: The term Original Material is used by the UBMTA to distinguish the actual material transferred from Progeny and Unmodified Derivatives, which are also included in the UBMTA's definition of Material. The actual material being transferred is described in the UBMTA Implementing Letter.

PROGENY: Progeny are unmodified descendants from the Material, such as virus from virus, cell from cell, or organism from organism. Under the UBMTA, Progeny are included in the definition of Material.

PROVIDER: Organization providing the Material.

RECIPIENT: Organization receiving the Material.

UNMODIFIED DERIVATIVES: The UBMTA defines Unmodified Derivatives as follows:

> Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: 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.

Under the UBMTA, Unmodified Derivatives are included in the definition of Material.

3.0 TERMS AND CONDITIONS

The terms and conditions in an MTA typically include:

* Definition of the material
* Restrictions on recipient's use of the material
* Provider's rights to inventions and research results
* Recipient's obligation of confidentiality
* Provider's access to reports and publications
* Warranty disclaimer and indemnification

Each of these terms and conditions may not appear in every MTA that a non-profit receives. As most grant rights to the provider and prescribe obligations for the recipient, their absence is likely to be in the recipient's best interest. Whatever the variation for individual MTAs, non-profits must be adept at negotiating the language of such terms and conditions. The following sections discuss each of these terms and conditions individually.

As stated previously, this monograph concerns the transfer of materials from for-profits to non-profits. Throughout the rest of this monograph, "providers" are understood to be for-profit institutions and "recipients" are understood to be non-profit institutions. An example of a Material Transfer Agreement suitable for many for-profit to non-profit transfers is attached as EXHIBIT A.

3.1 Definition of Material:

The definition of material proposed by the provider often includes the original material, any progeny of the original material, and any modifications or derivatives of the original material. For example, the definition might read:

> "Material" shall mean the XXX plasmid and its progeny, any modifications of the XXX plasmid, and any substances derived using the XXX plasmid.

This expansive definition could give the provider ownership of the results of the institution's research. Ownership of these results gives the provider control over their disposition and use. The non-profit institution that created the results could be prevented from using them in further research, transferring them to other organizations, meeting obligations to research sponsors, or ensuring that the results are brought to the public.

For example, suppose the recipient's research entails removing one or more genes from the XXX plasmid, replacing them with a gene developed by the recipient that codes for a novel protein, inserting this modified plasmid into a cell line developed by the recipient, and isolating the novel protein then produced by the cell line. Under the above definition, the provider might argue that it owns not just the original plasmid, but also the plasmid with the recipient's new gene, as this would be a modification of the XXX plasmid. Furthermore, the

provider might argue that it owns the isolated protein because the protein was derived using the XXX plasmid.

A reasonable balance of rights between the research institution and the material provider would be to define the material to include the original material, any progeny, and *unmodified* derivatives. This mirrors the language of the Uniform Biological Material Transfer Agreement. Unmodified derivatives would be defined as substances created by the recipient that constitute an unmodified functional subunit or product expressed by the original material. Examples of unmodified derivatives include 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.

A summary of the ownership rights held under this kind of compromise is as follows:

Owned by the provider:

* original materials, including any material contained or incorporated in modifications
* progeny
* unmodified derivatives

Owned by the recipient:

* modifications, except that the provider retains ownership of the material (including original materials, progeny, and unmodified derivatives) included therein
* all other substances created that are not progeny, unmodified derivatives, or modifications

In the example of the XXX plasmid, this compromise would result in the provider owning the XXX plasmid and its progeny, including any DNA sequences from the original XXX plasmid that are still found in the modified plasmid. The recipient would retain ownership of the gene for the novel protein, including copies of the gene that are found in the

modified plasmid, and the novel protein produced by the cell line containing the modified plasmid.

In negotiating the materials definition, the recipient institution must also take into account rights in the research results that have been or may be granted to the research sponsor. If these rights cover substances that the MTA defines as materials and that are therefore owned by the materials provider, a conflict can exist between the rights of the research sponsor and those of the materials provider. This issue is covered in more detail in section 5.0 Avoiding Conflicts.

An example of a definition of material acceptable in most situations is as follows:

> For purposes of this Agreement, "Material" shall be defined as the XXX plasmid, any progeny, and unmodified derivatives.

3.2 Restrictions on Recipient's Use of the Materials:

An MTA will typically prohibit transfer of the material outside of the recipient institution. Most MTAs will restrict use of the materials to the specifically designated research project. Many MTAs will also forbid transfer of the material outside the requesting researcher's laboratory. An example of such a restriction is as follows:

> The Materials shall not be transferred by Recipient to anyone other than employees, post-docs, and students working under the principal investigator's immediate control and supervision at Recipient institution, and shall not be provided or made available to any other person or entity.

