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# Materials Transfer in Academia

**COGR**

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## Council on Governmental Relations

The Council on Governmental Relations is an association of leading research-intensive universities. COGR's primary function consists in helping to develop policies and practices that fairly reflect the mutual interest and separate obligations of federal agencies and universities in federal research and training. COGR deals primarily with policies and technical issues involved in the administration of federally sponsored programs at universities. It keeps under continuing review the problems potentially inherent in the development of federal policies, regulations and other federal initiatives.

This booklet does not claim to be a manual of university technology transfer, nor does it offer model policies. It attempts, however, to inform the debate about transfer of biological materials in academia.

For the preparation of the material, the COGR Technology Transfer and Research Ethics Committee gives credit and thanks to Dr. Susan Cullen, Washington University. Other members of the COGR Committee are: Joyce Brinton, Harvard University, Chair; Terrence Feuerborn, University of California; Ann Hammersla, Syracuse University; Karl Hittelman, University of California, San Francisco; Mary Ellen Sheridan, University of Chicago; Francis Meyer, University of North Carolina; Julie Watson, Indiana University; and Kate Phillips, COGR. In addition, the Committee gratefully acknowledges the assistance of many of its member universities.

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## **Materials Transfer in Academia**

### **Objective of this Brochure**

This brochure about transfer of biological materials addresses many of the issues in the ongoing national technology transfer debate. It is provided in an effort to create better understanding between scientists in commercial and academic laboratories, as well as between academic investigators and their administrative support staff. With improved understanding of the goals and the process, we believe that the beneficial exchange of materials will be more timely while avoiding risk to academic principles.

The brochure, much of it in question and answer format, is for faculty who are or will be involved in the exchange of research materials either with industry colleagues or with academic colleagues outside the home campus. It provides explanations for the procedures and agreements that cover transfer of incoming and outgoing research materials. The brochure points out potential problems in draft agreements sent by the providers of materials, and it explains the consequences of accepting agreement terms that are overly broad or restrictive. While the focus is on biological materials, the issues discussed are similar for samples of chemical compounds, other types of tangible research materials and even for some types of software.

### **Different objectives lead to different expectations.**

Institutions involved in the exchange of unique materials include federal laboratories, industrial research laboratories, and laboratories in universities, hospitals, or independent research institutes. Given their diverse structures and missions, these entities are likely to have their own specific expectations regarding “compensation” for the help they provide. The desired compensation may range from acknowledgment in a publication to ownership of inventions made with the aid of the provided material, depending on the purpose of the providing entity.

Consistent with its mission, industry enhances and defends its commercial interests vigorously. To reward

its investors and be successful, industry needs to offset risk by acquiring and protecting exclusivity in the market that either can be obtained under patent law or by use of trade secrets. Industry's mission is clear and unconflicted.

In contrast, the federal government and its academic grantees have several missions that are not always consistent. First is a mission to preserve the flow of ideas for public benefit, primarily through timely publication. Second is a mission to serve as the public's steward of inventions by preserving the potential for new knowledge to generate a product from which the public may benefit. The latter mission was encouraged in law starting in 1980. There are times when these two missions seem to conflict, making it difficult for federal labs, universities, hospitals and independent research institutions to maintain consistency. The most frequent example of the clash of internal academic goals is found in the material transfer agreement. It is the attempt to balance these conflicting goals that has triggered the increased care and rigor in the negotiation of material transfer agreement terms. The unfortunate consequence of this increased attention is the delay in the material exchanges that is so frustrating to investigators. The fortunate consequences are less easy to appreciate, because they manifest themselves as an absence of downstream problems.

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. There is a discussion of the Uniform Biological Material Transfer Agreement (UBMTA) in Q&A #10.

The exchange of materials between universities and industrial laboratories is often difficult, and despite some ongoing efforts, is not likely to be standardized in the near future. Irrespective of whether or not such agreements can be successfully standardized, it is critical to realize that the agreements that cover these exchanges are contractually binding upon the parties, and that breach of these agreements creates a legal and financial risk for the institutions and investigators involved.

