Specific Issues with Material Transfer Agreements

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ABSTRACT

In the health and agricultural sciences, biological materials were once freely and widely exchanged. But more and more, these materials have gained commercial value. Public sector institutions, as well as private companies, have recognized, therefore, that proprietary protection of these materials may be necessary. Material transfer agreements (MTAs) are legal instruments that define terms for the transfer of tangible biological materials between or among two or more parties. MTAs are bailments that transfer possession but not title: the party who transfers the materials retains full ownership; the party who receives the materials holds them in trust. Transfer is governed by contract, ideally specifying the term of the transfer, how the materials may and may not be used, and other related issues, such as confidentiality. In addition, an MTA may contain licensing provisions for the transfer of embedded intellectual property (IP) rights (patent rights). Hence, an MTA can be a hybrid instrument, covering the transfer of both tangible property (via bailment and contract) and intangible property (via licensing of patent rights). Biological materials transferred using MTAs include reagents, cell lines, antibodies, research tools, insertional mutant populations, genome sequence databases, novel vectors, and plant genetic resources. Due to divergent institutional priorities, material transfers between the private and public sectors are generally more complex than those between public sector institutions.

1. INTRODUCTION

There is a long history of sharing biological materials, such as plant germplasm or genetic stocks, and for the most part this has been done freely and often without any form of a legal agreement. This has not typically been the case in health research, where reagents, cell lines or antibodies that have potential therapeutic implications have been transferred under specific agreements that define the terms of the transfer. In both agricultural and health research, the increasingly sophisticated research approaches that rely heavily on access to biological or bioinformatic resources created by other researchers have dramatically increased the need for researchers to share research tools. This trend has been advanced further by the investment of federal agencies (notably the National Science Foundation [NSF] and the National Institutes of Health [NIH]) and private companies in the development of genomic resources that are intended primarily as vehicles for further discovery of gene function and/or gene regulation. These types of biological and bioinformatic resources (such as insertional mutant populations, genome sequence databases, and novel vectors) are the most problematic with regard to sharing, because they are the research tools that can lead to potentially valuable discoveries, invariably leading to the question of who will own or control those downstream discoveries.

The NIH considers the sharing of research tools so important to future research progress that the agency issued strong guidelines on the appropriate terms for transfer of research materials that contribute to, or result from, NIH-funded

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research.[1] Similarly, the NSF has issued guidelines for data and materials release and requires investigators to describe the timing, constraints, and means of release of materials developed, particularly for programs (such as the Plant Genome Research Program) that focus on the generation of research resources and tools.[2]

Plant genetic resources represent another area of increasing concern regarding how freely these resources can be exchanged. Even those plant genetic resource centers that are most committed to the free exchange of germplasm now utilize specific agreements to govern the transfer of seeds, if only to specify that the recipient cannot seek intellectual property (IP) rights on the materials (the African Rice Center, WARDA; Box 1 [see end of chapter])[3] or to ensure that the recipient understands that there is no warranty on the transferred material (Tomato Genetics Resource Center; Box 2 [see end of chapter]).

Scientists have traditionally shared research materials freely, and, indeed, an important criterion for scientific publication has been the ability of other researchers to experimentally reproduce and thereby test published results. The ability to replicate results will often rely on access to the underlying biological materials or information, but that access is not assured today. So what has changed? Probably the most significant change has been the narrowing of the gap between fundamental research and commercial developments, particularly in health research, but also in agriculture.[4] Materials that at one time would have been useful almost exclusively for fundamental research purposes are increasingly seen as having direct commercial value, and this trend has generated a new breed of researchers and companies that focus on leveraging novel research tools to discover new commercially valuable traits, genes, or compounds. Particularly, in the case of companies, they may be reluctant to share their "crown jewels" without making sure that their business interests are protected. As a result of the Bayh-Dole Act, many universities actively use the patent system as a means to transfer research results to industry. In addition, universities increasingly conduct research that is sponsored by industry. As a consequence, they may have concerns similar to those of private companies. So a company that traditionally had little concern over a university's use of its property may now be appropriately concerned that its proprietary materials may lead to valuable inventions or even to fueling a competitor's business interests. Universities and nonprofit research institutions have also become much more aware and protective of research materials. The result has been a slow but steady evaporation of unrestricted transfers of research materials between scientists, in general, and particularly between industry scientists and those in universities.

With growing regularity, the sharing of research materials takes place under material transfer agreements (MTAs). MTAs are legal agreements (bailments) that govern the transfer of a tangible property between parties. For example, the University of California, Davis, executed over 470 MTAs in 2005, and this number had been increasing every year since 2001. At the same time, the *complexity* of MTAs is increasing dramatically, with restrictions and obligations potentially reaching far beyond the material itself, to data or inventions made using the material and/or to derivative materials. As a consequence, each MTA has begun to take on the complexity of a license agreement, and a high level of skill and time are required to ensure that the MTA can be executed without compromising key principles and will not conflict with other agreements. Hence, an MTA can be a hybrid instrument: covering the transfer of both tangible property (via bailment and contract) and intangible IP (via licensing of patent rights). To complicate things even further, provisions of an MTA may stipulate how any future IP rights, arising from the use of the materials transferred, will be allocated.