These restrictions are clearly reasonable. Because transferred materials are typically not patented, the MTA may be the provider's only protection of its rights in the materials.

If the materials are transferred outside of the institution or the designated laboratory, the provider may have an action for breach of contract. Even if the provider does not sue, it may well terminate the Agreement and require return of all unused materials.

Another serious problem can result if the materials are used in additional research outside of the designated research project. If an

invention or discovery results, the MTA may give the provider rights that conflict with rights granted to the sponsor of the additional research or that conflict with rights granted to other parties who have provided materials to the additional research. Even if the rights granted to the various parties do not conflict, some MTAs prohibit use of the materials in research programs that grant license rights to third parties. Without further clarification, this would include not just research in which an industrial sponsor or material provider has been granted license rights, but would also include government sponsored research, as the federal government receives license rights under statute. Whatever the MTA's restrictions, recipient institutions must have procedures in place to avoid conflicts between multiple MTAs and between MTAs and sponsored research agreements. Examples of some procedures are given in section 5.0 Avoiding Conflicts.

Institutions accepting materials under an MTA must ensure that the individuals working with the materials are aware of the restrictions on their use. Researchers should receive a copy of the MTA and an explanation of the pertinent clauses. Researchers must be made especially aware of the problems that could result from use of the materials outside of the designated research project.

If students will be using the materials, the recipient should make sure that the MTA does not restrict use of the materials to employees. A given student may or may not be an employee of the recipient for purposes of the MTA. If a student is not an employee, that student may not be bound by the terms of the MTA unless a separate agreement is in place between the student and the institution. Sometimes students may be asked to sign agreements directly with the providing company. This sets up issues that must be carefully considered. Ensuring that all users are properly subject to the terms agreed to by the institution is the most prudent course for the institution.

Many MTAs also prohibit use of the materials for "commercial purposes." Determining what constitutes a commercial purpose for materials transferred to non-profit research institutions is not always easy. As generally accepted, industrially funded academic research that does not grant the funding entity rights in the results of the research is not considered a commercial purpose. Conversely, the license or other transfer of research results to a for-profit organization is often considered a commercial purpose. Between these two examples is a vast area where there is no consensus. The Uniform Biological Materials Transfer Agreement defines commercial purposes to include

contract research, screening compound libraries, and the production or manufacture of products for general sale.

If the recipient anticipates that the material may be used in any of these ways, the wisest course of action would be to delete the commercial purposes restriction. If that is not possible, the provider may be convinced to replace the restriction with language permitting the anticipated use, but prohibiting the materials themselves from becoming part of any deliverable to a sponsor or licensee. Alternatively, the replacement language might state that any commercial use of the material will require a further agreement between the parties, which will be negotiated in good faith. Of course, any terms must be subject to the rights that have been or will be granted to the research sponsor or other material providers.

3.3 Provider's Rights in Inventions and Research Results:

Providers often seek extensive rights in any intellectual property arising from the research project in which their materials are used. For example, they may ask for terms in the MTA that grant them one or more of the following rights:

* Ownership of all inventions, discoveries, improvements, and research results

* An exclusive or non-exclusive commercial license to all inventions, discoveries, and know-how arising out of the research

* A first option to negotiate a license

* A right of first refusal on any prospective license

* A right to require the recipient institution to file patent applications at the institution's expense for any invention arising from the research using the materials

* A right to prohibit the filing of a patent application without the provider's approval

Each of these can be problematic. Most are disproportionate to the benefit derived by the institution from use of the materials. They may be greater than the rights granted to the sponsor funding the research,

resulting in disproportionate benefits going to the materials provider. They may prevent the recipient institution from ensuring that inventions and other research results will be commercialized for the benefit of the public. If license rights have been granted to a research sponsor or separate materials provider, there is the ever present danger that granting these rights will place the recipient institution in breach of these previous agreements.

As a first step, the recipient institution should perform a conflicts check, to see what rights have already been granted and what rights are still available. (Refer to section 5.0 Avoiding Conflicts for more on this issue.) In negotiating available rights, the recipient institution should attempt to limit license rights to those discoveries, improvements and/or inventions that could not have been made *but for* the direct use of the material. The extent of this limitation is dependent on the definition of the material, as discussed above.