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## Twenty Questions and Answers About Material Transfer Agreements

The recurring questions in this area do have answers, and there are even some solutions to problems. By and large, all who work with material transfers in universities want to help investigators acquire materials to advance research, but they also want to make sure that an MTA agreement does not foreclose an investigator's freedom to select a future research problem, and that their institution can live up to its contractual obligations. The questions below deal with:

- what hinders agreement on MTA terms? (Q1-9)
- timeliness of negotiation (Q10-12)
- authorization to negotiate and enforcement (Q13-14)
- financial or other costs of transfer (Q15-16)
- responding to federal regulations on transfers (Q17-20)

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**1. Why isn't material transfer informal and collegial, rather than bureaucratic and legalistic?**

**F**rom the point of view of advancing science – the process should be as simple as possible, but providers of materials want to have written agreements to be sure that there is a common understanding of how the materials can be used. Unfortunately, some proposed agreements undermine an academic scientist's ability to carry out future work with freedom, or place investigators and their universities at unnecessary risk. Since MTAs are actually binding contracts, both the scientists and the academic institutions are obliged to live up to the provisions they contain. If the provisions conflict with academic missions or create unnecessary risk, the institutions usually feel obligated to remove the conflict by changing “problem” MTA terms.

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**2. What MTA terms frequently raise problems?**

**T**erms that:

- (a) restrict academic freedom
- (b) assert excessive rights of ownership
- (c) ask for inappropriate indemnification by the university

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### How do agreement terms restrict academic freedom?

The most obvious restriction on academic freedom is a limitation on the ability to publish the results of research. Many agreements may require the investigator to provide an advance copy of any manuscript or proposed public disclosure of results obtained with the material. The purpose is not unreasonable. It is to allow the provider to determine whether its own confidential information (if any) has been improperly disclosed in the manuscript or presentation, and whether there are new intellectual property rights that may be important for the provider to know about, and to protect. When this provision is couched in equitable language, the recipient investigators and their institutions still need to decide whether they can comply with such a restriction, and if not, the agreement should not be signed. In some agreements, the publication provision may be stated in unacceptable language. The language may give the provider control of publication, and may assert that nothing is to be published or otherwise disclosed without provider approval. Other agreements may demand excessive delays. Typically, universities will not accept language controlling publication in this way, even if their investigators are, for some reason, willing to agree. For another type of restriction on academic freedom, see the next question and answer.

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#### 4. Why is there concern about ownership rights?

While it is quite obvious that the physical materials are the property of the provider, providers may also assert ownership not only to the physical material being provided, but also to new materials created by the recipient or inventions made through the use of the provided materials. Thus, some agreement terms may cause the recipient to lose control of his/her own creations, including inventions and intellectual property. This not only represents a direct loss, but can cause indirect damage by limiting the freedom of the recipient to continue a line of inquiry because he/she no longer owns his/her research results.

An MTA may also include a more subtle kind of capture of intellectual property rights. While an agreement may not claim actual ownership, it may award the provider an automatic license to resulting intellectual property for little or no compensation. Nonetheless, when a company makes what it regards as available materials available for use in university research, it generally expects some access to resulting intellectual property. This might be in the form of granting the provider an opportunity to negotiate a license so that the company can develop the intellectual property into useful products. However, since the provider of the material is (usually) not funding the research, the institution needs to ensure that its intellectual property obligations to those sponsors who are funding the work do not conflict with the proposed obligations to the provider of the material. Because so much academic research is federally funded, it may be important to clearly acknowledge in the MTA the rights of the federal government regarding inventions that may be made with the material.<sup>1</sup> Similar issue may exist for other sources of sponsorship.

Terms which give the provider licensing rights to resulting intellectual property must be carefully crafted to ensure that (a) the rights of research sponsors are protected, (b) the licensee company will diligently develop the intellectual property for public use, and (c) the university receives fair compensation for its contribution. Still it must be recognized that granting the provider licensing rights does limit the investigator's ability to seek future research funding from competitor companies to continue this research. The bottom line is that getting the material may open new avenues of research, but careless acceptance of terms that surrender intellectual property rights may close them down.