Because MTAs are contractual agreements between two or more parties, the agreements typically do not have the geographic or temporal limitations of patented technologies (patents are territorial, issued by countries, with limited terms, typically 20 years from filing) and, consequently, can be much farther reaching than the scope of patent rights. It is interesting to note that an evaluation of the property rights associated with "GoldenRice" indicated that 44 patented products or processes and at least 15 materials, many of which were governed by

MTAs, were potentially used in its development.[5] In navigating the intellectual and technical property landscape surrounding "GoldenRice," Potrykus reported that the restrictions imposed by one MTA had been particularly problematic.[6]

Just as universities are experiencing an increase in the use of MTAs for receiving and disseminating materials, so are companies. One large pharmaceutical company indicated that it had six administrators dealing with more than 1,000 MTAs in the year 2000 and that many of these agreements required lengthy negotiations. Some companies have questioned whether it is worth their while to exchange research tools with university scientists at all.[7] In our own experience, agreements for transfer of research materials from industry to the university often have a low priority for attention within company legal departments, particularly because such transfers are often only incidental to, or may actually compromise, their main commercial interests. We estimated that 10%–25% of MTAs received from industry for incoming materials to the University of California were never executed because the terms compromised fundamental academic principles or created legal obligations that the university cannot fulfill. An example of a deal-breaking term in an MTA is one that specifies that the provider maintain ownership of data resulting from use of the materials. This term could prevent publication or prevent the continuation of the very research that the material was intended to advance. Thus, universities in general are in a situation in which the exchange of research materials is of increasing and indeed critical importance, but both universities and private companies are having difficulty finding easy ways to share these resources. As Eisenberg summarized *"Although there are many points on which they disagree, most people from each of these quarters seem to agree that the problem is growing rather than diminishing."*[8]

2. WHAT IS A MATERIAL TRANSFER AGREEMENT?

Fundamentally, an MTA is a *bailment*, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties. In addition to the tangible property rights being owned by the provider, the material(s) may be the subject of a patent or patent application. In this case, the MTA may need to account for the transfer of IP rights as well as the transfer of tangible material. Transfer of IP rights would be in the form of a license, for example, to make, use, sell, and so forth, that is, a license is permission to do what would otherwise violate the provider's IP rights. This chapter deals with materials that are intended to be used for research purposes, usually in the absence of planned research collaboration between the provider and recipient. Such a collaboration could be accommodated by a separate *collaboration agreement* that would accompany the MTA. The MTA defines the rights of the provider and recipient with respect to the materials and derivatives of the materials.

At most institutions, researchers themselves are not authorized to sign either outgoing or incoming MTAs for their institutions. The MTAs must be reviewed and approved by an authorized institutional official. Agreements that are not signed by an institutional official may not be valid or enforceable. These functions usually reside in the Office of Research Administration (Sponsored Programs) or the office that manages IP and technology transfer for the institution. Because the researcher utilizing the material(s) is ultimately responsible for fulfilling the obligations of the MTA, most MTAs require the signature of the recipient of the material acknowledging their recognition of their responsibilities and duties under the agreement.

3. STRUCTURE OF A MATERIAL TRANSFER AGREEMENT

An MTA can range in size from a few hundred words on one page to several thousand words on more than a dozen pages. The NIH's "Simple Letter Agreement for the Transfer of Materials" (Box 3 [see end of chapter]) is an excellent example of

a short, easy-to-understand, one-page MTA. The Simple Letter Agreement requires no negotiation and is used by academic institutions throughout the United States to transfer materials, and, in the case of research consortia composed of multiple academic or nonprofit institutions, this type of agreement can be modified to provide an umbrella for easy transfer of materials between consortium members. On the other end of the spectrum, a complex and lengthy MTA from a company willing to provide innovative and highly proprietary materials can take years to negotiate.

The standard MTA used by the Davis campus of the University of California (Box 4 [see end of chapter]) represents an MTA that a university would use to provide materials to another university. An MTA, regardless of its length and complexity, may incorporate many if not all of the following:

- a preamble
- definitions
- a description of use of the materials
- confidential information
- IP rights
- warranties
- liability and/or indemnification
- publication
- governing law
- termination
- signatures
- exhibits or appendices

3.1 *The preamble*

The preamble of an MTA is like an abstract of a manuscript or a prologue to a novel. The preamble lays the groundwork for the MTA and sets the stage for the legally binding terms and conditions that follow. The preamble identifies parties to the agreement and specifies the MTA's effective date. It may also include the addresses of the parties. It may even contain recitals or whereas clauses describing the material, the goal of the research, and the intent of the parties.

3.2 *Definitions*

An MTA may have a separate section to define specific terms such as *materials*, *use of the materials*, *modifications*, or *inventions*. On the other hand, an MTA may define these terms as they first appear within the agreement. In a third approach, an MTA may define the terms that will be used throughout the agreement in a separate section for definitions and define the terms that are used only in one or two sections as they first appear within the agreement.

The definition of *materials* should be limited to that of the actual materials being transferred, including progeny and unmodified derivatives, and should not include substances or inventions created by the recipient of the materials. *Progeny*, as defined in the Uniform Biological Material Transfer Agreement (UBMTA), are unmodified descendents of the original material. Progeny can include a virus from a virus, a cell from a cell, or an organism from an organism. Unmodified derivatives, according to the UBMTA, are substances created by the recipient that constitute an unmodified functional subunit or an expression product of the original material that was provided. Unmodified derivatives can include purified or fractionated subsets of the original material; progeny or products thereof; subclones of unmodified cell lines; transcription and translation products, such as RNA and protein derived from provided DNA; reverse transcription and reverse translation products, such as DNA synthesized on a template using provided RNA; monoclonal antibodies secreted by a hybridoma cell line; and chemically synthesized copies. Since a provider usually asserts ownership of materials, the definition of materials should not overreach to modifications, derivatives, crossbred progeny (in animals), mutants, or other substances that are not being provided by the provider.