The provider may argue that the research could not occur without its material and that this entitles it to expansive rights in the research results, such as ownership or an automatic license. The recipient can respond that it is directing and performing the research and is responsible for creation of the research results. Furthermore, the provider is not funding the research. Finally, as a non-profit research institution, the recipient has a duty to ensure that the public benefits from its research activities to the greatest extent possible.

As a possible compromise, the recipient can offer a non-exclusive license for the provider's internal research use only. This gives the provider use of the research results, while still allowing the recipient to license inventions and discoveries to other entities.

Provided there are no conflicting obligations, the recipient may wish to offer the provider an option to negotiate a commercial license. The option can be for a stated period of time after the provider has been notified of an invention or that a patent application has been filed. While materials providers will often ask for license rights to be granted automatically under the MTA, this should be resisted by the recipient. Ensuring future negotiation of the license, places the recipient in a good position contractually to require commercialization of the invention.

If there are no conflicting obligations, there may be some benefits in offering the provider rights to an exclusive license. Certain products, such as pharmaceuticals, require a huge financial investment and

elaborate regulatory approvals before they can be sold commercially. Because commercial entities see overwhelming value in market exclusivity in such cases, licensing a provider non-exclusively may preclude any possibility of serious commercialization. Exclusivity may be narrowed to a "field of use," such as "therapeutic and diagnostic uses." Exclusivity may not be as important for other products and technologies. In some instances, such as the licensing of research tools, the recipient may wish to offer only non-exclusive licenses so that the technology may be used throughout the scientific community. The level of exclusivity and the scope of the license should be determined on a case-by-case basis after the probable character of the invention is known.

A period for negotiating the license should also be specified. If agreement on the terms of the license cannot be reached within the specified negotiating period, the recipient should be free to license the invention to third parties.

The provider may ask for a right of first refusal on such third-party licenses. A right of first refusal requires that, prior to granting a license to a third party, the recipient must inform the provider as to the terms and conditions of the proposed license and, if requested, grant the provider a license on those terms. This is not a good situation for the recipient, as it will make negotiations with third parties extremely difficult. If it is necessary to grant such a right, the recipient should attempt to place a time limit on this right. For example, the right of first refusal might exist for one year after termination of the original period for negotiating a license. It is also important that the provider be required to exercise a right of first refusal quickly—more than a 30 to 60 day response time is difficult to justify.

An alternative to a right of first refusal is a clause stating that the recipient will not grant licenses to third parties on terms more favorable than those offered to the provider. Again, the recipient should carefully weigh such restrictions as they hamper attempts to license third parties. As with a right of first refusal, if it is necessary to incorporate this clause, the recipient should attempt to place a time limit on this restriction.

The provider may ask for certain procedures covering when and how patent applications should be filed on inventions made using the material. These procedures typically are not problematic. However, the recipient institution should still review them carefully. The recipient

should not grant the provider the right to prohibit the filing of a patent application. Some institutions agree to allow the provider to file patent applications on inventions of interest to them. In such situations, the MTA should state clearly that any patents will be filed in the recipient's name. Some institutions agree to file patent applications upon the provider's request. In these cases, the MTA should state that the provider will cover the patent costs. More generally, the recipient should ensure that any procedures for patent filings can be carried out by its administrative staff without undue time and effort.

An example of a more balanced provider's rights clause is as follows:

> Recipient shall promptly notify Provider of any inventions made during the Research using the Material. Subject to pre-existing contractual obligations, Recipient hereby grants Provider a first option to obtain an exclusive/non-exclusive, worldwide, royalty-bearing commercial license under any patents to inventions made during the Research that could not have been made but for the direct use of the Material. Provider may exercise this license option upon written notice to Recipient within ninety (90) days from the date upon which Provider receives notice of the invention. In the event that Provider elects to exercise the license option, the parties shall attempt to negotiate in good faith a license agreement containing commercially reasonable terms. If the parties are unable to reach agreement within one hundred and eighty (180) days after the date upon which Provider exercised the license option, then Recipient will be free to offer such rights to third parties.

3.4 Recipient's Obligation of Confidentiality:

MTAs may contain confidentiality clauses requiring the recipient institution and its researchers to hold as confidential any proprietary information received from the provider. The recipient should review confidentiality provisions in MTAs with the same scrutiny it gives to such provisions in other contracts.

The first consideration is institutional policy. As a non-profit research institution, the recipient may have a policy that prohibits it from accepting confidential information. If institutional policies permit confidentiality provisions, the recipient must ensure that the provisions do not conflict with obligations to the research sponsor.

