COMMENT

UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENTS: AN ARGUMENT FOR UNIFORM USE*

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I. GENERAL INFORMATION

The purpose of Article I, section 8, clause 8 of the U.S.

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Constitution is to encourage advances in science and the useful arts.[1] Material transfer agreements aid in this goal by allowing access to products discovered by a research institution or company. It is important that a material transfer agreement include all clauses necessary to adequately protect both the granting and receiving institutions and simplify the process so that research will not be delayed.[2] Protection of the granting and receiving institution includes liability for use of the materials in addition to intellectual property rights. There is currently a problem with access to research materials due to demands by providing institutions for rights to products created from those materials.[3] Material transfer agreements are binding contracts, so it is important that an institution not execute a document that it is not prepared to litigate.[4]

Recent events have added a new element of concern in the area of material transfer agreements.[5] The possibility of bioterrorism is a concern shared by many, including the government of the United States.[6] In addition to being important for protection against liability, that a granting institution should be able to verify that it is transferring a potentially dangerous material to a valid recipient is now a matter of widespread public concern. This has been a consideration for many years but the danger appears more imminent in the current environment.[7] As stated in 1987, "[a]nother consideration is the concern that health regulatories have with regard to improper use of biological materials or inappropriate handling; i.e., biological warfare or release to the environment of a toxic microorganism."[8] The

1. U.S. CONST. art. I, § 8, cl. 8 (stating "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

2. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999).

3. *Id.*

4. COUNCIL ON GOVERNMENTAL RELATIONS, MATERIALS TRANSFER IN ACADEMIA 4 (1997), *available at* http://www.cogr.edu/mta.htm (last visited Nov. 24, 2002).

5. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002) (codified at 42 C.F.R. pt. 73).

6. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002).

7. John H. Woodley, *Capitalizing on Wealth in Biotechonology*, *available at* http://www.usa-canada.les.org/membersonly/les/les/ke40295.htm (June 1, 1987).

8. *Id.* The author further states that:

> [i]n the United States, the National Institute of Health has rigid guidelines covering the development, use, and testing of genetically engineered biological materials. It is important to ensure that the group receiving the biological material agree to use the materials in compliance with all laws and regulations of their country . . . .

current climate has made the United States only too aware of the possibility of this occurrence.[9]

The National Institutes of Health published the Uniform Biological Material Transfer Agreement (UBMTA) in 1995 and recommends its use by public and non-profit institutions.[10] UBMTAs were originally created to increase the efficiency of the biological material transfer process by decreasing delays in research progress during negotiation of material transfer agreements and providing uniform protection for biological materials.[11] The UBMTA is composed of a material transfer agreement with generic language to which institutions become a signatory.[12] Each time an institution wants to provide or receive materials, an Implementing Letter is used to describe the material, recipient and provider.[13]

The UBMTA may provide an additional layer of protection against bioterrorism in addition to providing minimum liability and maximum efficiency when transferring biological materials. The current text of the UBMTA may contain definitions and clauses that may need to be amended to provide a more useful document but the UBMTA is otherwise an extremely useful tool that should be utilized to a greater extent in non-profit institutions.

II. THE NECESSITY OF REGULATING TRANSFERS OF BIOLOGICAL MATERIALS

Following September 11, 2001 and the anthrax scare that followed; multiple Acts have been drafted by Congress that address the possibility of certain biological materials being used as weapons.[14] The USA Patriot Act criminalizes the possession of

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> Furthermore, the group receiving the biological materials should agree to save and hold harmless the transferor of the material in the event of improper use by the receiving group.

Id.

9. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002) (codified at 42 C.F.R. pt.73).

10. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12, 771 (Mar. 8, 1995).

11. *Id.*

12. *Id.*

13. *Id.*

14. Tony DeCrappeo, *Bioterrorism and University Research*, *available at* http://www.ncura.edu/newsroom/newsletters/ dec01/capview.doc (last visited Feb. 9, 2003) (discussing the *USA Patriot Act*, P.L. 107-56 (2001)); Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002) (codified at 42 C.F.R. pt. 73).

select biological agents in quantities not for research or peaceful purposes.[15] That Act also prohibits possession of these agents by 'restricted persons.'[16]

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 details the procedures for possession, use and transfer of listed substances and is implemented by the Interim Final Rule: Possession, Use, and Transfer of Select Agents and Toxins.[17] The effective date of the Interim Final Rule is February 7, 2003.[18] The list of select agents and toxins affected is found in 42 C.F.R. §§ 73.4 and 73.5.[19] The HHS select agents and toxins include Crimean Congo haemorrhagic fever virus, Ebola viruses, Cercopithecine herpesvirus 1 (Herpes B virus),

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15. Tony DeCrappeo, *Bioterrorism and University Research*, *available at* http://www.ncura.edu/newsroom/ newsletters /dec01/ capview.doc (last visited Feb. 9, 2003) (discussing the *USA Patriot Act*, P.L. 107-56). The USA Patriot Act states that:

> No restricted person described in subsection (b) shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in subsection (j) of section 72.6 of title 42, Code of Federal Regulations, pursuant to section 511(d)(l) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), and is not exempted under subsection (h) of such section 72.6, or appendix A of part 72 of the Code of Regulations.

Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001, Pub. L. No. 107-56, 115 Stat. 386.

16. USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 386. The act states:

> The term 'restricted person' means an individual who—(A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year; (B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year; (C) is a fugitive from justice; (D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)); (E) is an alien illegally or unlawfully in the United States; (F) has been adjudicated as a mental defective or has been committed to any mental institution;(G) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or (H) has been discharged from the Armed Services of the United States under dishonorable conditions.

Id.

17. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002)(codified at 42 C.F.R. pt. 73).

18. *Id.*

19. *Id.*

Lassa fever virus, Marburg virus, Monkeypox virus, South American Haemorrhagic Fever viruses, Tick-borne encephalitis complex (flavi) viruses, Variola major virus and Variola minor virus, Rickettsia prowazekii, Rickettsia rickettsii, Yersinia pestis, Coccidioides posadasii, Abrin, Conotoxins, Diacetoxyscirpenol, Ricin, Saxitoxin, Tetrodotoxin, Shiga-like ribosome inactivating proteins, select agent viral nucleic acids that can encode infectious and/or replication competent forms of any of the select agent viruses, nucleic acids that encode for the functional form(s) of any of the toxins listed (if the nucleic acids are in a vector or host chromosome, can be expressed in vivo or in vitro or are in a vector or host chromosome and can be expressed in vivo or in vitro), and viruses, bacteria, fungi, and toxins listed if they have been genetically modified.[20] There are also agents listed in 42 C.F.R. § 73.5 that are called "overlap select agents and toxins" because they are covered under this act and The Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins.[21] The Interim Final Rule for Possession, Use, and Transfer of Select Agents and Toxins contains the following requirements that must be met for

transfer of a listed agent:[22] The agent may not be transferred, unless:

1) The sender has a certificate of registration for that agent, meets the exemption requirement, or is transferring the agent from outside the United States;[23]

2) The recipient has a certificate of registration for the agent;[24]

3) Both the recipient and sender complete CDC Form EA-101 and the recipient submit it to the Health and Human Services (HHS) Secretary prior to the transfer;[25]

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20. *Id.* at 76,898 (listing the viruses and toxins at 42 C.F.R. § 73.4).