3.3 *Use of the materials*

An MTA specifies how the recipient can and cannot use the material. Usually, the MTA contains a blank space for the researcher to include a description of the research use with the material. Sometimes an MTA has a separate appendix with a very detailed description of the intended research use. An MTA will usually prohibit the recipient from using the materials in a manner other than that intended by the original research. An MTA will also typically prohibit provider's material from being tested in humans and used in plants and

animals consumed as food. Other prohibitions may include using the material in research that has IP obligations to third parties, or with other materials from third parties, or transferring the material to third parties or even to other researchers within the recipient's institution. Finally, most MTAs have prohibitions for the material to be used for commercial purposes.

3.4 *Confidential information*

Often, providers of materials include, on the MTA form, proprietary or confidential information. Therefore an MTA may contain a provision to protect the provider's confidential information. Confidential information can be defined as "information, data, or material, in written or other tangible form related to the material, that is identified as confidential at the time of disclosure." However, confidential information should ***not*** include information that is:

- generally known to the public at the time of disclosure to the recipient
- already in the recipient's possession at the time of disclosure by the provider
- disclosed to the recipient on a nonconfidential basis by a third party having the right to make such disclosure
- independently developed by the recipient without the use of the confidential information disclosed by the provider as evidenced by written records
- required to be disclosed by law or governmental rule or regulation

The MTA should include language to make clear to the provider that the above information is not considered confidential.

An MTA may also specify that the recipient of the confidential information treat it as confidential and maintain it in confidence for a certain period of time. A long period of nondisclosure, for example, over five years, may be very difficult for a university to manage. Generally, an MTA may require that all confidential information be marked "Confidential" and be reduced to writing. Reducing confidential information to writing places an additional administrative burden on both parties, but it does make it easier for the recipient to know precisely what information must be kept confidential.

The MTA may stipulate that the recipient can disclose the provider's confidential information only to the recipient's own personnel who have a need to know and who use the confidential information. The MTA may also require that the recipient take the same steps and use the same methods to prevent the unauthorized use or disclosure of the provider's confidential information as the recipient would take to protect its own confidential information. Requirements such as these are generally appropriate when confidential information is being exchanged.

3.5 *Intellectual property*

Nearly every MTA will address IP matters such as the disclosing of inventions, the prosecuting of patents and plant variety protection certificates, and the granting of options and licenses. IP rights language is perhaps the most challenging language to negotiate. An MTA may contain overarching IP language that can reach to a researcher's and/or institution's past inventions and future inventions, which may have little or nothing to do with the materials provided, and could impact the researchers ability to continue doing related research.

The MTA may specify that the recipient disclose, assign, and/or license any inventions to the provider, free of any royalties and fees. While most institutions will agree to certain licensing rights, they are generally unable to assign an invention because doing so may violate:

1. the Bayh-Dole Act if the invention resulted from research funded by the U.S. federal government
2. the Tax Reform Act of 1986 by possibly jeopardizing the U.S. federal tax-free status of bonds that were issued to build or improve research facilities
3. the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, by restricting the accessibility of research materials

4. an institution's own principles, policies, and practices if the invention was not developed for the public benefit
5. other laws, regulations, rules and policies

It is generally reasonable to grant a limited subset of IP rights to the provider of the materials. For example, to the extent that the recipient is legally able to do so, the recipient could grant a nonexclusive royalty-free research license to any inventions that necessarily use or necessarily incorporate the material and are conceived and first actually reduced to practice in the performance of the research. The recipient, in many cases, may be able to grant a first right or an option to negotiate a non-exclusive or exclusive commercial license to such inventions. In some cases, when a provider provides innovative and valuable compounds, a recipient may have to grant a nonexclusive, royalty-free research license to such inventions if the provider is concerned about being blocked from practicing new uses for its materials especially when the provider is performing or sponsoring similar research.

3.6 *Warranties*

An MTA nearly always stipulates that the material does not come with any warranties. A typical warranty clause, usually written in capital letters, may read:

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.

The language is nearly always written in uppercase letters to make the clause stand out.

3.7 *Liability and indemnification*

An MTA usually stipulates that the recipient of the materials assumes all liability for damages that may arise from the recipient's use, storage or disposal of the material, and modifications. In addition, many providers will stipulate that the recipient indemnify, hold harmless, and defend the provider against any claims, costs, or other liabilities that may arise as a result of recipient's use, storage, or disposal of the material. A number of state institutions, for example in Alabama, Georgia, Kentucky, New York and other states, are prohibited from indemnifying other parties and must limit their indemnification to the extent permitted by state law. In addition to recipient liability, some MTAs will make the providers liable for losses, claims, or demands made by the recipient, or made against the recipient by any other party, that are due to the provider's negligence or misconduct.

3.8 *Publications*

An MTA should enable the recipient of the materials to publish or present the results of the recipient's research using the materials without the approval of the provider. An MTA can require that the recipient send the provider a copy of any proposed manuscript, abstract, poster session, or presentation prior to such publication or presentation so that the provider can review it, provide any comments, or request the removal of the provider's confidential information. A review period of 30 to 45 days is sufficient for most providers and is acceptable to most academic recipients. The MTA may require that the publication or presentation be delayed for an additional period of time to allow for the filing of patent applications. An additional period of 30 to 45 days is sufficient for most providers. An MTA can also require the recipient to acknowledge the provider for providing the materials in any publications or presentations.