As an educational institution, the recipient may not be able to control the movement of information to the same extent as a for-profit corporation. The recipient should avoid language requiring that proprietary information be kept "strictly" confidential or that "best efforts" be used in keeping the information confidential. Such terms will hold the recipient to the highest standards for preventing inadvertent disclosure. Preferable language is the requirement that "reasonable efforts" be used to prevent disclosure and/or that the proprietary information will be treated "with the same degree of care as recipient gives its own proprietary information."

Primary responsibility for protecting proprietary information falls to the researchers who use the materials and related information. Obligations to hold information confidential should not be agreed to without the approval of the principal faculty researcher for the project. Some institutions take the position that obligations to protect confidential information will not be assumed institutionally, but are for their researchers to accept or reject personally. In any event, researchers must be made aware of the confidentiality restrictions placed on them by the MTA.

To ensure that protected information is clearly delineated from non-protected information, the recipient should require that proprietary information be clearly marked as confidential by the provider. If the information is disclosed orally or visually, the provider should be required to summarize the information in a confirmatory writing, marked confidential, within a specified time period after disclosure, usually 10 days.

The confidentiality clause should include standard exceptions to confidentiality requirements. Among these should be an exception for independent development of the information and an exception for information that must be disclosed to a competent judicial or administrative body. Obligations to provide written records of prior possession or independent development impose a burden on the recipient that the law may not require. The requirement for written records should be resisted in favor of a requirement for "competent evidence."

A paramount concern of non-profit research institutions and their faculty, research staff, and students is the right to publish their research results. The effect of confidentiality requirements on the researcher's ability to publish research results should always be considered. For

example, in order for a publication to be of scientific value, it may be necessary to include key properties of a transferred material. If the recipient were required to hold such properties as confidential, the value of any publication is lost. Some MTAs will require the recipient to hold the materials themselves as confidential. It is difficult to imagine how the researcher could realistically publish research results without identifying the materials used in the research. The recipient should never agree to confidentiality requirements that are likely to prevent the researcher from publishing research results. Publication is discussed in more detail in the next section.

An example of a confidentiality clause that may be acceptable is shown in the attachment to EXHIBIT A.

3.5 Provider's Access to Reports and Publications:

Some MTAs require the recipient to submit periodic reports detailing research results. Because these reports may describe patentable inventions and may contain unpublished information, they should be subject to confidentiality restrictions to preclude a subsequent bar to patentability or a premature release of research results.

The researcher who will have responsibility for providing the reports should always be consulted before agreeing to reporting requirements. It may save time to have the researcher talk directly to the provider about the reports. These conversations typically result in a mutually acceptable reporting schedule.

Many MTAs require papers or other public disclosures to be submitted to the provider for review prior to their publication or release. The MTA should clearly state that the purpose of the review is solely to allow the provider the opportunity to identify patentable inventions and to ensure that the paper does not contain provider's proprietary information. If patentable material is found, publication can be delayed for an additional period in order to allow for drafting and filing of patent applications. Any delay should preferably be limited to thirty to sixty days. Some institutional policies will not permit any delay.

A conflict may arise if both the materials provider and the research sponsor are granted a pre-publication review. A review by either entity might result in the inadvertent release of confidential information to the

other. Such difficulties will have to be worked out between all the concerned parties on a case-by-case basis.

The MTA should clearly state the recipient's right to publish research results. Publication is central to a non-profit research institution's obligation to disseminate its research results; it is of primary interest to faculty and students; and it is an important element in preserving an institution's tax-exempt status. The provider should never be given a right of pre-approval of publications or any other right that could interfere with publication of research results.

The following is a review clause that is acceptable in most situations:

> Recipient will be free to publish the results of research performed using Provider's materials. Recipient agrees to submit a copy of any proposed publication to Provider and allow Provider a thirty (30) day period in which to review each publication for patent purposes and to identify any inadvertent disclosure of the Provider's proprietary information. If necessary to permit the preparation and filing of U.S. patent applications, the Principal Investigator may agree to an additional review period not to exceed thirty (30) days.

3.6 Warranty Disclaimer and Indemnification:

Under most MTAs, the provider will disclaim standard warranties with respect to the materials transferred. By agreeing to such disclaimers, a recipient institution may be waiving certain statutory rights. To determine if this is acceptable, the rights waived should be weighed against what is being provided. However, this task can be complicated by many issues. For example, is the material to be provided available commercially? If so, would a purchaser of the material get the benefit of standard warranties? Is the material experimental and are some of its properties unknown? Is the material known to be dangerous? What warranties is the provider specifically disclaiming? Is the provider disclaiming strict liability? What state law would apply, and how does it impact the recipient's rights? Because of the complexity of these issues, they are best considered with the help of legal counsel.

