The Uniform Biological Material Transfer Agreement: Origin and Evolution

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The Origin

In the late1980s, there was a rising tide of concern about the impact of material transfer agreements (MTAs) on the research enterprise. A number of articles were written about the problem, faculty members were complaining, and technology transfer offices were feeling the heat. The National Institutes of Health (NIH) Office of Technology Transfer was receiving so many complaints that it convened a meeting in 1990 to discuss possible solutions. That meeting was held on the NIH campus and drew a considerable number of concerned technology transfer professionals and Association of University Technology Managers (AUTM) leaders. That was the beginning of the effort that resulted in the uniform biological material transfer agreement (UBMTA).

The goals of the participants in the effort were lofty—to develop an agreement or agreements that would simplify exchanges of biological materials among nonprofit institutions and, perhaps, even transfers from the for-profit sector to nonprofits. Unfortunately, the latter goal was not achieved, but the first was. On March 8, 1995, the NIH and Public Health Services published in the Federal Register (page 12771 et seq., see http://www.autm.net/aboutTT/aboutTT_fedReg.cfm) the UBMTA and its implementing letter (see Appendix 1).

The Issues

The first challenge for the working group was agreeing upon a set of definitions. While this may seem trivial, it turned out to be surprisingly difficult. First, you had the stuff that one scientist transferred to another—the original material. The recipient scientist might (a) grow up more of the *original material* without introducing changes (*progeny*); (b) divide that original material or its progeny into its component parts

(*unmodified derivatives*); (c) alter the original material, progeny, or unmodified derivatives or combine any of them with other substances to create *modifications*; or (d) use the original material, progeny, unmodified derivatives, or modifications in some way to create substances that are not themselves progeny, unmodified derivatives, or modifications of the original material.

Once having agreed upon these definitions, it was important to agree which of the above the provider or recipient scientist owned and/or controlled. It was easy to agree that the provider owned and/or controlled the original material, progeny, and unmodified derivatives (taken together, the *material*). It was also fairly easy to reach agreement that the recipient scientist owned and/or controlled substances created through the use of the original material, progeny, or unmodified derivatives so long as the substance created was not itself progeny, unmodified derivatives, or modifications of the original material.

The big issue was ownership and/or control of modifications. These clearly included some portion (or even all) of the original material or its progeny, but they also included something contributed by the recipient scientist. The solution was to treat modifications much as a book written by one person (the recipient scientist) that contains a chapter written by another person (the provider scientist); the book is owned and/or controlled by its author, but he or she is constrained regarding what he or she can do with the book by an agreement with the author of the chapter.

The UBMTA stipulates that the recipient scientist owns the modification, but the provider scientist still owns the part of the modification that is the original material, progeny, or an unmodified derivative. The provider scientist agrees that the creator of the modification can distribute the modification to other scientists at nonprofit organizations (under agreements equivalent to the UBMTA) but cannot provide them to for-profit entities or for any commercial purpose.

The next major issue was how to handle any resulting patents. It was agreed that the provider should not restrict the recipient from filing patent applications on inventions made through the use of the material, but if a patent application claims modifications or methods of manufacture or use of the material, the provider must be notified.

Finally, there was the issue of potential liability for the provider or the recipient. The solution was essentially that neither party made any warranties and each assumed any liability for damages resulting from its actions.

Implementation

When the UBMTA and its implementing letter were published in the Federal Register in 1995, AUTM committed itself to maintaining a list of those institutions that agreed to be bound by the terms of the UBMTA when the providing and receiving institutions both signed an implementing letter. To date, more than 300 institutions have signed on to the UBMTA (see http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm).

Unfortunately, many nonprofits often failed to use the UBMTA, even though they had signed on, and nonprofit-to-nonprofit transfers continued to require negotiation on a case-by-case basis. This, coupled with the more difficult problems experienced by scientists at nonprofits who wished to obtain materials from the for-profit sector, led NIH to establish a blue-ribbon Working Group on Research Tools. The working group deliberated for more than a year and issued its report in June 1998 (see http://www.nih.gov/news/researchtools).

Based on this report, NIH published a final notice in the Federal Register (see http://grants1.nih.gov/grants/intell-property_64FR72090.pdf) entitled *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice*—commonly referred to as NIH's research tools guidelines.

These guidelines endorsed the use of the UBMTA but went further by strongly recommending the use of the simple letter agreement for the transfer of materials (see Appendix 2) when transferring unpatented research tools unless the tools are licensed to an exclusive distributor.

Next Steps: Addressing Continuing Problems

So where are we today? Technology transfer offices still feel overburdened by the increasing flow of MTAs, and scientists at nonprofit institutions still complain about the length of time it takes to negotiate MTAs. While many nonprofits do base their MTAs largely on the principles and even the text of the UBMTA, they invariably include some changes, and the MTAs are presented as separate documents rather than using the implementing letter approach.