3.9 *Governing law*

An MTA may specify that it is governed by the laws of a particular jurisdiction, state, or country. This may present a problem in cases in which the provider and the recipient are located in separate jurisdictions, states, or countries. Most providers and recipients will agree to be silent on governing law.

3.10 *Termination*

An MTA should specify an expiration date for the agreement. Otherwise, the recipient's obligations will continue forever. The parties should be able to terminate the MTA earlier by providing advance, written notice. When the MTA expires or terminates, the recipient is generally required to stop using the material and may be required to return or destroy any remaining material. A termination clause may also delineate certain obligations that survive termination. These surviving obligations may be related to areas dealing with confidentiality, IP, warranties, liability, and indemnification. The MTA can always be extended by the mutual agreement of both parties.

3.11 *Signatures*

The signature section is usually the last part of an MTA. A typical MTA may have the signatures of the following individuals:

- the authorized official of the organization or company receiving the materials
- the researcher receiving the material
- the authorized official of the organization or company providing the materials
- the researcher providing the material

Some MTAs may require only the signature(s) of the authorized official and/or the researcher of the recipient of the materials. Researchers may sign as acknowledging, reading, and/or understanding the MTA but should not sign as legal parties to the MTA. Doing so could place them at risk of being personally liable and being sued in a court of law.

3.12 *Exhibits or appendices*

An MTA may include an exhibit or appendix that is attached to the end of the agreement. In many cases, the attachment is a detailed description of the research, a protocol, or a long list of materials. Sometimes confidential information is put in the exhibits or appendices so that it can be redacted more easily than if it were put into the agreement.

4. MATERIAL TRANSFER BETWEEN UNIVERSITIES

Sharing of materials between university scientists is generally less problematic than transfers between industry and academia, primarily because the cultures and motivations of each institution involved in the exchange are similar. In the United States, most universities readily transfer materials for academic research purposes under terms that typically have no restrictions other than a requirement not to transfer the materials to third parties without approval or notification. These transfers are often accomplished using the NIH-facilitated UBMTA[9], the NIH's Simple Letter Agreement, or an equivalently benign agreement. The UBMTA incorporates a very narrow definition of the material to be transferred and the agreement does not give a provider rights beyond the "*original material, progeny and unmodified derivatives*." This narrow definition and the lack of "reach through" to new materials and to new research results is the hallmark of agreements between universities that greatly facilitates these transfers.

When a problem does occur in a transfer between academic institutions, it is usually because the material has been exclusively licensed and the terms of that agreement impose some constraints on the institution providing the material. However, this problem is usually avoidable, particularly if such exclusive licenses specifically reserve the right to use the materials for internal research purposes and to transfer the materials for research at other academic institutions. For example, the University of California routinely incorporates the following clause into its exclusive license agreements:

Nothing in this Agreement will be deemed to limit the right of The Regents (i.e. University) … to make and use the Invention … and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.

5. MATERIAL TRANSFER FROM PRIVATE COMPANIES TO UNIVERSITIES

Material transfers between private and public sector institutions are typically much more complex than transfers between two universities and are much more prone to failure, particularly when the transfer is from a company to a university researcher.[10] What are some of the features of these MTAs that create difficulties, particularly for

universities? Contrary to popular belief, the primary issues for most universities do not concern the ability to profit from licensing future inventions, but center on:

- a few fundamental academic principles
- the need to avoid incurring unfunded financial obligations
- the need to avoid creating conflicting legal obligations with third parties

These issues primarily reflect most universities' concern with protecting the fundamental mission of the institution and their low tolerance for financial or legal risk.

5.1 *Dissemination of research results*

The single most obvious and fundamental principle for the university and university researchers is to preserve the unrestricted ability to publish their research results. The freedom to publish can be restricted by MTAs when the provider requires editorial rights in a publication or the right to approve and, by inference, to disapprove a publication. Publication restrictions can show up in MTAs in indirect ways as well. For example, the material itself may be specified as confidential, making a meaningful publication impossible. Of particular concern are the serious consequences that a publication restriction can have on students, whose future depends so heavily on publication. Clearly, this is one principle a university cannot compromise and the principle is so widely recognized that one would think it would not even be on the table for discussion. However, it occasionally is.

Typically, the material provider's underlying concern is not to restrict academic publication but to protect its confidential information related to the material and to preserve patentability of inventions. Both are legitimate concerns and can usually be met by agreeing to remove a company's confidential information from publications and to delay publication for a limited time (usually 60 to 90 days) to permit the evaluation of potentially patentable inventions and to file patent applications, when appropriate. Universities readily agree to these types of provisions, but further restrictions on publication rights are typically nonnegotiable.

5.2 *Rights in research results*

Universities also need to preserve the ability of their researchers to use their own research results in future research. This may seem obvious, but if a provider of material insists that it own the results of research conducted with its material (sometimes including data, inventions, and reports), researchers and universities can lose all access to these products of their own research, making it difficult, if not impossible, to perform any follow-on research. An example of how this appears in an MTA would be a case in which a provider asserts ownership of new substances created by the university researcher while using its proprietary material, sometimes reaching to substances or compositions that don't contain the original material in any form (often referred to as *reach through* rights). This type of provision could have an impact on publication as well, since many journals require that materials discussed in a paper be made available for replication of the research. Yet in this case such availability would be controlled by the material provider, not the researcher. In many cases, a for-profit provider may have a legitimate reason to insist on retaining ownership of any modifications of its original material. For example, if a vector that took years to create could now be easily modified to incorporate new functions, the provider would be understandably reluctant to relinquish rights to improvements that can now be relatively easily incorporated. In these cases, it may not be appropriate or possible to share this material. However, in many cases this kind of provision is the result of a provider using too broad an approach to ensure no possible loss of its own rights. Negotiations can often identify a balanced solution in which the provider is assured that it maintains ownership of its proprietary material, and while a recipient may own the narrow improvement it created, the provider would still own the original material if it continued to be included as a component.