21. *Id.*; Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins, 7 C.F.R. § 331 (2003), 9 C.F.R. § 121 (2003).

22. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76, 886, 76, 903 (codified at 42 C.F.R. pt. 73) (listing requirements for transfer of listed agents in 42 C.F.R. § 73.14 (2003)).

23. *Id.*

24. *Id.*

25. *Id.*

4) The CDC authorizes the transfer prior to the transfer occurring;[26]

5) The sender complies with all packaging and shipping laws;[27]

6) Within 2 days of the receipt of the agent, the recipient provides a completed copy of the CDC Form EA-101 to the sender and the HHS Secretary;[28]

7) If the agent has not been received within 48 hours of the expected delivery time or the package was damaged, the recipient reports it to the HHS Secretary; and[29]

8) The recipient notifies the HHS Secretary within five business days of consumption or destruction following a transfer.[30]

An exemption is possible if an entity's activities with the agents consist of agents that are "contained in specimens or . . . isolate[d] from specimens presented for diagnosis, verification, or proficiency testing."[31] Clinical laboratories often benefit from this exemption.[32]

The importance of keeping a record of the use, transfer and destruction of biological materials has been shown in a recent occurrence.[33] A Texas Tech professor reported vials of bubonic plague missing after he had accidentally destroyed the vials and did not keep proper documentation of the destruction.[34] Requiring documentation of what has happened to materials is important, whether it is documentation of it being destroyed or

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26. *Id.*

27. *Id.*

28. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886, 76,903 (codified at 42 C.F.R. pt. 73) (listing requirements for transfer of listed agents in 42 C.F.R. § 73.14).

29. *Id.*

30. *Id.*

31. *Id.* at 76,888.

32. *See id.* at 76,899 (listing the exemption requirements in 42 C.F.R. § 73.6).

33. CNN, *Scientist Free on Bond in Plague Case*, *available at* http://www.cnn.com/2003/LAW/01/21/plague.case/index.html (Jan. 21, 2003).

34. *Id.*

transferred to another laboratory.

III. THE ENDURING NEED FOR MATERIAL TRANSFER AGREEMENTS (MTAS)

MTAs are important because they include a requirement of the recipient to take care in handling the materials, maintain control over their distribution, address issues as to ownership, address acceptable uses of the material, and acknowledge the provider in publications.[35]

On the face of the matter, MTAs appear to be inconsistent with a research environment dedicated to the fostering of free exchange of data and materials. However, protecting both parties in an exchange of materials could actually increase the amount of research because it forces parties to address potential problems with the relationship from the start and may head off costly litigation regarding e.g., ownership or liability.

With MTAs directed to the transfer of biological materials it is important that precise meanings are given to the material and derivatives thereof and that the MTA list who owns and is liable for each. A MTA is not suitable if material can be purchased elsewhere.[36] A MTA needs to have a terminating event.[37] The National Institutes of Health (NIH) has a policy that private parties are not permitted to control a NIH scientist's publications.[38] It is possible that a case could be made for unconscionability in the creation of a contract between two institutions when the material is necessary for one institution to advance their research.[39] A UBMTA allows research institutions to interact on equal footing.

Institutions should take care in signing MTAs because they are contractually binding.[40] These contracts create risk for generally risk-adverse institutions that are dependent upon federal funding and/or an endowment for their survival. The federal government has rights to materials created with federal grant money.[41] Therefore, it is important that institutions make

35. Uniform Biological Material Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

36. BRUCE GOLDSTEIN, OVERVIEW OF TECHNOLOGY TRANSFER 22, *available at* http://www-otd.nci.nih.gov/article.pdf (last visited Nov. 4, 2002).

37. *Id.* at 24.

38. *Id.* at 23.

39. BLACK'S LAW DICTIONARY 1059 (6th ed. 1995) (defining unconscionability as unreasonably favorable to one party, with no meaningful choice).

40. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4.

41. *Id.* at 7.

sure that the rights the institution is promising to a provider in a MTA do not conflict with rights promised to the sponsor of the research. Institutions also need to verify that if their researchers create a substance using materials from two providers, the researchers have not promised rights to that work to both of them.[42] Even if there is not a current conflict, promising extensive rights to a provider of a material may prohibit interaction with a future sponsor.[43]

Many state universities and federal laboratories cannot agree to indemnification.[44] The Adequacy of Appropriations Act and Anti-deficiency Act prohibit a governmental agency from incurring a debt or liability in excess of the amount appropriated to that agency by Congress.[45] In situations other than those of state universities and federal laboratories, there can be liability outside of what the agreement states.[46]

MTAs may cause a number of difficulties within a research environment. MTAs may delay research by not allowing the material to be transferred until the MTA has been negotiated and signed.[47] MTAs may restrict academic freedom by not allowing a researcher to work with other scientists due to promises to a provider.[48] MTAs may also restrict publication, assert excessive rights of ownership and ask for inappropriate indemnification by university.[49] An institution must view all MTAs entered into with equal care as it is not possible to predict which will lead to litigation.[50]

IV. BACKGROUND CASES ON MATERIAL TRANSFER AGREEMENTS (MTAS)

The following cases depict the importance of using material transfer agreements and some of the problems encountered in

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42. *Id.* at 11.

43. NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN RES., NIH GRANTS POLICY STATEMENT 120–21 (Mar. 2001), *available at* http://grants2.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf (last visited Jan. 25, 2003).

44. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4.

45. BRUCE GOLDSTEIN, OVERVIEW OF TECHNOLOGY TRANSFER 27, *available at* http://www-otd.nci.nih.gov/article.pdf (last visited Nov. 4, 2002).

46. *Id.* at 25.

47. *Stem Cell Research: Hearing Before the Senate Comm. On Health, Education, Labor and Pensions*, 107th Cong. (Sept. 5, 2001) (statement of Karen Hersey, Senior Counsel for Intellectual Property, Massachusetts Institute of Technology).