Providers also usually demand that the MTA contain a very broad indemnification clause. This clause usually requires the recipient institution to indemnify the provider for all liability arising out of recipient's use or handling of the materials. It should be noted that indemnification clauses may not be acceptable to state institutions that

are subject to statutes capping liability or that are precluded by statute from entering indemnification agreements.

Ideally, a non-profit would not indemnify the provider, but would assume responsibility for its own use of the material. The UBMTA uses the following language:

> Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

However, many providers will insist on indemnification where not prohibited by law. Indemnification clauses can be revised to minimize the potential risk to the recipient institution. At a minimum, the recipient should seek exemptions from indemnification for negligent or wrongful acts or omissions by the provider, and for infringement of third-party intellectual property rights.

An indemnification clause containing these exceptions is as follows:

> Recipient agrees to hold Provider harmless from any claims of liability or wrongdoing related to Recipient's use or storage of the Material, unless such claim results from Provider's negligence or wrongdoing or from the Material infringing on third party intellectual property rights.

3.7 Signatory Authority

MTAs should be executed by an authorized representative of the recipient. Occasionally, a provider will only request the principal investigator's signature. In such situations, an authorized representative's signature should be added.

The identity of persons authorized to execute agreements on behalf of the recipient depends on the organization and policies of the recipient institution. If the recipient institution does not have a policy authorizing specific individuals to execute MTAs, one should be formulated with

input from the office in charge of sponsored research programs, the office in charge of licensing, and the legal office.

Institutions should carefully consider the consequences before authorizing researchers to execute MTAs on behalf of the institution. Such a practice heightens the risk that a researcher will sign an MTA without sending it to the responsible individual for review. However, some institutions find it valuable to require investigators to sign MTAs in addition to the authorized institutional representative. This reminds the investigator of the obligations he or she is assuming, particularly in situations where the terms are less desirable than usual. It also provides a clear record of the investigator's agreement to abide by those terms.

4.0 GENERAL CONSIDERATIONS

For a recipient institution contemplating an MTA, the tenor of negotiations with the provider should be influenced by certain general considerations. For example, is the material commercially available? If it is, the cost of obtaining the material commercially can be calculated and compared to the projected value of any rights sought by the provider. If this analysis shows that the provider is obtaining a benefit that is disproportionate to the value of the materials provided, the recipient may wish to take a firmer stand in the negotiations. Purchasing the materials with no obligations attached may be an attractive alternative.

Another consideration is whether the recipient requested the material from the provider, or the provider suggested the research using the material to the recipient. If the research project using the material was proposed by the provider, the recipient can reasonably expect a more flexible bargaining position from the provider. The recipient can also request that the provider pay for the research project under a sponsored research agreement.

The importance of the material to the research project should always be considered. The individual negotiating the MTA should talk to the principal researcher about how the research project would be affected if the material were not obtained. Important questions to ask are: Has the research project started? Is there another material that may be substituted for the requested material? Will loss of the requested material result in failure to fulfill obligations owed to a sponsor? If this research project is successful, will it result in additional sponsored research?

The value of the research should also be considered. Does the research look promising? If successful, will it result in a widely beneficial discovery? Will the discovery be commercially valuable?

While gathering and considering this information, it is important that the principal faculty researcher for the project using the material be consulted and kept informed. As the individual in charge of the research using the material, he or she is usually best placed to make judgments concerning the value of the material to the research and its probable results. He or she can be asked to verify any information obtained from other researchers, such as post-docs and graduate students. Reviewing the various considerations affecting an MTA with the principal faculty researcher will help to sift through the information received and isolate the issues of real importance to the research.

Another very important consideration is institutional policy. If MTAs are negotiated solely on a case-by-case basis without institutional guidelines, the recipient institution may find that it has granted widely disparate rights to different materials providers. In certain instances, these rights may be greater than those granted to research sponsors. By establishing institutional guidelines setting forth the rights that the institution is willing to grant, and under what circumstances, this disparity can be reduced. The individual negotiating the MTA on behalf of the recipient institution will be able to turn to guidelines that set limits on the restrictions that can be agreed to and the rights that can be granted. Researchers may turn to the guidelines to determine if a research project they wish to perform will be possible, based on discussions with a materials provider. The process of establishing guidelines enables the recipient institution to review the possible effects of MTAs on its overall research programs.