5.3 *Conflicting legal obligations*

Perhaps the most difficult issue presented by MTAs is the potential for entering into agree-

ments that create conflicting legal obligations. This situation routinely arises because, while the material is coming from one source, the funding for the research is usually provided by a different source, typically public agencies but also, potentially, other private companies. To the extent that the MTA and relevant funding sources carry IP obligations, it is easy to see how conflicts can arise. While such obligations are typical of private research support, public funding also carries legal IP obligations to the government. The most prominent of these obligations includes requirements in the United States under the Bayh-Dole Act, such as, a prohibition on assigning title to inventions to third parties, the provision of a nonexclusive license to the government to practice or have practiced the invention on behalf of the government, and the right of the government to march in. Clearly, the university cannot enter into an MTA that creates a new obligation that is in conflict with such obligations of law or its contractual obligations to others. For example, if access to a particular research tool or material requires that the provider be offered an exclusive license to inventions, then this restricts the project from receiving any other material or research funding that carries a similar obligation—exclusive access to inventions from the same project can be given only once! The university and its researchers need to be very careful in determining how important are specific inputs to the project, and they may need to decide which IP rights can be apportioned to research sponsors and/or material providers and prioritize those rights. It is clear from the complexity of inputs to research projects and the increasing complexities of ownership of research tools and materials, that access to the full set of tools for certain projects may simply be impossible. This situation is analogous to that which has been described as the "tragedy of the anticommons" where the fragmentation of IP ownership becomes so complex that no single entity can acquire all the rights it needs to develop products.[11] In a similar sense, the fragmented ownership of research materials or information can impact the practical ability to conduct fundamental research or at least to do so using the most efficient research tools.

5.4 *Public benefit of university research*

Universities, particularly public universities and those whose research is supported largely by public funds, have an obligation to see that their innovations are made available to the public in a diligent and timely manner. In the United States, this obligation is based on the Bayh-Dole Act, which has a stated objective "to promote … public availability of inventions," as well as on the philosophical missions of most universities. One means of accomplishing availability is through the licensing of inventions to private companies that can invest the often substantial additional R&D effort required to produce real products. The public benefit obligation can be compromised by MTAs that require the granting of a nonexclusive, royalty-free license to inventions back to the provider. If the company were not interested in commercializing the invention, the existence of its nonexclusive, royalty-free license could prevent other companies from entering into a license, because they would lack the exclusivity needed to allow them to invest in the development of the technology, effectively "shelving" the technology. A solution that is often acceptable is involves linking such a license very narrowly to inventions that are dependent on the company's material. These inventions represent the company's legitimate business interest and are inventions that, typically, only the company providing the material would be in position to commercialize. While broader language seeking a license to inventions less closely linked to the material will not necessarily prevent a university from signing an MTA, such language should certainly provoke a careful evaluation of the situation.

5.5 *Fair consideration*

Most universities seek a financial return in exchange for the commercial use of their research results. Public institutions, in particular, are concerned that the public funds that are used to support the institution should not be used to indirectly support private companies. These considerations color the expectations of universities, particularly if the provider of a material seeks free license to resulting inventions. Here, the interests of the university's administration and researchers may diverge, with researchers needing, primarily,

to gain access to the material to advance their research and with the administration seeking to preserve the fundamental principles of the university and avoid costly legal battles. Where interests are divergent, the situation can become very complex. In our experience, a common underlying interest of all parties is to enable and accelerate research progress, and in most cases solutions can be developed that satisfy the essential needs of all parties. Unfortunately, developing these solutions can take a long time and, as mentioned earlier, for many private companies, negotiating MTAs for university researchers is a low priority in relation to the many IP-related transactions that may be more critical to the company's primary business interests.

6. CONCLUSIONS

Overall, the transfer of materials between researchers has been getting more difficult, and it appears that the days of open exchange of materials, particularly from researchers in industry to academic researchers in the life sciences, are over. While some domains of free exchange continue to thrive, and some funding agencies and foundations are actively promoting open exchange of materials, these are becoming exceptions rather than the rule. Both universities and private companies have legitimate interests, which they are trying to support when engaging in material transfers. When these interests collide, it can be difficult to find common ground. However, the mutual interest of both research-based private companies and of universities is to support research advances; and when both parties keep this overarching objective in mind, material transfers usually are possible. ■

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3 The sample agreements found at the end of this chapter are also available for free download at www.ipHandbook.org. An Adobe® Acrobat® reader or Microsoft® Word® are required. The Web site also contains many additional IP sample agreements.

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7 Eisenberg RS. 2001. Bargaining over the Transfer of Research Tools: Is This Market Failing or Emerging? In *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (eds. RC Dreyfuss, DL Zimmerman and H First). Oxford University Press: New York. pp 223–249.

8 See *supra* note 6.

9 ott.od.nih.gov/newpages/UBMTA.pdf.

10 Pool R. 2000. Material Transfer Agreements. In *Finding the Path: Issues of Access to Research Resources*. National Academic Press: Washington, D. C. www.nap.edu/catalog/9629.html.