48. *Id.*

49. *Id.*; Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771, 12,772–74 (Mar. 8, 1995).

50. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4.

their use.

A. *Wisconsin Alumni Research Foundation v. Geron*

The Wisconsin Alumni Research Foundation (WARF) holds a U.S. patent for stem cells and a method of isolating stem cells.[51] WARF established the WiCell Research Institute to distribute five stem cell lines under MTAs.[52] The terms of the MTAs required scientists to pay $5000 per human stem cell line and agree to restrictions.[53] The original research was funded in part by the Geron Corporation in return for WARF granting Geron exclusive commercialization rights to six cell lineages from five WARF cell types (hepatocytes, myocytes, neural cells, pancreatic islet cells, hematopoietic cells and osteoblasts).[54] Geron asserts that WARF is obligated to exclusively license additional cell types to Geron.[55] WARF filed suit seeking a declaratory judgment against Geron who is demanding that WARF include 12 more cell types in the license agreement.[56] WARF does not approve of the type of material transfer agreements that Geron is requiring researchers to sign to gain access to the Geron cell lineages. The Chancellor of the University of Wisconsin, John Wiley, was quoted as saying the suit "will ensure that future research is conducted in the public interest by preserving the broadest access to these original stem-cell lines."[57]

In January 2002, WARF and Geron reached an agreement resolving the lawsuit and allowing WiCell to distribute stem cell lines to academic and government researchers free of charge.[58] The new agreement allows Geron to create therapeutics and diagnostics from stem cell-derived osteoblast, hematopoietic, and chondrocyte cells under a non-exclusive license and from stem cell-derived cardiomyocyte, pancreatic islet, and neural cells under an exclusive license.[59] Geron also has a non-exclusive license for creating research products using myocytes, hepatocytes, hematopoietic cells, osteoblasts, neural cells, and

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51. Ted Agres, *Stem Cells: Steady Momentum Towards Funding*, THE SCIENTIST, Sept. 17, 2001 (online).

52. *Id.*

53. *Id.*

54. *Id.*

55. Andy Cohn, *WARF Files Lawsuit to Preserve Stem Cell Access*, Aug. 13, 2001, *available at* http://www.news.wisc.edu/view.html?get=6372 .

56. *Id.*

57. *Id.*

58. Andy Cohn, *Stem cell deal reached*, Jan. 9, 2002, *available at* http://www.news.wisc.edu/view.msql?id=6949 .

59. *Id.*

pancreatic islets.[60]

B. *Thai Rice Dispute*

In January 1995, the International Rice Research Institute (IRRI) shipped jasmine rice seeds from the Philippines to U.S. researchers, including Dr. Neil Rutger, without the MTA that is required by an agreement between the IRRI and the United Nations Food and Agriculture Organization.[61] The MTA guaranteed that the seeds would not be used to produce a strain of rice to be patented.[62] Thailand's Prime Minister has ordered legal action against the U.S. researchers.[63] IRRI said that the seeds were sent to the U.S. researchers without an MTA because the agreement between the IRRI and the United Nations Food and Agriculture Organization was not drafted until August 1995.[64]

C. *Yeshiva Univ. v. Greenberg*

Greenberg was an employee of Albert Einstein College of Medicine (AECOM), part of Yeshiva University.[65] While at AECOM she developed an antibody that can detect markers for Alzheimer's Disease.[66] Greenberg left the employ of AECOM and took the antibody with her.[67] Yeshiva University learned that Greenberg was distributing the antibody to third parties without approval of Yeshiva and without using Yeshiva's material transfer agreement.[68] The court determined that Yeshiva was the owner of the antibody because of Greenberg's work at AECOM.[69] The college directed her work as to area, method and intended result.[70]

D. *DuPont v. Okuley*

DuPont provided a professor at Washington State University

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60. *Id.*

61. Dennis Maliwanag, *Across the Nation IRRI Hit for 'Theft' of Thai Rice Variety*, PHILIPPINE DAILY INQUIRER, Dec. 5, 2001, *available at* http://archive.inq7.net/archive/2001-p/reg/2001/dec/06/reg_2-1-p.htm.

62. *Id.*

63. *Id.*

64. *Id.*

65. Yeshiva Univ. v. Greenberg, 681 N.Y.S.2d 71 (N.Y. 1998).

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.* at 72.

70. *Id.*

(WSU) access to a large library of its tagged *Arabidopsis* mutants under a research collaboration agreement in order for the professor to isolate and clone genes for fatty acid desaturase.[71] When WSU approved the research collaboration agreement, it agreed to give DuPont legal title to all inventions arising out of the collaboration.[72] During the course of defendant's work as a postdoctoral researcher in the professor's laboratory at WSU and in his work at Ohio State University, he discovered the FAD2 gene through use of the biological material library. DuPont filed a patent application on the FAD2 gene.[73] There were disagreements as to whether defendant had a legal interest in the gene.[74] The court held that he did not because all interests were assigned to DuPont as a result of the original research agreement for the access to the biological materials.[75]

E. *Davidson v. Cao*

Abbott Laboratories/Davidson (Abbott) sent samples of Kringle domains of plasminogen to Children's Hospital/Cao (CMCC) multiple times without a Confidentiality Disclosure Agreement (CDA).[76] Abbott sent a CDA to CMCC in June 1995, but CMCC did not execute it.[77] In July 1995, CMCC sent Abbott a proposal based on the UBMTA stating that CMCC "would be 'free to file patent applications' and claim inventions through the use of the material supplied by Abbott."[78]

Abbott did not execute the UBMTA but did send its own CDA to CMCC in January 1996. CMCC rejected this proposal. By May 1996, both parties had filed patent applications. Abbott and CMCC entered into a CDA in October 1997 and another in May 1998. Abbott also claims that its researcher should be listed as the named inventor on the patent obtained by CMCC, United States Patent No. 5,854,221.[79] CMCC states that the patent obtained by Abbott, United States Patent No. 5,801,146, was based on information that one of the CMCC inventors provided to Abbott.[80]

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71. E.I. du Pont de Nemours & Co. v. Okuley, 2000 WL 1911430, at *1–2 (S.D. Ohio Dec. 21, 2000) (unpublished).

72. *Id.* at *17.

73. *Id.*

74. *Id.*

75. *Id.* at *17, 27.

76. Davidson v. Cao, 211 F. Supp. 2d 264, 268 (D. Mass. 2002).

77. *Id.* at 268–69.

78. *Id.* at 269.

79. *Id.* at 270 n.10.

80. *Id.* at 271.