Returning to an earlier point, with biological materials capable of self-replication, there has been quite extended analysis of the dividing line between what the provider and the recipient should equitably own, and this is summarized in the table below. While looking at this table, bear in mind that in contracts, the usual meaning of words is often changed by establishing internally "defined terms" with meanings that are different than those in the table, and which are set by the contract itself. When a contract is interpreted by the court, it is the internal definitions that count the most.

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## Desirable Definitions of Terms in Material Transfer Agreements

<b>Material</b>	The physical substance being transferred, but in a proposed contract the term may be definitionally enlarged to include other items, including confidential information about the material, and the forms of the material which may arise from replication and maintenance in the recipient laboratory (see: Progeny, Derivatives). Occasionally, the proposed definition of “Material” in agreement drafts may even include new intellectual property arising through the use of the transferred material. (see: Modifications)
<b>Progeny</b>	Usually means the descendant copies of the material that are produced in the recipient laboratory as a result of replication (e.g. cell division, DNA copying). The implication is that progeny material is an essentially unchanged copy of the originally provided material, and thus is provider-owned.
<b>Unmodified Derivatives</b>	Usually means products of the original transferred material (e.g. monoclonal antibodies secreted by a hybridoma cell line) and these are also considered to be provider-owned. When the term “derivatives” is used in a contract, it should be clarified whether or not this term includes more than unmodified derivatives.
<b>Modifications</b>	Usually means <b>modified derivatives</b> (cf. Unmodified Derivatives) of the original material (e.g. the original provider-owned DNA molecule or a fragment thereof newly embedded in a recipient-owned expression vector and using a recipient-owned promoter). Modifications with new utility that include material from both the provider and the recipient may be inventions with ownership vesting in both the provider and the recipient, but each individual case must be well understood for such conclusions to be reached.

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**5. What is indemnification, and what is the importance of limiting indemnification requirements?**

**I**ndemnification is akin to releasing the provider from responsibility to make good on damage occurring as a result of provider action or inaction. It is a shifting of economic responsibility. An agreement term may require that the recipient institution indemnify the provider against any damage that may occur through use of the material, implying that the provider is not responsible even if the material was provided without proper warnings as to associated hazards or needed precautions. Some materials are in fact hazardous to the user, and academic institutions tend to require that such hazards be disclosed and that the provider take responsibility for negligence in disclosure of known hazards. This position is aimed at maintaining safety of employees, not all of whom may be equally knowledgeable about hazards. In addition, many state universities and the federal laboratories may not legally agree to indemnifications because of explicit statements in the laws that govern them.

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**6. How is ownership of combination materials determined when several parties have contributed the physical materials that are now combined?**

**E**quitable ownership of materials is determined in much the same way as ownership of intellectual property. Thus the owner of the expression vector with unique characteristics and the owner of the newly cloned gene which is to be inserted into that vector are co-owners of the resulting engineered material. If it is commercialized, all co-owners should benefit, and this can be managed with the help of the technology transfer office. Difficulties arise when the academic investigator who does the engineering has received the two materials from two different providers, or has made one of the materials under company sponsorship. In such a situation it is quite likely that the terms of the agreements (MTA agreements or research sponsorship agreements) covering the two materials are in conflict. This type of conflict should be avoided, and company providers are now often requiring investigators and their institutions to state in the agreements that no such conflicts currently exist, and none will be allowed to develop. Great care should be exercised in agreeing to such restrictions.

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7.

## **How does loss of control of intellectual property limit future research paths?**

If preemptive MTAs cloud ownership rights, investigators may be restricted in their ability to interact with a future sponsor. Even when investigators feel unfettered because their present work is federally supported, they may eventually need a commercial developer to convert an invention into a real product from which the public can benefit. Intellectual property terms in MTAs may prevent the institution from conferring rights on a future developer, just as a lien on real property may prevent subsequent transfer of title. No sponsor wants to pay for research benefits that it cannot have. In addition, the terms of an MTA may make it difficult to collaborate with other scientists.