11 Heller MA and RS Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280:698–701.

Box 1: Material Transfer Agreement (MTA) for plant genetic resources held in trust by the Africa Rice Center (WARDA)[1]

The plant genetic resources (hereinafter referred to as the "material") contained herein are being furnished by Africa Rice Center (WARDA) under the following conditions:

- Africa Rice Center (WARDA) is making the material described in the attached list available as part of its policy of maximizing the utilization of material for research, breeding and training. The material was either developed by Africa Rice Center (WARDA); or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made available for any agricultural research, breeding and training purposes under the terms and conditions set out in the agreement on 26 October 1994 between the Africa Rice Center (WARDA) and the Food and Agriculture Organization of the United Nations (FAO).

- The material is held in trust under the terms of this agreement, and the recipient has no rights to obtain Intellectual Property Rights (IPRs) on the material or related information.

- The recipient may utilize and conserve the material for research, breeding and training and may distribute it to other parties provided such other parties accept the terms and conditions of this agreement.

- The recipient, therefore, hereby agrees not to claim ownership over the material, nor to seek IPRs over that material, or its genetic parts or components, in the form received. The recipient also agrees not to seek IPRs over related information received.

- The recipient further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the material available, is bound by the same provisions and undertakes to pass on the same obligations to future recipients of the material.

- Africa Rice Center (WARDA) makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

- Upon request, Africa Rice Center (WARDA) will furnish information that may be available in addition to whatever is furnished with the material. Recipients are requested to furnish Africa Rice Center (WARDA) with related data and information collected during evaluation and utilization.

(Continued on Next Page)

1. This MTA covers materials which are being transferred before the entry into force of the International Treaty on Plant Genetic Resources for Food and Agriculture. The Treaty envisages that Africa Rice Center (WARDA) will enter into an agreement with the Governing Body of the Treaty, once the Treaty enters into force. Africa Rice Center (WARDA) has indicated its intention to conclude such an agreement with the Governing Body. This agreement, in line with the Treaty, will provide for new MTAs and benefit-sharing arrangements for materials transferred after the entry into force of the agreement. The attention of the recipient is drawn to the fact that the details of the MTA, including the identity of the recipient, will be made available to the public.

2. This does not prevent the recipients from releasing the material for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in this MTA are complied with.

Box 1 (continued)

- The recipient of material provided under this MTA is encouraged to share the benefits accruing from its use, including commercial use, through the mechanisms of exchange of information, access to and transfer of technology, capacity building and sharing of benefits arising from commercialization. Africa Rice Center (WARDA) is prepared to facilitate the sharing of such benefits by directing them to the conservation and sustainable use of the plant genetic resources in question, particularly in national and regional programs in developing countries and countries with economies in transition, especially in centers of diversity and the least developed countries.

The material is supplied expressly conditional on acceptance of the terms of this Agreement. The recipient's acceptance of the material constitutes acceptance of the terms of this Agreement.

Box 2: Material Transfer Agreement (MTA) for requesting plant materials from the C.M. Rick Tomato Genetics Resource Center (TGRC)

THIS AGREEMENT is made by and between The Regents of the University of California ("THE REGENTS") on behalf of the C. M. Rick Tomato Genetics Resource Center ("TGRC"), and _____ _____("RECIPIENT"). THE REGENTS asks that the RECIPIENT agree to the following before the RECIPIENT receives the plant materials requested from the TGRC.

1. The TGRC will make substitutions, as necessary, for items that are currently unavailable for distribution. For large requests, the TGRC may delete some items, as needed, to reduce its workload and accommodate other requests. The TGRC will provide a packing list detailing which accessions ("MATERIAL") have been shipped.
2. The MATERIAL is provided free of charge and, except as stated herein, without restrictions by the TGRC to support research, breeding, and/or educational projects involving tomato. The RECIPIENT may distribute the MATERIAL to third parties under an MTA that includes the language of terms 3, 4, 5, and 6.
3. THE REGENTS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, REGARDING THE FITNESS OR MERCHANTABILITY FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
4. The MATERIAL has not been thoroughly evaluated by the TGRC. THE REGENTS MAKES NO WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, REGARDING THE ACCURACY OF THE INFORMATION PROVIDED BY THE TGRC; THE QUALITY, HEALTH, OR PHYTOSANITARY CONDITION OF THE MATERIAL; OR THE GENETIC IDENTITY OF THE MATERIAL, INCLUDING ITS ORIGIN, PURITY, TRUENESS TO TYPE, GENETIC BACKGROUND, AND THE PRESENCE OR ABSENCE OF ANY TRANSGENES. The RECIPIENT is responsible for verifying that genetic identity is correct in its own plantings, and the RECIPIENT will notify the TGRC of any potential problems it observes with the MATERIAL, such as aberrant segregation, incorrect phenotypes, unexpected traits, or other problems.
5. Unless prohibited by law, the RECIPIENT assumes all liability for damages it incurs and for claims by third parties which may arise from the RECIPIENT's use, storage or disposal of the MATERIAL. RECIPIENT shall hold harmless, defend, and indemnify THE REGENTS against any claims, costs or other liabilities which may arise as a result of the RECIPIENT'S use, storage or disposal of the MATERIAL.
6. The RECIPIENT shall acknowledge the TGRC as the supplier of the MATERIAL in any publications which result from the RECIPIENT's use of the MATERIAL, and shall provide the TGRC with copies of the relevant publications.
7. Before the TGRC can send the MATERIAL, the RECIPIENT or other authorized official of the RECIPIENT's organization, must sign and deliver this MTA by mail, facsimile, e-mail or in person to the TGRC at the following address:

C. M. Rick Tomato Genetics Resource Center
Department of Plant Sciences (Mail Stop 3)
University of California, Davis
One Shields Avenue
Davis, CA 95616, U.S.A.