Abbott sued CMCC for misappropriation of trade secrets and breach of a confidentiality agreement.[81] CMCC counterclaimed for defamation, inequitable conduct, abuse of process and violation of Mass. Gen. Law ch. 93A, § 11.[82] Abbott moved to dismiss the counterclaims by CMCC.[83] The court dismissed the fraud on the court and breach of contract under the 1998 CDA counterclaims by CMCC.[84] Abbott's motion to dismiss the other counterclaims was denied. Abbott's counterclaim for breach of contract was not dismissed. As of April 2003, further developments in this case are unavailable.

V. THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT

A Uniform Biological Material Transfer Agreement (UBMTA) has been drafted and its use by public and non-profit institutions is encouraged by the Public Health Service, including the National Institutes of Health.[85] The final version was released on March 8, 1995.[86] A UBMTA is a material transfer agreement to which institutions become a signatory, thus promising to comply with text of the UBMTA.[87] When an institution desires to provide or receive a material, they need only send an Implementing Letter that describes the material, recipient and provider.[88] This decreases the amount of time it takes for an institution to receive a given biological material. All signatory institutions are previously aware of what the terms of the agreement are so there should be less noncompliance with material transfer agreements. Individual signatories have the freedom to use customized agreements for any material.[89] The

81. Davidson v. Cao, 211 F. Supp. 2d 264, 270 n.10 (D. Mass. 2002).

82. MASS. GEN. LAWS ANN. ch. 93A, § 11 (West 1997). This statute states:

> [a]ny person who engages in the conduct of any trade or commerce and who suffers any loss of money or property, real or personal, as a result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful . . . may, as hereinafter provided, bring an action in the superior court, or in the housing court . . . for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper.

Id.

83. *Davidson v. Cao*, 211 F. Supp. 2d at 267.

84. *Id.* at 291.

85. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.* at 12,771–72.

NIH predicted that the UBMTA would be "a 'living' document" that would be revised as needed.[90] A UBMTA draft was also created for transfer from industry to a non-profit organization but it was not adopted.[91]

A UBMTA aids recipients of NIH funding in complying with the requirements of Bayh-Dole Act and NIH funding agreements.[92] Program announcements by the NIH call for use of an agreement no more restrictive than the UBMTA.[93] The Bayh-Dole Act allows universities to retain title to inventions created with federal funding.[94]

The NIH Grants Policy cautions against entering into agreements that constrain research.[95] The UBMTA is in effect a treaty between research institutions regarding the transfer of biological materials. The UBMTA requires the recipient scientist, or authorized official of the institution if the recipient scientist is not authorized, to sign the Implementing Letter to certify that an unmodified UBMTA has been signed by that institution.[96] A Simple Letter Agreement is available for use

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90. *Id.* at 12,772.

91. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771, 12,772 (Mar. 8, 1995).

92. *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999)

93. NAT'L INSTITUTES OF HEALTH, PA NUMBER: PAR-03-007, NOVEL GENETIC METHODS TO MAP FUNCTIONAL NEURONAL CIRCUITS AND SYNAPTIC CHANGE (Oct. 10, 2002), *available at* http://grants2.nih.gov/grants/guide/pa-files/PAR-03-007.html (last visited Oct. 8, 2003).

94. *See* 35 U.S.C. § 200 (2000)(stating "It is the policy and objective of the Congress to use the patent system . . . to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery . . . ."); COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4.

95. NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN RES., NIH GRANTS POLICY STATEMENT 120–21 (Mar. 2001), *available at* http://grants2.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf (last visited Jan. 25, 2003). The Policy Statement notes:

> [r]ecipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant co-authorship or copyright to the provider of an invention used primarily as a research tool. NIH also recognizes the need for reasonable restrictions on collaboration by academic researchers involved with an industrial partner that avoid conflicting obligations to other industrial partners.

Id.

96. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

with non-proprietary material.[97] There was a draft agreement developed in 1992 by AUTM, NIH and the Pharmaceutical Manufacturer's Association for use when a for-profit is transferring material to a non-profit.[98] The draft was provided to the AUTM members in 1993 but has never been formalized.[99]

The UBMTA provides a set form giving a record of the institution, researcher and material involved. The requirement of signatures in order to use of the UBMTA impresses upon the parties the importance of the document. UBMTA will leave a paper trail of the transfer of materials.

Bearing the title of Uniform Biological Material Transfer Agreement, one may think that the agreement is related to uniform acts drafted by the National Conference on Commissioners on Uniform State Laws or that it is in some way a law. This is incorrect.

Approximately four and one half years after release of the UBMTA, the NIH released the "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," including a principle for use of UBMTAs.[100] The Principles and Guidelines request that NIH funded institutions: "ensure academic freedom and timely disclosure of research findings," "ensure appropriate implementation of the Bayh-Dole Act," "minimize administrative impediments to academic research," "develop and implement clear policies articulating acceptable conditions for importing resources" and "ensure dissemination of research resources developed with NIH funds."[101] It is a grants policy only; it does not create a mandatory rule.[102] The NIH has not precluded

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97. ASS'N OF UNIV. TECH. MANAGERS, INTRODUCTION TO THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT, *available at* http://www.autm.net/index_ie.html (last visited Feb. 1, 2003).

98. *Id.*

99. *Id.*

100. NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN RES., NIH GRANTS POLICY STATEMENT 120 (Mar. 2001), *available at* http://grants2.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf (last visited Jan. 25, 2003).

101. Letter from Kate Phillips, NIH Research Tools Policy Requires Utmost Attention, to Primary Representatives of Member Universities (Feb. 15, 2000), *available at* http://www.cogr.edu/docs/ResearchTools.htm (last visited Jan. 25, 2003).

102. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999); *see also* NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN RES., NIH GRANTS POLICY STATEMENT 119 (Mar. 2001), *available at* http://grants2.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf (last visited Jan. 25, 2003) (stating that "these regulations *encourage* grantees to utilize patent and licensing processes to transfer grant-supported technology to industry for development")(emphasis added).

making it a regulatory process if access to NIH-funded research tools is not sufficient.[103]

The format of the UBMTA enables a granting institution to verify that the institution and personnel requesting the material are indeed signatories. The current 229 signatories include institutions from various countries, not just the United States.[104] There were 9 new signatories in 2002 and no new signatories in 2003 as of February 1, 2003.[105] Over one third of the total signatories signed the agreement in 1995, the year of its release.[106] In 2002, a record low of signatories signed the UBMTA agreement.[107] It was approximately half the number per year that had signed each year in the preceding 6 years following 1995 (See Appendix I).[108] Although an institution may not be a signatory for many reasons, if they do not appear on the list it alerts the researcher to further investigate the recipient before sending the material.

