Material Transfer Agreements

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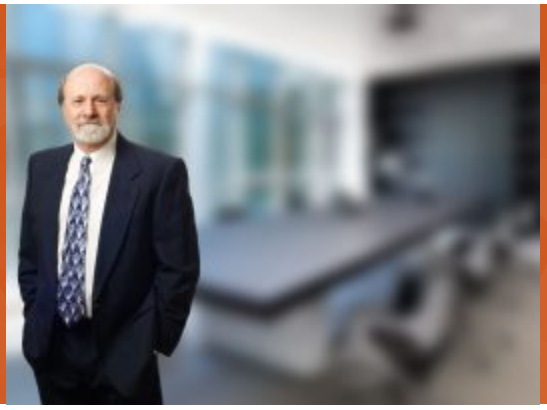

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I. What Are Material Transfer Agreements And Why Are They Needed?

A. Material Transfer Agreements, or MTAs, are agreements that establish the terms under which one entity or scientist will transfer to another entity or scientist unique biologic materials for purposes of research, testing and perhaps distribution for further research and testing.

B. MTAs can be used for other purposes, including (1) the transfer of other types of materials (e.g., specially-developed inorganic compounds or computer software) and (2) granting rights of commercialization. However, the most common types of MTAs involve the transfer of biologic materials for research. When commercialization is intended, a more standard commercial license agreement generally is used.

C. MTAs may be used by "federal laboratories, industrial research laboratories, and laboratories in universities, hospitals, or independent research institutes." "Materials Transfer in Academia," Council on Governmental Relations, www.cogr.edu/mta.htm (hereafter, the "COGR Brochure").

D. MTAs may also be used by industry, for example, to make its unique materials available to universities for pro bono research or in connection with ongoing or potential sponsored research, or to obtain university material for its own R&D.

E. "MTAs are important because they require the recipient to exercise care in the handling of the materials, to maintain control over the distribution of the materials, to acknowledge the provider in publications, and to follow relevant PHS [Public Health Service] guidelines relating to recombinant DNA, protection of human subjects in research, and the use of animals." "Uniform Biological Material Transfer Agreement: Discussion of Public comments Received," published in the Federal Register March 8, 1995.

F. "When scientists began warning that the progress of research was increasingly hampered by lengthy MTA negotiations, universities and the National Institutes of Health (NIH) took action by joining to develop a standard material transfer process for transfers between academic entities." COGR Brochure, id. The result was the Uniform Biological Material Transfer Agreement. See Part II below.

II. Uniform Biological Material Transfer Agreement

A. Following years of discussion, in 1995 the National Institutes of Health issued "the final version of the Uniform Biological Materials Transfer Agreement ("UBMTA") to be used by public and nonprofit organizations, an implementing letter to memorialize individual exchanges under the UBMTA, and a simple letter agreement for transferring nonproprietary biological materials among public and nonprofit organizations." NIH Guide, Vol. 24, No. 14, April 14, 1995.

B. Once adopted by an institution, the UBMTA can be made to apply to any transfer transaction by proper execution of a simple letter agreement (the form for which was also issued by the NIH). An adopter is not required to use the UBMTA for all transactions, and usually could not use it with respect to industry-sponsored research projects (since such projects usually involve commercial rights).

C. At least 109 institutions have adopted the UBMTA. COGR Brochure, Q10.

D. Among the issues covered by the UBMTA – and most well-written MTAs – are permitted uses, further distribution, ownership, liability, publication, compliance with law, term and any applicable costs.

E. Most MTAs require certain technical definitions, including the following terms:

1. Progeny: "Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism." UBMTA §I.7. Thus, "Progeny" are essentially unaltered copies of the Original Material.

2. 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, protein expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line." UBMTA §I.8.

3. Modifications: "Substances created by the Recipient which contain/incorporate the Material." UBMTA §I.8.

III. Materials and Scope of Use

A. The MTA must clearly identify the Materials to be transferred. Typically these are biological materials, such as bacteria, cell lines, cultures, nucleotides, plasmids, proteins, reagents, transgenic animals, vectors and pharmaceuticals.

B. MTAs involving nonprofit institutions generally allow only noncommercial uses of the transferred material, typically research, testing and teaching uses.

C. Where industry or for-profit institutions are involved, the typical MTA is not adequate; commercial rights are generally sought, which often suggests working from a standard commercial development and license agreement.

D. Many MTAs prohibit further distribution of the original Material, even for noncommercial research. UBMTA §4 requires the receiving scientist to refer requests for the Material to the provider; the provider agrees that, to the extent it has sufficient supplies and is reimbursed for its costs, it will make the Material available to other researchers who wish to replicate the recipient's research.

E. Many MTAs permit the recipient to distribute freely materials created by the recipient, generally provided that they are not Progeny, Unmodified Derivatives or Modifications.

See UBMTA §5(a).

F. Because the Bayh-Dole Act generally requires recipients of federal funds to make their findings available for commercialization, MTAs often address commercial use. Thus, UBMTA §§5(c) and 7 permit the recipient to license its IP in its Modifications to industry, but makes clear that the provider is not required to license its Materials (including those incorporated in Modifications) commercially.

IV. Fees and Costs

A. Most institution do not charge license or similar fees for noncommercial use of their unique biological materials.

B. However, many biologic materials are costly to produce, package and ship. Institutions will generally seek reimbursement for their costs of providing unique biologic materials to other researchers pursuant to an MTA.