Tel.: +1-530-754-6059
Fax: +1-530-752-9659
tgrc@ucdavis.edu
http://tgrc.ucdavis.edu

CERTIFICATION BY RECIPIENT OR OTHER AUTHORIZED OFFICIAL:
I have read and understand the conditions outlined in this Agreement and I agree to fully abide by them in the receipt and use of the MATERIAL.

Signature, Name and Title: _____

Institution:_____Date:_____

Box 3: Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL _____ _____ 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 RECIPIENT'S 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: _____

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.

(Continued on Next Page)

Box 3 (continued)

_____ _____ _____ _____

Signature of 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.

_____

Recipient Scientist Date

Box 4: Material Transfer Agreement with the University of California, Davis

This Agreement is made this _____ of _____, by and between THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, as represented by its Davis campus, ("UC DAVIS"), having an address at the Office of Research, Technology and Industry Alliances, Technology Transfer Services; University of California, Davis; 1850 Research Park Drive, Suite 100; Davis, CA 95616-6134, and ___ _____ ("RECIPIENT"), having its principal place of business at _____ (collectively "the PARTIES").

RECIPIENT has requested from UC DAVIS the MATERIAL defined in Section 1.B. below for the RESEARCH USE defined in Section 1.F. below by the RECIPIENT INVESTIGATOR(S) defined in Section 1.G. below. In consideration of the supply of MATERIAL from UC DAVIS to RECIPIENT, the PARTIES agree as follows:

1. Definitions

A. "ORIGINAL TRANSFERRED MATERIAL": The physical material actually delivered to the RECIPIENT by UC DAVIS, as identified in Exhibit A attached hereto.

B. "MATERIAL": ORIGINAL TRANSFERRED MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES.

C. "PROGENY": Unmodified descendant from the MATERIAL. Examples include but are not limited to: virus from virus; cell from cell; and organism from organism.

D. "UNMODIFIED DERIVATIVES": Substances created by the RECIPIENT that constitute an unmodified functional sub-unit or an expression product of the ORIGINAL TRANSFERRED MATERIAL. Examples include but are not limited to: purified or fractionated sub-sets of the ORIGINAL TRANSFERRED MATERIAL; PROGENY or products thereof; subclones of unmodified cell lines; transcription and translation products (e.g., RNA and protein derived from provided DNA); reverse transcription and reverse translation products (e.g., DNA synthesized on a template using provided RNA); monoclonal antibodies secreted by a hybridoma cell line; and chemically-synthesized copy or copies.

E. "MODIFICATIONS": Substances created by the RECIPIENT that either contain or incorporate the MATERIAL or were created through the use of the MATERIAL.

F. "RESEARCH USE": The scientific RESEARCH USE specified in Exhibit A.

G. "RECIPIENT INVESTIGATOR(S)": The RECIPIENT's scientific investigator(s) specified in Exhibit A.

H. "CONFIDENTIAL INFORMATION": Information, data or material in written or other tangible form related to the MATERIAL that is identified as confidential at the time of disclosure. CONFIDENTIAL INFORMATION does NOT include information that is:

(i) generally known to the public at the time of disclosure to the RECIPIENT;

(ii) already in RECIPIENT's possession at the time of disclosure by UC DAVIS;

(iii) disclosed to RECIPIENT on a non-confidential basis by a third party having the right to make such disclosure;

(iv) independently developed by RECIPIENT without the use of the CONFIDENTIAL INFORMATION disclosed by UC DAVIS as evidenced by written records; or

(v) required to be disclosed by law or governmental rule or regulation.

(Continued on Next Page)

Box 4 (continued)

2. Terms and Conditions

A. Use

i. The RECIPIENT shall use the MATERIAL solely for the RESEARCH USE. Any other use of the MATERIAL by the RECIPIENT is expressly prohibited without the prior written consent of UC DAVIS. In addition, the RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including, but not limited to, those related to research involving the use of animals or recombinant DNA. The MATERIAL may not be used on any human subjects or for commercial purposes or any other use other than the RESEARCH USE.

ii. RECIPIENT will not analyze the MATERIAL for chemical composition or physical structure or have or allow any component of the MATERIAL to be analyzed or make any use of any such analysis. The RECIPIENT will not alter the chemical structure of the MATERIAL in any way.

B. Tangible Property Ownership: UC DAVIS retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

C. Confidentiality: Any CONFIDENTIAL INFORMATION disclosed by UC DAVIS to RECIPIENT shall be treated as confidential and maintained in confidence by RECIPIENT for five (5) years after disclosure. RECIPIENT shall not disclose any CONFIDENTIAL INFORMATION of UC DAVIS, except to its own personnel who have a need to know. Without limiting the foregoing, RECIPIENT agrees to take the same steps and use the same methods to prevent the unauthorized use or disclosure of CONFIDENTIAL INFORMATION of UC DAVIS as it takes to protect its own CONFIDENTIAL INFORMATION or proprietary information.

D. Distribution: RECIPIENT agrees NOT to transfer the MATERIAL or MODIFICATIONS to anyone other than to one who works under the direct supervision of the RECIPIENT INVESTIGATOR within the RESEARCH USE without the prior written consent of UC DAVIS.