The need for UBMTAs arises from concerns within areas of intellectual property, contracts and torts and the necessity to increase the efficiency of the process of transferring biological materials. In the past, the lack of a standardized material transfer agreement delayed research while the technology transfer personnel negotiated on the terms of the agreement. It is important that institutions do not grant rights in a material transfer agreement that hinder later research, i.e. by preventing a sponsorship agreement, or that are not even the institution's right to give, i.e. in the case of federally funded research.[109] Additionally, even if an institution does not wish to have intellectual property rights to the material transferred, if the research is federally funded, the institution must give the government the right to take title before the institution transfers the rights in a material transfer agreement.[110]

It is likely that many transfers between non-profit institutions occur without an MTA at all, with an insufficient

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103. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999).

104. Signatories to the March 8, 1995 Master UBMTA Agreement, *available at* http://www.autm.net/ubmta/signatories-list.cfm (last visited Oct. 17, 2003) (other countries include Canada, China, Germany, France, Belgium, Japan, Israel and the United Kingdom).

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4, at 7,12.

110. *Id.* at 13.

MTA or with MTAs that are individually negotiated with each transfer.[111] The release of the UBMTA was supposed to alleviate the delays caused by negotiations over individual material transfers and provide protection for both parties to the transfer.[112] "[A]lthough many universities have signed the UBMTA, few seem actually to use it even for routine exchanges of materials."[113] The UBMTA should decrease the amount of time dedicated to the procedural aspects of a material transfer, but do the limited rights given to the provider deter the transfer of the material or at least deter the use of the UBMTA?[114] Alternatively, does the confusing language of the UBMTA force institutions to use their own material transfer agreements out of apprehension of how the UBMTA will be interpreted in litigation?

The UBMTA does not contain information relating to the requirements for transfer of selected agents mentioned in the Bioterrorism Act.[115] Therefore, the UBMTA can provide another layer of protection in addition to the requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the regulations that the Act implements.[116] However, in order for the UBMTA to better serve this function, its use needs to be explicitly required. The UBMTA could provide a method of assuring responsible transfer of all biological substances. Even if a substance was not considered dangerous enough to be included upon the select agents list, it does not mean that the agent is not capable of harm.

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111. *See id.* at 14 (stating that "[i]t is no doubt true that many transfers within academia are still informal . . .").

112. *See* NAT'L INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS, REPORT PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (June 4, 1998), *available at* http://www.nih.gov/news/researchtools/ (last visited Feb. 13, 2003).

113. *Id.*

114. *See* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 149 (1999).

115. *Compare* Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995), *with* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 231, 116 Stat. 595, 660 (2002), *and* Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002)(codified at 42 C.F.R. § 73) (implementing provisions of Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, 116 Stat. 595).

116. *Compare* Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995), *with* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 231, 116 Stat. 595, 660 (2002), *and* Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002)(codified at 42 C.F.R. § 73).

VI. FORCE OF NIH POLICY RECOMMENDING THE USE OF UBMTAS

The NIH is an administrative agency.[117] It operates under the Administrative Procedure Act.[118] The NIH's publication of the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources recommend the use of UBMTAs.[119] The Principles and Guidelines qualify as a policy, not a regulation.[120] Therefore, this policy is not enforceable as law, as it would be if it were a regulation.[121] The NIH may enforce specific grant requirements if the Guidelines are not followed.[122]

In regard to NIH, the most severe penalty is likely to be loss of funding.[123] However, it is possible that in failing to comply with the Guidelines, one could violate the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.[124] The penalties for violating the Act include both civil fines and criminal penalties.[125]

VII. REASONS FOR USE OF THE UBMTA

Some research entities have previously found themselves hampered by extensive agreements that negatively affect the manner in which they may perform research.[126] MTAs may restrict the ability to publish, require unreasonable ownership rights or place the institution at risk due to liability.[127]

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117. Mark Stevenson, *Technology Transfer and March-in at the National Institute of Health: Introducing Uncertainty into an Era of Private-Public Partnership*, 50 ADMIN. L. REV. 515, 524 (1998).

118. *Id.*

119. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,092 (Dec. 23, 1999).

120. *Id.*

121. Letter from Kate Phillips, NIH Research Tools Policy Requires Utmost Attention, to Primary Representatives of Member Universities (Feb. 15, 2000), *available at* http://www.cogr.edu/docs/ResearchTools.htm(last visited Jan. 25, 2003).

122. *Id.*

123. *See id.*

124. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 231, 116 Stat. 595, 660.

125. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886, 76,892 (Dec. 13, 2002)(implementing provisions of Public Health Security and Bioterrorism Preparedness and Response Act of 2002); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 231, 116 Stat. 595 (stating the penalties for transfer to unregistered person or unregistered for possession are fined, imprisoned for no more than five years or both).

126. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4.

127. *Id.* at 6–10.

Additionally, research is delayed while the terms of the MTA are negotiated.[128]

Although many institutions have become signatories to the UBMTA, it is not used as widely as hoped. Many institutions still negotiate material transfer agreements on a case-by-case basis for each biological material.[129] This comment will review possible reasons for the lack of use of UBMTAs. Some reasons that UBMTAs may not be used may be a lack of knowledge that the Agreement exists, the document is not clearly written or that the UBMTA does not provide for aggressive protection.[130] Many institutions may not use the UBMTA when they feel that the particular biological material requires greater protection and they want to maintain a greater interest in the material than directed by the UBMTA. This comment will explore possible improvements to the UBMTA.

Commentators have speculated why the UBMTA has been underutilized and this author agrees with their observations. For example, Rai and Eisenberg state:

> The limited success of the 1995 Uniform Biological Materials Transfer Agreement ("UBMTA") demonstrates the collective action problem . . . . Many of these same institutions, however, have substituted their own form agreement for the UBMTA when they send materials out to other universities . . . . The university technology transfer officials who draft agreements for the transfer of research materials tend to see their primary job as bringing licensing revenue into the university. Their ability to bring in license revenue may also be an important criterion by which their performance is assessed. Adherence to norms of open science is at odds with this primary mission and tempts technology transfer professionals to depart from the form whenever they think a particular material may have commercial value. The limited province of the UBMTA, which is not mandatory even for all

128. *Id.*

129. NAT'L INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS, REPORT PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (June 4, 1998), *available at* http://www.nih.gov/news/researchtools/ (last visited Feb. 13, 2003).

130. BRUCE GOLDSTEIN, OVERVIEW OF TECHNOLOGY TRANSFER, *available at* http://www-otd.nci.nih.gov/article.pdf, (last visited Nov. 4, 2002).