By weighing each of these general considerations for any given MTA, the recipient institution can foster an equitable approach to material transfers overall, while still recognizing the special circumstances surrounding any individual material transfer.

5.0 AVOIDING CONFLICTS

Any time an MTA is signed, there is a possibility that the MTA contains obligations that conflict with obligations contained in a pre-existing agreement. For example, the transferred material may be used in research performed under a sponsored research agreement that gives

rights in resulting inventions to the research sponsor. Also, the material may be used in conjunction with a separate material received under another MTA. These situations could result in the recipient institution granting two or more parties exclusive rights to the same invention.

If the individual in charge of the sponsored research agreement for a research project is also responsible for the MTAs for that project, then the individual can easily compare the pertinent contracts. However, these responsibilities often fall into different departments. If the individual negotiating an MTA is not privy to other agreements touching the research project, a conflict between the MTA and another agreement could expose the institution to liability. In order to find ways of minimizing this exposure, recipient institutions should have policies and procedures in place to discover possible conflicts before they occur. Some possible policies and procedures are reviewed below.

5.1 MTA Language:

The easiest way to avoid conflicting contractual rights is to specify which rights take precedence within the contract. This can be accomplished between MTAs and sponsored research agreements by requiring all MTAs to include language that gives research sponsors' rights preeminence over the rights of materials providers. For example, any grant of rights within the MTA could be preceded by the following language:

> Subject to the Recipient's obligations to third parties who may provide funding for the research utilizing the Material....

If both a materials provider and a research sponsor have been given the right to negotiate an exclusive license to an invention, this language gives the research sponsor first crack at the negotiation. The materials provider may not agree to such an arrangement, leading to further negotiation. However, the above language is still beneficial in that it requires any competing rights of the research sponsor to be brought to light.

The above language does not alleviate the situation where multiple materials have been received for the same research project under conflicting MTAs. Any attempt to contractually define whose rights take precedence will normally bring a swift response from the materials provider. An alternative is to lump the rights of the research sponsor

and pre-existing materials providers together. In this case, the recipient can ask that any grant of rights within the MTA be preceded by the language:

> Subject to the Recipient's pre-existing contractual obligations....

Again, such language may elicit an emphatic refusal from the materials provider, but such a response should force the recipient to unearth any pre-existing obligations.

The negotiator can also attempt to limit the duration of a provider's rights. For example, the MTA language could read:

> ...a first option to acquire a license to inventions or discoveries that are conceived or reduced to practice within one year of the Material transfer and that could not have been made but for the use of the Material.

Although this language does not extinguish all possible conflicts, it provides the double benefit of tying rights to the use of a specific material and limiting the time within which a conflict could occur.

5.2 Gathering Information from Researchers:

To avoid conflicts between agreements connected to a research project, one needs to know what agreements exist. Discovering this information is not always easy. The best place to start is with the researcher in charge of the research project. The researcher is a valuable source of information. The researcher can be asked: Who is funding the research? Will any other materials received under an MTA be used in this research? Will the material be modified? Is there any other information that the researcher sees as pertinent? Etc.

In order to ensure that the proper information is obtained from the researcher, the negotiator can use a questionnaire. The questionnaire can ask all the basic questions. If the questionnaire is stored electronically, questions can easily be added, deleted, or revised as necessary. The recipient institution can institute a policy that the researcher requesting materials must fill out a questionnaire. The policy can require the requesting researcher and the principal researcher on the research project to sign the completed questionnaire. These steps

promote a thorough review, by both the researchers and the negotiator, of pertinent information held by the researchers.

An example of an MTA questionnaire is attached as EXHIBIT B.

Besides the researchers, various administrators and assistants can also be valuable sources of information concerning a research project. As the positions of such individuals vary significantly between institutions, they are not discussed here.

5.3 Databases:

Although researchers and administrators can be excellent sources of information, their help does not guarantee that all pertinent facts will be discovered. As in any endeavor, human error may occur. Important facts may be forgotten or overlooked. Others may not be seen as important and omitted. When individuals leave an institution, valuable institutional memory, including information pertinent to an MTA, may leave with them.

The information for a proper conflicts check should be maintained somewhere within the recipient institution. Again, methods of storing this information differ widely. The MTA negotiator must be able to access this information. A review of such stored data can act as a check against mistakes or omissions by other sources.

An excellent way to ensure proper review of pertinent information is to set up an electronic MTA database that stores a summary of MTAs and references them by researcher and materials provider. For all incoming MTAs, the database can be searched to find those existing MTAs currently affecting the investigator's research. After obtaining this list, the existing MTAs can be checked for possible conflicts with the newly requested MTA. The list can also be sent to the researcher along with the MTA questionnaire. This will help to ensure that the researcher does not forget about other materials received under MTAs that might be used in the same research project.