E. Disclosure, Inventorship, and Intellectual Property Rights

i. Disclosure: The RECIPIENT shall promptly notify UC DAVIS of any potentially patentable discoveries or inventions made through the use of the MATERIAL, whether or not made within the specified limits of the approved RESEARCH USE. The RECIPIENT shall promptly supply UC DAVIS with a copy of the invention disclosure.

ii. Inventorship: Inventorship shall be determined according to United States patent law.

iii. Intellectual Property Rights: Collaborative efforts of UC DAVIS and the RECIPIENT may create inventorship rights under United States patent law as well as under the law of any applicable jurisdiction in which a party or the PARTIES may elect to file patent application(s). Each party shall own its undivided interest in joint inventions. The PARTIES shall cooperate in discussing and securing intellectual property rights to protect potentially patentable inventions.

iv. No Implied Rights: 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 license or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of UC DAVIS, including any altered forms of the MATERIAL made by UC DAVIS. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS or any related patents of UC DAVIS for commercial use or any other use other than the RESEARCH USE.

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Box 4 (continued)

F. Warranty and Licenses:

i. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. UC DAVIS 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.

ii. If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for profit-making or commercial purposes, the RECIPIENT agrees, in advance of such use, to negotiate in good faith and conclude a license agreement containing terms typically required in license agreements executed by UC DAVIS. It is understood by the RECIPIENT that UC DAVIS will have no obligation to grant such a license to RECIPIENT, that future licensing rights, if any, may be subject to preexisting contractual obligations of UC DAVIS, and that UC DAVIS may grant exclusive or non-exclusive commercial licenses to others.

G. Liability: The RECIPIENT assumes all liability for damages that may arise from its use, storage or disposal of the MATERIAL and MODIFICATIONS. UC DAVIS 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, storage or disposal of the MATERIAL and MODIFICATIONS by the RECIPIENT. The RECIPIENT agrees to indemnify, hold harmless and defend UC DAVIS against any claims, costs or other liabilities which may arise as a result of RECIPIENT'S use, storage or disposal of the MATERIAL.

H. Publication of Research Results: The RECIPIENT may publish or present results of research relating to the MATERIAL, provided the RECIPIENT provides UC DAVIS with a copy of any proposed manuscript, abstract, poster session or presentation at least thirty (30) days prior to such publication or presentation. UC DAVIS shall review such publication or presentation for CONFIDENTIAL INFORMATION or patentable material and may request a delay of the proposed publication or presentation for up to an additional thirty (30) days to allow for the removal of CONFIDENTIAL INFORMATION or the filing of patent application(s). Unless UC DAVIS directs otherwise, any publication or presentation reporting the research carried out with the MATERIAL shall contain proper referencing in academic journal format, acknowledging UC DAVIS as the source of the MATERIAL.

I. Termination:

i. Date: This Agreement will terminate on the earliest of the following dates:

(a) on completion of RECIPIENT'S current RESEARCH USE with the MATERIAL;

(b) on thirty (30) days' written notice by one party to the other; or

(c) (____) years from the date of execution of this Agreement by UC DAVIS.

ii. Surviving Obligations: Obligations with respect to Tangible Property Ownership (2.B.), Confidentiality (2.C.), Distribution (2.D.), Disclosure, Inventorship, and Intellectual Property Rights (2.E.), Warranty and Licenses (2.F.), Liability (2.G.), Publication of Research Results (2.H.), and this Section (2.I.ii) shall survive termination.

iii. Return of MATERIAL: As directed by UC DAVIS, RECIPIENT shall stop using the MATERIAL and shall return or destroy any remaining MATERIAL on the termination of this Agreement.

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Box 4 (continued)

J. Applicable Law: The validity and interpretation of this Agreement and legal relations of the PARTIES in the performance of this Agreement shall be governed by the laws of the State of California without regard to conflicts of law provisions.

K. Notice: Any notice required under this Agreement will be considered properly given and effective on the date of the postmark if mailed by prepaid postage first-class certified mail; on the date of delivery if delivered in person; or on the date of receipt if mailed by any global express carrier service that requires the recipient to sign the documents demonstrating the delivery of such notice. Notice shall be given to the designated authorized official at the address provided below:

FOR THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

Authorized Official:	Executive Director, Technology and Industry Alliances
Address:	Technology Transfer Services, Office of Research, Technology and Industry Alliances, University of California, Davis 1850 Research Park Drive, Suite 100
City, State, Zip:	Davis, CA 95616-6134
Country:	USA
Telephone:	530.757.3432
Fax:	530.758.3276

FOR RECIPIENT:

Authorized Official: _____

Recipient Institution: _____

Address: _____

_____

City/State/ZIP: _____

Country: _____

Telephone: _____

Fax: _____

3. Complete Agreement

This Agreement constitutes all the agreements between the PARTIES, both written and oral with respect to the subject matter hereof. All prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, between the PARTIES are hereby canceled.

(Continued on Next Page)

Box 4 (continued)

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	RECIPIENT
Name:	Name:
Associate Director, Technology Transfer Services	Title:
Date:	Date:

UC DAVIS INVESTIGATOR and RECIPIENT INVESTIGATOR acknowledge reading and understanding this Agreement and shall abide by the terms and conditions thereof.

UC DAVIS INVESTIGATOR	RECIPIENT INVESTIGATOR
Name:	Name:
Title:	Title:
Date:	Date:

Exhibit A

1. ORIGINAL TRANSFERRED MATERIAL:
2. RESEARCH USE:
3. RECIPIENT INVESTIGATOR (name):