As a result, the potential to streamline MTA review is largely lost, with nonprofit-to-nonprofit transfers continuing to require detailed document review and some negotiation on a case-by-case basis. Admittedly, the longest negotiating delays occur when the supplier of the material is a for-profit. That's understandable since the company is concerned about protecting its investment in the material in question. Still, many of these company-supplied materials are of limited value and should be able to be distributed with few or no restrictions.

But, aside from materials coming from the for-profit sector, why are nonprofit to nonprofit transfers still the subject of so much negotiation? Increased use of the UBMTA and the simple letter agreement (as recommended by NIH) would go a long way toward making life a lot easier, as would Web-based systems utilizing these agreements. The following are several examples of recent initiatives seeking to improve the transfer of materials.

Science Commons has under way the Biological Materials Transfer Agreement Project, which is working to develop and make available standard, modular contracts for the exchange of a variety of types of biological materials. These will include existing standard agreements (UBMTA and simple letter agreement), along with a suite of alternative clauses in a Web-based library.

Addgene is a nonprofit depository for plasmids that uses the UBMTA for almost all of its materials, although special MTAs are required for some materials when proprietary technology is included, e.g., Cre-Lox. Addgene offers its materials via the Web, and most transactions are handled electronically.

AUTM's MTA Special Interest Group is developing an eMTA Commons, which it hopes will become a global Web-based MTA system that will provide efficient work-flow management and tracking as well as materials search capability to both principal investigators and technology transfer offices. The eMTA Commons is being designed to afford institutions the ability to establish their own review and approval processes and will handle standardized, dual-party-specific as well as custom agreements. The lead institution is City of Hope, with the assistance of approximately two dozen individuals from institutions around the country. Both Science Commons and Addgene are participating in this effort.

So there is hope, and, perhaps, these efforts and others like them will one day create agreements and systems that will make complaints about MTAs a thing of the past. And best of all, science will be able to move forward without the frustration of long negotiations to obtain essential research materials.

In the meantime, I encourage you to make use of the existing UBMTA and simple letter agreement formats for as many of your materials exchanges as possible.

Appendix 1:

UBMTA and Implementing Letter

Upon execution of an Implementing Letter in the form attached which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement ("UBMTA") published in the Federal Register on March 8, 1995.

Attachments:
UBMTA
Implementing Letter

Organization:
Address:
Authorized Official:
Title:

Signature:
Date:

Please return an executed copy of this Master Agreement to: The UBMTA Project, Association of University Technology Managers (AUTM), 111 Deer Lake Road, Suite 100, Deerfield, IL 60015. AUTM will be maintaining signed originals and the official list of signatory organizations.

The Uniform Biological Material Transfer Agreement

March 8, 1995

I. Definitions:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

2. PROVIDER SCIENTIST: The name and address of this party will be specified in an implementing letter.
3. RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.
4. RECIPIENT SCIENTIST: The name and address of this party will be specified in an implementing letter.
5. ORIGINAL MATERIAL: The description of the material being transferred will be specified in an implementing letter.
6. MATERIAL: 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.
7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.
8. UNMODIFIED DERIVATIVES: 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.
9. MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.
10. COMMERCIAL PURPOSES: 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.
11. NONPROFIT ORGANIZATION(S): 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.

II. Terms and Conditions of this Agreement:

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.
2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2(a) or 2(b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.
3. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

   (a) is to be used solely for teaching and academic research purposes;
   (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;
   (c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and
   (d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.

4. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least

those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

5. (a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.

   (b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.

   (c) Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

7. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commer-

cial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.
9. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
10. 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.
11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.
12. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.
13. This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, though reagent catalogs or public depositories or (b) on completion of the RECIPIENT's cur-

rent research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

(i) if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and

(ii) if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and

(iii) in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.

14. Paragraphs 6, 9, and 10 shall survive termination.

15. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested by the PROVIDER, the amount will be indicated in an implementing letter.

UBMTA Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL:

Organization: _____
Address: _____

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL:

Organization: _____
Address: _____

3. ORIGINAL MATERIAL (Enter description):

4. Termination date for this letter (optional):

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional). Amount: _____.

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: _____
Title: _____
Address: _____

Signature: _____
Date: _____

RECIPIENT SCIENTIST

Name: _____
Title: _____
Address: _____

Signature: _____
Date: _____

RECIPIENT ORGANIZATION CERTIFICATION

Certification: I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized
Official: _____
Title: _____
Address: _____

Signature: _____
Date: _____

Appendix 2:

Simple Letter Agreement

PHS Simple Letter Agreement Rev. 12/1999

Simple Letter Agreement for the Transfer of Materials

In response to the RECIPIENT's request for the MATERIAL [insert description]

_____

to be used for the purpose of _____

_____

the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement, to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which

may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: [insert fee] _____.

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist:_____
Provider Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____

Certification of Authorized Official: This Simple Letter Agreement __has / __has not [check one] been modified. If modified, the modifications are attached.

_____ _____
Signature of Provider's Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____
Recipient Organization: _____
Address: _____

Name of Authorized Official: _____

Title of Authorized Official: _____

Signature of Authorized Official:_____

Date: _____

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____ _____

Signature of Recipient Scientist Date