Many institutions already have databases that track sponsored research agreements. To further the usefulness of the MTA database, the two databases may be combined. A search can be performed to identify all the MTAs and sponsored research agreements affecting the researcher or materials provider. This will usually give the individual negotiating an MTA a comprehensive picture of the obligations tied to a given

research project. The researcher can be sent the MTA questionnaire along with a database list of MTAs and sponsored research agreements touching the researcher. This will help ensure that the researcher correctly identifies the research project in which the transferred material will be used.

5.4 Education:

Education is an often overlooked method of avoiding contractual conflicts between MTAs and other agreements. It is incumbent upon those individuals with responsibility for such agreements to explain their significance to researchers and others who may not be aware of the impact MTAs can have on their research and on an institution.

Researchers can be given written information explaining MTAs and describing how these agreements can affect their research; highlighting the possible problems that can arise; and outlining their institution's policies and procedures with respect to MTAs. Seminars can also be held to reinforce the importance of this information.

On a day-to-day basis, the negotiator can take the time to explain the issues clearly to the researchers, so that they may gain a better understanding of these agreements and an appreciation for the relevance of the terms and conditions to their work.

In summary, educating the community about these agreements and about the problems that can arise will enlist allies in avoiding these pitfalls. It can even engender understanding and appreciation of the role played by the MTA negotiator.

EXHIBIT A
MATERIAL TRANSFER AGREEMENT
(For-Profit to Non-Profit; Industry to Academic Institution)

_____ ("Provider") agrees to provide _____ ("Recipient") with material as described below as requested by _____ ("Scientist") for use in a research project, subject to the terms and conditions set forth in this Agreement.

1. This Agreement applies to _____, which is received by Recipient from Provider under this Agreement, and any additional progeny or unmodified derivatives (collectively, the "Material") for use in Scientist's research relating to _____

_____

_____("Research").

2. Legal title to the Material will remain with Provider. If, in the performance of the Research, Scientist is given access to information that the Provider considers confidential, the rights and obligations of the parties with respect to such Confidential Information shall be governed by the terms and conditions set forth in Attachment A.

3. Provider grants Recipient a nonexclusive license to use the Material solely for the scientific research of Recipient. The Material is provided to Recipient for use only in laboratory animals or in vitro experiments. THE MATERIAL WILL NOT BE USED IN HUMANS.

4. To the best of Provider's knowledge and experience, the Material has no known toxicity. However, the Material is experimental in nature and will be used with prudence and appropriate caution, as not all of its characteristics are known. THE MATERIAL IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5. Recipient may publish or present results of the Research. Recipient shall submit a copy of any proposed manuscript, abstract or poster session to Provider at least thirty (30) days prior to publication. Provider will review the copy for Confidential Information or patentable material. At the request of the Provider, Recipient will delay the proposed publication for up to an additional thirty (30) days to allow for removal of Confidential Information or filing of patent applications. Scientist and Recipient will acknowledge Provider as the

source of the Material in any publication of Research results relating to the Material.

6. Recipient shall promptly notify Provider of any inventions made during the Research using the Material. Subject to pre-existing contractual obligations, Recipient hereby grants Provider a first option to obtain an exclusive/non-exclusive, worldwide, royalty-bearing commercial license under any patents to inventions made during the Research that could not have been made but for the direct use of the Material. Provider may exercise this license option upon written notice to Recipient within ninety (90) days from the date upon which Provider receives notice of the invention. In the event that Provider elects to exercise the license option, the parties shall attempt to negotiate in good faith a license agreement containing commercially reasonable terms. If the parties are unable to reach agreement within one hundred and eighty (180) days after the date upon which Provider exercised the license option, then Recipient will be free to offer such rights to third parties.

7. By transfer of the Material, Provider grants to Recipient no rights in the Material other than those specifically set forth in this Agreement. Recipient will, at the request of Provider, return or destroy all unused Material.

8. Scientist and Recipient will use the Material in compliance with all applicable laws, governmental regulations and guidelines, including current National Institutes of Health guidelines or their equivalent, and any regulations or guidelines pertaining to research with animals or recombinant DNA.