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**8. Is there an option for an institution to forego ownership rights?**

Investigators may be willing to forego inventor's rights because they believe it would expedite MTA processing, and intellectual property rights and commercialization are not that important to them personally. Investigators who have federal funding should be aware that although the federal government does not demand active participation in commercialization by anyone, it does require that its grantees avoid impeding commercialization. Thus, federally-supported investigators and their institutions are obligated to report inventions, and if title to inventions will not be claimed by the institution, the government requires sufficient notice to be able to take title itself and file patents when warranted [37 CFR 401.14(c)(1-3)]. Thus the institution cannot "give away" rights which it has previously agreed either to claim itself or waive to the federal government. Obviously, some judgment must be exercised in deciding what kind of research finding constitutes an "invention." Investigators can get advice about what is reportable from the office responsible for invention disclosures.

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**9. Why is it useful to use MTAs when materials are being sent to academic colleagues?**

It is no doubt true that many transfers within academia are still informal, even though the use of an MTA is recommended so that disputes about use do not arise. The National Laboratories may have rules that require agreements in order to transfer materials outside the Laboratories. However, there is one type of situation that actually requires use of an agreement. If a material to be transferred includes material that is still owned by a third party provider, further transfer of that material is almost certainly contractually restricted by the MTA or other agreement that covered its receipt. It is improper to transfer material that was received even in part from another source with obligations attached to it. However, it is often possible to transfer material anyway, provided that the new recipient agrees to honor the obligations imposed by the original provider. Providing the material without such an agreement can provoke litigation.

Even if the material to be transferred is owned free and clear by the provider, informal transfers done without MTAs confer little protection on either the provider or the recipient. As more faculty members become interested in working with industrial sponsors and in developing inventions that can be licensed to provide income to the inventors and/or to the laboratory, there is a need to establish the ownership of inventions. Even if investigators are not personally interested in working with industry, they may still want to forestall having their inventions commercialized by others without any compensation to the creator. In addition to intellectual property concerns, there are also other issues to consider, such as protection of an investigator and institution against liability arising from potential misuse (whether unintentional or negligent) of hazardous material by another party.

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## 10. Can MTA agreements be expedited through standardization?

Some progress has been made in standardization. For certain transfers between academic institutions, there is a standardized approach available called the Uniform Biological Material Transfer Agreement (**UBMTA**). A group convened by the National Institutes of Health worked out standard terms for exchanges in 1995. If a university joins the pact group (now 109 institutions), it may use the UBMTA when appropriate. When it does, material transfers only need to be recorded, not negotiated. This helps by making at least one class of transfers routine.

However, there is another class of transfer between universities that is more difficult to standardize. When the material was made or will be used in an academic project supported by industry, it essentially makes the industrial sponsor a silent third party to the material transfer agreement, and the UBMTA may not be a usable vehicle. When the academic institution negotiates an MTA to offer or accept material developed under industrial funding, it must take into account the relevant obligations to the industrial sponsor, and sometimes those obligations must be passed through to the other collaborators. Investigators who feel that a potential sponsor of their research is making unacceptable restrictions on future material transfers should enlist the help of their institutional negotiator to deal with the issue at the time when the *sponsorship* agreement is negotiated, i.e., when provisions allowing transfers for research purposes can still be adjusted.

A logical extension of standardization would be to develop some appropriate form of agreement specifically for academic-industry transfers. This approach is considerably more difficult, because many companies believe that they compromise their rights as a result of standardization. Several initiatives are being undertaken by the university intellectual property community. In one of these, it is proposed that industry-to-university exchanges be classified according to the degree of exclusivity needed by the provider company relevant to a particular material. Lower-risk exchanges could then be standardized, and higher risk exchanges could occur according to agreed-upon general principles, with latitude to negotiate. These efforts are continuing, but are impeded by the varying positions among companies.