> exchanges among universities and makes no attempt to extend the principle of open access to exchanges between academic institutions and industry, opens the door for case-by-case departures that further weaken the power of the norms.[131]

UBMTAs address concerns from various areas of law including intellectual property, tort and contract law. A material transfer situation can cause concerns in the area of trade secret law, patent law, liability in tort for injury caused by use of the material and breach of contract. The UBMTA addresses areas that may additionally be covered by statutes. Many of the statutes relate to intellectual property due to the concern of the effect of the transfers on patent and trade secret rights.[132] Statutes relating to liability in torts also come into play due to the possibility of harm from a biological material. Suits dependant upon the interpretation of an UBMTA could be for misappropriation of trade secrets, conversion, liability for tortuous injury or breach of contract.

The effect of UBMTAs is untested. It is possible to look to courts' interpretations of material transfer agreements in general to predict their interpretation of the UBMTA. It is likely that there will be difficulty in determining what clauses apply to a given transferred substance, given the circular definition of "material." It is important that an institution verifies that the other party is actually a signatory to the UBMTA or the agreement may not be binding.[133] If they are not a signatory, it would be difficult to show that they are a party to the contract.

The UBMTA appears to apply to any material to be transferred. In the case of specific materials that are deemed to be a threat to public safety, additional requirements should be added to the document. This could include verifications that that a qualified individual at a qualified institution is making the request. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 details "safety procedures for the possession, use and transfer of the listed

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131. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 305–06 (2003).

132. *See* 35 U.S.C. § 102 (2001); 35 U.S.C. § 103 (2001); 35 U.S.C. § 112 (2001); 35 U.S.C. § 116 (2001); 35 U.S.C. § 271 (2001); Uniform Trade Secrets Act § 1 (1985).

133. *Uniform Biological Material Transfer Agreement Finalized*, 24 NAT'L INST. OF HEALTH GUIDE No. 14 (1995), http://grants1.nih.gov/grants/guide/notice-files/not95-116.html(last visited Feb. 9, 2003).

agents and toxins."[134] Ideally, the additional requirements should satisfy the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

It is naïve to think that a potential terrorist could not falsify this information. However, any barrier, such as the requirement of the use of an UBMTA for transfer of material, placed in their path may act as a deterrent to someone wanting to obtain a dangerous substance.

The use of UBMTAs will also aid in keeping an inventory of research as there will be a record of the materials that have been transferred. As long as the laboratory also maintains a record of materials used within the institution, it should be evident if any material is missing. Having a record of materials transferred, in addition to materials used within the institutions will allow for easier preparation of an institution's statistical reports.

VIII. ANALYSIS OF UBMTA DEFINITIONS, TERMS AND CONDITIONS

The definitions, terms and conditions of the UBMTA are included below with comments included for each clause.

"Uniform Biological Materials Transfer Agreement
March 8, 1995

Definitions:

> 1. PROVIDER: Organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter."[135]

Comment: The implementing letter that is completed for each transfer will contain the name and address of the organization that is providing the original material.

> "2. PROVIDER SCIENTIST: The name and address of this party will be specified in an implementing letter."[136]

Comment: The implementing letter that is completed for each transfer will contain the name and address of the individual scientist(s) at the organization that is transferring the original material.

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134. Possession, Use and Transfer of Select Agents, 7 C.F.R. § 331.2 (2002).

135. *Uniform Biological Material Transfer Agreement*, http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

136. *Id.*

> "3. RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter."[137]

Comment: The implementing letter that is completed for each transfer will contain the name and address of the organization that is receiving the original material.

> "4. RECIPIENT SCIENTIST: The name and address of this party will be specified in an implementing letter."[138]

Comment: The implementing letter that is completed for each transfer will contain the name and address of the individual scientist(s) at the organization that is receiving the original material.

> "5. ORIGINAL MATERIAL: The description of the material being transferred will be specified in an implementing letter."[139]

Comment: The implementing letter that is completed for each transfer will contain a detailed description of the original material. Original material refers to the material that is physically transferred from the provider to the recipient. Dependant upon what is the original material, the description should contain information as to the species, strain, type of cell or molecule and sequence of the material. The description must be specific enough to enable comparison between the original material, modifications and progeny. It could be difficult to provide such a description based on the definitions found in the UBMTA of original material, modifications and progeny. A maxim of contract interpretation, '*contra proferentum*', translated as "against the offeror" means that "in interpreting documents, ambiguities are to be construed unfavorably to the drafter."[140] In this situation, the description would likely be construed against the institution that drafted it, the providing institution.

> "6. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not

137. *Id.*
138. *Id.*
139. *Id.*
140. BLACK'S LAW DICTIONARY 328 (6th ed. 1999).

> include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES."[141]

Comment: As used in this document, material includes the original material, unmodified descendants of the material and substances created by the recipient that constitute an unmodified functional subunit or product expressed by the original material. Material does not include substances created by the recipient that contain or incorporate the material or any substance that is not one of the aforementioned substances. These definitions are circular, as material is defined by terms which include the term 'material' in the term name or definition (See Appendix II). The definition of 'material' is stated in indefinite terms. Additionally, is it confusing to refer to 'material' as not including 'substances' 'which are not' 'modifications, progeny, and unmodified derivatives.'[142]

The language defining what is classified as an unmodified derivative and what is a modification is confusing. The addition of examples of modifications may aid in classification. It is especially important to determine what is classified as a derivative or modification. The Bayh-Dole Act and implementing regulations prevent the assigning of title to a provider for a derivative or modification of the material received for use in research funded by the NIH.[143]

> "7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism."[144]

Comment: Progeny includes the substance received when the original material is reproduced by the recipient without any alterations. Progeny is defined using the word material, which is defined using the word progeny.

> "8. UNMODIFIED DERIVATIVES: Substances

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141. *Uniform Biological Material Transfer Agreement*, http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

142. *Id.*

143. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,095 (Dec. 23, 1999).

144. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

> created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line."[145]

Comment: Unmodified derivatives include those substances that have not been altered by the recipient and are produced from the material that is physically transferred from the provider to the recipient.

> "9. MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL."[146]

Comment: Modifications include those substances that the recipient creates where the original material, progeny or unmodified derivative constitutes only a portion of a composition.

> "10. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met."[147]

145. *Id.*
146. *Id.*
147. *Id.*

Comment: The recipient institution and scientist are not allowed to sell, lease, license or transfer any substance created by or from the original material to any for-profit organization. The recipient institution also may not perform research activities for a for-profit organization if any of the conditions within section 10 are met. This may be difficult to enforce if a given laboratory does both NIH funded and for-profit research.