9. This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of Provider.

RECIPIENT
By _____
Name _____
Title _____
Date _____

PROVIDER
By _____
Name _____
Title _____
Date _____

INVESTIGATOR (Optional)
By _____
Name _____
Title _____
Date _____

ATTACHMENT A
PROVIDER CONFIDENTIAL INFORMATION

In furtherance of the transfer of Material by Provider, Recipient may be provided with or given access to certain information that Provider considers confidential. The rights and obligations of the parties with respect to such information are as follows:

1. CONFIDENTIAL INFORMATION. For the purposes of this Agreement, "Confidential Information" refers to information of any kind that is disclosed by Provider to Recipient and that, by appropriate marking, is identified as confidential and proprietary at the time of disclosure. In the event that Confidential Information must be provided visually or orally, obligations of confidence shall attach only to that information which is confirmed by Provider in writing within ten (10) working days as being confidential.

2. LIMITATIONS ON USE. Recipient shall use the Provider's Confidential Information solely for the purposes of this Agreement. It is agreed by Provider and Recipient that the transfer of Confidential Information shall not be construed as a grant of any right or license with respect to the information delivered except as set forth herein or in a duly executed license agreement.

3. CARE OF CONFIDENTIAL INFORMATION. The Provider and Recipient agree that all Confidential Information communicated by Provider and accepted by Recipient in connection with this Agreement shall be kept confidential by Recipient as provided herein unless specific written release is obtained from Provider. Recipient agrees to make Confidential Information available only to those employees and students who require access to it in the performance of this Agreement and to inform them of the confidential nature of such information. Recipient shall exert reasonable efforts (no less than the protection given its own confidential information) to maintain such information in confidence.

Recipient shall be deemed to have discharged its obligations hereunder provided Recipient has exercised the foregoing degree of care and provided further that Recipient shall immediately, upon discovery of any disclosure not authorized hereunder, notify Provider and take reasonable steps to prevent any further disclosure or unauthorized use.

When the Confidential Information is no longer required for the purpose of this Agreement, Recipient shall return it or dispose of it as directed by the Provider. Recipient's obligations of confidentiality with respect to Confidential Information provided under this Agreement will expire five (5) years after the date of this Agreement.

4. INFORMATION NOT COVERED. It is agreed by Provider and Recipient that the above obligations of confidentiality shall not attach to information that:

(a) is publicly available prior to the date of the Agreement or becomes publicly available thereafter through no wrongful act of Recipient;
(b) was known to Recipient prior to the date of disclosure or becomes known to Recipient thereafter from a third party having an apparent bona fide right to disclose the information;
(c) is disclosed by Recipient in accordance with the terms of the Provider's prior written approval;
(d) is disclosed by Provider without restriction on further disclosure;
(e) is independently developed by Recipient;
(f) Recipient is obligated to produce pursuant to an order of a court of competent jurisdiction or a valid administrative or Congressional subpoena, provided that Recipient (a) promptly notifies the Provider and (b) cooperates reasonably with the Provider's efforts to contest or limit the scope of such order.

EXHIBIT B

MATERIAL TRANSFER AGREEMENT QUESTIONNAIRE

Investigator:
Principal Investigator:
Provider:
Material:

In order to evaluate the acceptability of the proposed Material Transfer Agreement with _____ consistent with applicable Institution policies, please provide answers to the following questions. You may use the back of this questionnaire or add additional sheets if you require more space for your answers:

1. What is the intended use of the material?

2. Will federal government research funds be used to support the research utilizing the material? If so, please provide the government department(s) or agency(s) and the applicable Institution Account No., if known.

3. Will industrial or foundation research funds be used to support the research utilizing the material? (Note: Please include funding sources for those students and/or post-docs who will be working on this research.) If so, please provide the sponsor(s) name(s) and the applicable Institution Account No., if known.

4. Will the materials be used with other materials provided by a third party? If so, what are these other materials and who provided them?

5. Will you be modifying the material? If so, how?

6. Will any progeny be produced (i.e., unmodified descendants from the material, such as virus from virus, cell from cell, etc.)?

7. Do you intend to publish your findings? If so, are you willing to provide an advance copy of the paper to the materials provider for review?

8. Will students be using the material? If so, will this work be part of a thesis?

9. Is the material known to be toxic?

10. Is the material sold commercially? If so, approximately what would the amount of material you are requesting cost? Is the material available from another source? If so, who?

Feel free to add any additional information that you believe to be pertinent. Once you have completed the questionnaire, please sign it and return it and any attachments to this office. Depending on the terms and conditions of the proposed Material Transfer Agreement and on your responses, the Agreement may require revisions in order to protect your and the institution's intellectual property interests and outstanding obligations.

Your patience and cooperation are appreciated.

_____

Investigator

_____

Principal Investigator