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**11. Can processing of MTAs within an institution be streamlined?**

**M**any academic institutions are expediting transfer by collecting a standard set of data from the intended faculty recipient. These data describe the material, its properties (including biohazards), its uniqueness (ascertaining whether the provider is the sole source), the potential to create and develop intellectual property using the material, and the type of sponsorship for the proposed research use. By providing such information to the institution early in the process, the investigator can help make the negotiation process more informed and expeditious.

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12.

## **What else holds up the MTA negotiation process?**

One factor that is out of control of the university negotiator is the willingness of the provider to negotiate, and the timeliness of their negotiation. However, often the university official has enough experience to know which negotiations may be difficult or slow. Investigators who ask about prior experience with a source of material may learn of likely problems, and sometimes may be able to find another source of the material, or use a substitute that will be easier to acquire.

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**13. Who has the authority to sign MTA agreements?**

**I**n almost all cases investigators are required to co-sign the agreement as evidence that they have read it and will comply with its terms. However, since MTA agreements are contracts, the official signature can only come from those in the institution who are charged with the task of reviewing them, and who have been delegated authority to bind the university contractually. Typically this authority will reside in a central office at the school or institution level, e.g. an office of sponsored projects or a technology transfer office. The validity of MTA agreements signed only by investigators, department chairs, or other individuals who do not have delegated institutional signature authority is questionable. Delegated authority is usually recognized in an explicit written internal institutional document that names the authorized individuals and defines the scope of authority. Many company attorneys verify authenticity of signatures on MTA agreements.

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#### 14. Are MTA agreements ever enforced?

The short answer is that they will be enforced when the stakes are highest, and the stakeholders care about them the most. The corollary is: It is impossible to predict which transfers will become a focus of concern. The academic institution cannot view some agreements as “more important” than others, or more worthy of correction by vigorous negotiation. When important commercialization opportunities arise, they can have significant impact on small company value, or can critically affect the value of risk investments by large companies. Under such circumstances, there is a strong likelihood that any investigator or university activities that have an adverse effect on commercial interests may trigger lawsuits. Such lawsuits are as likely to involve MTAs as any other contracts with the university. Ignoring detrimental MTA provisions places both investigators and their institutions at risk. Even if an institution is exonerated in court, the costs of defending against such actions are very large.

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15. **Is there any way to recover cost of transfers?**

Some materials can be very costly to make, and it can be financially unreasonable to supply them to multiple investigators, or even prohibitively expensive to send them out just once. If this is the only deterring factor, the MTA can include the proposal of a one-time fee to allow cost recovery. Such a fee can reasonably include the cost of materials, the extra labor required to make them, and shipping or other fees. If the material arose under federal sponsorship, such revenue may be considered “Program Income”, and may, therefore, be reportable as such. NIH information on Program Income can be found in the NIH Grants Manual. Other federal agencies employ similar concepts. If the material was developed under federal funding *and* title is established by reporting it to the agency as an invention<sup>2</sup> (patented or not patented), it can be licensed for fees that will be accounted for as income from intellectual property. As such, like royalty income, it is distinguished from other kinds of program income and sheltered under current federal policy (OMB Circular A-110, .24(h)), and thus may be distributed according to university policy.

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**16. Is there a way to supply materials when the obstacle is time and effort?**

There are two ways to handle this problem, neither involving an MTA. (1) The materials may be suitable for deposit in a publicly-supported or user-fee-supported facility. For example, some cell lines may be accepted for maintenance and distribution by the American Type Culture Collection. (2) The right to make and distribute the materials may be licensed to a company that sells reagents to the research community. For example, a unique hybridoma cell line producing monoclonal antibodies important for research could be licensed. The licensee company would agree to sell the antibodies to researchers, and in return for the license, would share revenue from sales in the form of royalty payments to the provider. Investigators may even be able to solve their own internal supply problems by negotiating a cost-free return supply of the reagent as part of the license agreement. It is not necessary to report royalty income as “Program Income” and thus it can be distributed according to university policy, benefiting the creator(s) and their research. If the material was produced under NIH funding, licensing is allowed upon proper reporting of the material as an invention and election of title.