C. If the material was developed with industry grants, the institution may be required to pass-through certain fees.

V. Intellectual Property and Ownership Rights

A. Nonprofit institutions are increasingly sensitive to IP issues, especially as these may affect their ability to benefit financially from their unique creations and derivatives thereof.

B. These concerns are less significant when the MTA permits only nonprofit research and teaching. However, often more is allowed, at least respecting derivatives that are neither Progeny, Modifications, nor Unmodified Derivatives.

C. Typically the provider of the original Material will retain ownership and all IP rights in that Material, as well as in its Progeny, Unmodified Derivatives, and perhaps Modifications. Often (but not always) the recipient will retain the IP rights in its own creations, provided they are neither Progeny nor Unmodified Derivatives.

D. UBMTA §2 provides that the recipient retains ownership of all Modifications, though not ownership of the original Materials, Progeny or Unmodified Derivatives incorporated therein. Thus, the recipient may distribute Modifications to nonprofit organizations for research and teaching, and may grant commercial licenses to its IP rights in the Modifications; but it may not distribute Modifications (which by definition contain original Material) for commercial purposes without specific license from the provider. UBMTA §5.

E. Providers, especially industry providers, may seek licenses to use derivatives developed and owned by the recipient.

1. This is reasonable if the license is limited to noncommercial use.

2. However, if the provider seeks use of the recipient's derivatives for commercial purposes, the recipient generally should seek compensation.

3. Otherwise, in essence it may have just performed valuable commercial research – research it could have charged significant dollars for – for free.

4. Providers — again, particularly industry, may request an option to acquire exclusive rights.

VI. Confidentiality, Publication and Attribution

A. In those cases where institutions treat their unique biological creations as confidential and proprietary, they will require confidential treatment of these Materials, as well as their derivatives and progeny, by recipient organizations and individuals.

B. In those cases where the institutions do not consider a particular material as confidential – because it is patented, described in published literature, or available from other sources – some form of transfer agreement is often advisable, for example, to deal with ownership of derivatives, reimbursement and liability. The UBMTA was issued accompanied by a "Simple Letter Agreement for Transfer of Non-Proprietary Biological Material."

C. Most academics require the ability to publish their research findings.

D. UBMTA §11 provides that it will not "prevent or delay publication of research findings resulting from the use of the Material or the Modifications."

E. That section also requires that the scientist "provide appropriate acknowledgement of the source of the Material in all publications."

VII. Liability

A. The provider obviously desires to minimize its potential liability for transferring and permitting use of its unique biological Materials. Similarly, the recipient will not want full exposure for risks that in fairness should belong to the provider, for example, risks arising from any dangerous or toxic properties of the original Materials, unless these risks are obvious or the recipient has been properly warned.

B. In most MTAs the provider gives NO WARRANTY for the Materials it furnishes.

C. Providers also typically require recipients to use caution and take full responsibility for use of the provided Material; disclaimers of liability are common.

D. UBMTA §10 provides that the provider is not liable for any loss, claim or demand by the recipient, "except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider."

E. Each party may desire some form of indemnity from the other.

1. For example, a provider may desire indemnification from damages and third party claims resulting from the recipient's use or misuse of the Materials, or at least from the recipient's (gross) negligence and (willful) misconduct.

2. Similarly, the recipient may desire indemnification from damages and third party claims resulting from the provider's failure to use proper safety measures or provide notice of known hazards, or at least from the provider's (gross) negligence and (willful) misconduct.

3. Bear in mind that many federal laboratories and state universities are prohibited from giving indemnities.

VIII. Term and Termination

A. The MTA must state how long the recipient may use the Material.

B. The MTA should permit either party to terminate if the other party breaches or is guilty

of misrepresentation.

C. The MTA may allow either party to terminate at will, with reasonable notice (typically 30 days to the other).

D. This may be unfair to the recipient, particularly if it is building a research project around the use of the Material.

E. UBMTA §13 states that if the provider terminates for reasons other than the recipient's breach or other cause (e.g., health risk or patent infringement), upon request the provider will defer termination for up to a year to permit completion of research in progress.

IX. Compliance with Law

A. Many laws will apply to both the provider's transfer, and the recipient's use, of the Materials. MTAs should obligate the recipient to comply with these laws. Consider the following.

B. There are many laws that apply to hazardous materials, including occupational health and safety laws and laws governing the storage, transport, use and disposal of hazardous materials. Ideally, the provider will inform the recipient of those relevant environmental laws and regulations familiar to the provider and, of course, the provider should give the recipient sufficient information about the material for the recipient to determine on its own what laws apply. However, this should not absolve the recipient from the obligation to learn and comply on its own.

C. Federal and state privacy laws may apply, for example, to the handling and use of personal data and human genetic materials.

D. Certain rules may apply when importing materials into the United States. "Importation of many biological materials to the U.S. requires USDA permits." COGR Brochure, Q17.

E. Another set of laws concerns export of materials. Although U.S. export control laws will allow most materials to leave the U.S. without a special license, special licenses may be required for materials that could be used in chemical or biological weapons, including for example human pathogens and toxins. See COGR Brochure, Q20.

F. UBMTA §12 requires that the recipient use the Material "in compliance with all applicable statutes and regulations, including … those relating to research involving the use of animals or recombinant DNA."

If you would like to discuss material transfer issues, please feel free to contact **Howard G. Zaharoff**.