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**17. What can be done to expedite receipt of materials subject to U.S. Department of Agriculture importation regulations?**

Overseas suppliers of materials may employ agreements like the MTAs that are so common in the U.S. but in addition there may be USDA import regulations covering biological materials. Importation of many biological materials to the U.S. requires USDA permits. If the proper documentation does not accompany packages, they may be quarantined or otherwise delayed, and they may suffer damage in the process. Many departmental administrators have experience with this issue, and occasionally there is a designated institutional staff person to help. One place to check is the office that manages biohazardous materials for your institution. It is better to determine early whether such permits will be needed. USDA forms are available on-line at <<http://www.aphis.usda.gov/forms>>.

Likewise, export from the U.S. to other countries may require analogous permits (sometimes called export licenses, not to be confused with intellectual property licenses) and import permits from the receiving country. Occasionally, brokers are employed by the recipient to expedite such deliveries.

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**18. Are there special requirements for importation of biological materials from developing countries?**

Developed under United Nations auspices, the Convention on Biological Diversity of 1992 is principally concerned with the conservation of diverse ecological systems. However, it also contains certain provisions relating to the commercialization of genetic materials obtained from developing countries. The treaty adopting the Convention was signed by President Clinton in 1994, and awaits ratification by the U.S. Senate. There are some objections to the treaty in the Senate. Nevertheless, other countries have expectations that the treaty represents an international norm of conduct. Thus, researchers obtaining materials from developing countries may be asked to find a mechanism to compensate the country of origin, should the materials be commercialized. Researchers may encounter proposed conditions including sharing of commercial revenue, participation in research using the materials, or sharing of the new technology. This is an area that is still evolving, and not many institutions or countries have either experience or mechanisms in place to handle such arrangements. Researchers should call on the resources of their technology transfer offices, and for the immediate future, it will probably be useful to have the technology transfer professionals consult their experienced colleagues<sup>3</sup> for assistance in this area. It would not be realistic to expect that agreement on such transfers will be rapid.

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**19. Are there regulations to take into account when transferring hazardous biological materials within the United States?**

**Y**es, there are regulations covering the methods used to package and transport hazardous biological materials. In addition, these regulations<sup>4</sup> have recently been modified to require that senders and recipients of such materials be pre-registered with the Centers for Disease Control and Prevention (CDC), and that the individual transfer be registered with that agency. It is recommended that when you plan to transfer any agent covered by the regulations, that you or a staff member from the office handling your MTA should begin early to work with your institutional biohazard control officer to perform the necessary registration and to ship correctly.

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## When is a U.S. export license needed to transfer biological materials outside of the United States?

Under U.S. export control laws, automatic licenses can apply to most biological materials. In some cases, however, a license may be required from the Bureau of Export Administration of the Department of Commerce. There are, for instance, controls on the export of materials that could possibly be used in chemical or biological weapons. Examples given of such materials include human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens<sup>5</sup> An investigator planning to transfer materials, which are controlled by the Export Administration Regulations, outside the United States should work with the appropriate institutional staff person to obtain the required license. There are civil and criminal penalties for violating the Export Administration Regulations. Please also note that some highly hazardous biological materials may require multiple permits, e.g. for export from the U.S., *and* for import into another country.

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## Endnotes

<sup>1</sup> The widely cited Bayh-Dole Act and follow-on legislation addresses management of intellectual property developed under funding from any federal agency. The law is implemented in the Code of Federal Regulations at 37 CFR 401.

<sup>2</sup> Discussed in the May 17, 1996 issue of the NIH Guidelines.

<sup>3</sup> Two potential sources of assistance are the Office of Technology Transfer, University of California, and the University of Illinois at Chicago, where an institutional policy has been developed [published by S. Bertha in *Journal of Ethnopharmacology* **51**: 59-73 (1996)]

<sup>4</sup> The regulation is found at 42 CFR Part 72, "Additional Requirements for Facilities Transferring or Receiving Select Agents." Available on-line at <<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>>

<sup>5</sup> The Export Administration Regulations are at 15 CFR Parts 768-799. The section covering the scope of materials covered is 15 CFR Part 742 Supplement No. 1(12).

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