> "11. NONPROFIT ORGANIZATION(S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies."[148]

Comment: Nonprofit organization(s) are defined in order to determine which activities the recipient may undertake with which organizations. They include institutions of higher education, IRC § 501(c)(3) organizations and state nonprofit scientific or educational organizations.[149]

> "Terms and Conditions of this Agreement:
>
> 1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL

148. *Id.*

149. I.R.C. § 501(c)(3)(2000). The Internal Revenue Code states:

> [c]orporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation (except as otherwise provided in subsection (h)), and which does not participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.

Id.

> contained or incorporated in MODIFICATIONS."[150]

Comment: The providing organization retains ownership of any original material, progeny and unmodified derivations as well as any of the aforementioned that are contained as a portion of a composition produced by the recipient. Ownership is not defined. The author assumes that the general definition of ownership would be applicable here. Ownership is defined generally as "[t]he collection of rights allowing one to use and enjoy property, including the right to convey it to others; ownership implies the right to possess a thing, regardless of any actual or constructive control."[151] In practice, this suggests that in order for the recipient to sell anything that has been created incorporating or containing the original material, progeny, or unmodified derivatives, the recipient would need to expressly obtain transfer of ownership rights for the material received from the provider. Is it proper for the agreement to state that either a provider or a recipient has ownership when the material was created with grant money? 35 U.S.C. § 202 allows a nonprofit organization or small business firm to retain title to any subject invention.[152] Title is defined as "[t]he union of all the elements which constitute ownership."[153] It appears that it is appropriate to say that the provider or recipient has ownership. The Guidelines for Acquiring Research Resources for Use in NIH-Funded Research state that "[u]nder the Bayh-Dole Act and its implementing regulations, agreements to acquire materials for use in NIH-funded projects cannot require that title to resulting inventions be assigned to the provider." [154] "For this reason, definitions of materials that include all derivatives or modifications are unacceptable."[155] Since this clause only prohibits the recipient from having ownership in 'unmodified derivatives,' it appears to comply with the Bayh-Dole Act.

> "2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the

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150. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

151. BLACK'S LAW DICTIONARY 765 (6th ed. 1996).

152. 35 U.S.C. § 202 (2000).

153. BLACK'S LAW DICTIONARY 1485 (6th ed. 1990).

154. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,095 (Dec. 23, 1999).

155. *Id.*

> MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2 (a) or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated."[156]

Comment: The receiving organization retains ownership of substances created by the recipient, which contain or incorporate the material and that are not considered progeny, unmodified derivatives or modifications of the original material. However, this author suggests that 2b. should not include 'modifications' in the phrase stating "which are not PROGENY, UNMODIFIED DERIVATIVES OR MODIFICATIONS." The clause 2a. and the preceding phrase in 2b. state that the recipient retains ownership to modifications and substances created through their use. This author suggests that the agreement should state "original material" in place of "modifications" based on the statement included in parentheses. Additionally, joint ownership is not defined. It is not known if the parties would each have the ability to sell the material without the consent of one another.

> "3. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:
> (a) is to be used solely for teaching and academic research purposes;
> (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;
> (c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and
> (d) will not be transferred to anyone else

156. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

> within the RECIPIENT organization without the prior written consent of the PROVIDER."[157]

Comment: This clause is present for the purpose of control of liability as opposed to ownership and for protection of intellectual property rights. The authorizing official from the recipient institution only has to sign if the recipient scientist is not authorized to bind the institution. Regardless of whether the authorized recipient scientist alone or the recipient scientist and authorized official from the recipient institution sign the Implementing Letter, it should be sufficient to bind the institution because either way, the signatory has authority from the principal, the institution.[158] This clause is important in regard to safeguarding public health (in preventing a careless accident or terrorism) by impressing upon any recipient the possibility of a breach of contract action for not adequately assuring the whereabouts and security of the material.

> "4. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST'S direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL."[159]

Comment: In this clause, the receiving institution and scientist

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157. *Id.*

158. *See* RESTATEMENT (SECOND) OF AGENCY §§ 1, 7 (1958). The Restatements are only model laws; it is necessary for the jurisdiction to have adopted them as law before they have binding effect.

159. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

agree not to transfer material to anyone not bound by that implementing letter. The recipient is required to refer others desiring to obtain the material to the providing institution where an implementing letter will be signed by those parties.[160] This assures that all parties will be bound by these clauses. The provider is bound to provide the material to those wishing to replicate the recipient's research.[161] This furthers an objective of scientific research to verify and improve upon current knowledge. However, it is unclear why the phrase "who wish to replicate the recipient scientist's research" is included, as the primary purpose of the UBMTA is to share research tools, why should there be a limit as to the third party's purpose? It also makes it unclear as to what is the standard for determining if that is the third party's purpose.

> "5. (a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY,UNMODIFIED DERIVATIVES, or MODIFICATIONS.
>
> (b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.
>
> (c) Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this

160. *Id.*
161. *Id.*

> paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use."[162]

Comment: This clause is drafted in a confusing manner. It allows the receiving institution to distribute those compositions it creates using the original material that are not unmodified descendants of the material (progeny), substances created by the recipient that constitute an unmodified functional subunit or product expressed by the original material (unmodified derivatives) or substances that contain or incorporate the material (modifications). Basically, the receiving institution has the right to distribute, without restriction, any substance that does not contain, incorporate, descend or derive from in an unmodified manner, the material. Under a separate implementing letter the recipient may distribute substances that contain or incorporate the material to non-profit organizations.

Does the recipient really have ownership of modifications, as stated in clause 2 of the Terms and Conditions, when they are only able to distribute them to nonprofit organizations and under an agreement as protective as a UBMTA? The recipient is prohibited from distributing modifications for commercial purposes without written consent from the provider. If the reason for this is to protect the rights of the provider in its material included in the modification, this clause could have been drafted in a clearer fashion. In response to clause 5a, what substances does the recipient have the right to distribute? What substance is created by the use of the original material but not progeny, unmodified derivatives, or modifications?

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

162. *Id.*

> particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES."[163]

Comment: This clause reserves the right of the provider to sue the recipient for infringement once a patent issues on the material if the recipient uses the material outside of the scope of the UBMTA.[164]

> "7. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government."[165]

Comment: The language of clause 5c is reiterated in that the recipient must obtain a commercial license before use or transfer of material or modifications for commercial purposes. This clause makes it clear that the recipient would not have an exclusive license and may actually lose use of the material, at least commercially, if the provider grants an exclusive commercial license to another.

> "8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of

163. *Id.*

164. 35 U.S.C. § 271 (2000).

165. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

manufacture or use(s) of the MATERIAL."[166]

Comment: The recipient may file a patent application on an invention made through use of the original material, progeny and unmodified derivatives but must notify the provider if the application claims substances or methods of using substances created by the recipient which contain/incorporate the material. This allows the recipient to file without notification as long as the invention does not contain or incorporate the original material, progeny or unmodified derivatives. It does not make sense that a recipient does not have to notify the provider if he files an application on the actual physical material that was sent to him but must notify the provider if he files an application on an invention that incorporates that physical material.

> "9. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS."[167]

Comment: This clause contains disclaimers of warranties. Under an express or implied warranty of merchantability, one who regularly sells goods warrants to the buyer that the "goods are of good quality and are fit for the ordinary purposes for which they are used."[168] It is possible to disclaim this warranty by putting proper language in the contract.[169] U.C.C. § 2-316(2) states that to disclaim an implied warranty of merchantability, "the language must mention merchantability and in the case of a writing must be conspicuous."[170] Under U.C.C. § 1-201, the test

166. *Id.*

167. *Id.*

168. CHARLES L. KNAPP, NATHAN M. CRYSTAL & HARRY G. PRINCE, PROBLEMS IN CONTRACT LAW, CASES AND MATERIALS 529 (4th ed., Aspen Publishers, Inc., 1999) (discussing Uniform Commercial Code § 2-314).

169. *Id.* (discussing Uniform Commercial Code § 2-316).

170. *Id.* at 1218 (discussing Uniform Commercial Code § 2-316).

for conspicuousness is whether "a reasonable person against whom it is to operate ought to have noticed it."[171] It is likely that the language in the UBMTA disclaiming the warranty will be considered conspicuous as it is in all capital letters. An implied warranty of fitness for a particular purpose is created when "the buyer relies on the seller's skill or judgment to select suitable goods and the seller has reason to know of the reliance."[172] The goods do not have to be defective for there to be a breach, only unfit for the buyer's purpose.[173] Regardless of whether a transfer of scientific materials is found to be covered by the Uniform Commercial Code (U.C.C.), claims of implied warranty have been found in non-U.C.C. cases.[174] The provider also extends no warranty that the recipient will not need to receive a license from other parties in order to use the original material, progeny and unmodified derivatives.

> "10. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER."[175]

Comment: The clause states that the provider will not be liable except to the extent dictated by law.[176] The provider states that the only situation in which the provider will be liable for use of the original material, progeny or unmodified derivatives by the recipient is when the damage is caused by gross negligence or willful misconduct of the provider.[177] Does this amount to an indemnification of the provider? Many state universities or

171. *Id.* at 1219 (discussing Uniform Commercial Code § 1-201).

172. *Id.* at 529–530.

173. *Id.* at 530.

174. CHARLES L. KNAPP, NATHAN M. CRYSTAL & HARRY G. PRINCE, PROBLEMS IN CONTRACT LAW, CASES AND MATERIALS 530(4th ed., Aspen Publishers, Inc., 1999).

175. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

176. *Id.*

177. *Id.*

federal laboratories are prohibited from indemnifications and would thus be unable to sign the UBMTA.[178] It appears that that "to the extent permitted by law" is meant to address this problem.[179]

> "11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications."[180]

Comment: As one of the initial purposes of the UBMTA was to aid in the dissemination of research materials and knowledge, it is important that any agreements not limit publication of results obtained from use of the original material, progeny, unmodified derivatives or substances created by the recipient which contain or incorporate those substances.[181] Delay of publication had been a problem in general material transfer agreements as some providers required an opportunity to determine whether the publication would jeopardize any intellectual property rights of the provider.

> "12. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA."[182]

Comment: This clause merely states that the recipient agrees to follow all statutes, regulations and guidelines regarding his use of the original material, progeny and unmodified derivatives.[183] This would include the Principles and Guidelines for Recipients

178. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4 at 10.

179. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

180. *Id.*

181. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

182. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

183. *Id.*

of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.[184] Also included would be the HHS Interim Final Rule on Possession, Use and Transfer of Select Agents.[185]

> "13. This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, though reagent catalogs or public depositories or (b) on completion of the RECIPIENT's current research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:
> (i) if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and
> (ii) if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and
> (iii) in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of

184. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999). *See* NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN RES., NIH GRANTS POLICY STATEMENT 119–21 (Mar. 2001), *available at* http://grants2.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf (last visited Jan. 25, 2003).

185. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002).

> up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS."[186]

Comment: This clause controls termination of the agreement.[187] It is assumed that the lack of adherence under any circumstances other than those elaborated in clause 13 would constitute a breach of the contract.

There are four situations under which the agreement can be terminated.[188] First, it terminates if the original material, progeny or unmodified derivatives become publicly available.[189] This makes sense because the recipient should not be expected to follow the terms of this agreement while everyone else may freely obtain the substances without being bound by the agreement. If the agreement does terminate under this section, the recipient only has to abide by the least restrictive terms under which the provider distributes the material.

Second, the agreement terminates upon the completion of the recipient's current research with the original material, progeny or unmodified derivative. The agreement does not define what would be considered the "current" research. If litigated it may be difficult for either party to prove when the "current" research was completed. Upon termination under this section, the recipient will discontinue use of the original material, progeny or unmodified derivatives and destroy them or return them to the provider. It is up to the recipient to decide whether to destroy substances created by the recipient containing or incorporating the original material, progeny or unmodified derivatives. If the recipient chooses not to destroy those substances, he remains bound by the terms of this

186. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

187. *Id.*

188. *Id.*

189. *Id.*

agreement in respect to those substances.

Third, the agreement terminates upon thirty days written notice to the other party.[190] If the agreement terminates under this section, the provider must defer the termination of the agreement up to one year if the recipient requests as such in order to complete research in progress, unless the provider has terminated the agreement due to imminent health risk or patent infringement.[191] This makes sense as it would not be wise for the recipient to continue to use the original material, progeny or unmodified derivatives if it were dangerous or violating the patent rights of another. It is unknown what would be classified as an "imminent health risk." Upon termination, be it thirty days or up to one year following notice, the recipient will discontinue use of the original material, progeny or unmodified derivatives and destroy it or return it to the provider.[192] It is the recipient's decision on whether to destroy substances created by the recipient containing or incorporating the original material, progeny or unmodified derivatives.[193] If the recipient chooses not to destroy those substances, he remains bound by the terms of this agreement in respect to those substances.[194]

Fourth, the agreement terminates on a date specified in the implementing letter.[195] Following termination under this section, the recipient must discontinue use of the original material, progeny or unmodified derivatives.[196] Additionally, the recipient must destroy the original material, progeny or unmodified derivatives or return those substances to the provider.[197] The recipient may decide whether to destroy substances created by the recipient that contain or incorporate the original material, progeny or unmodified derivatives.[198] If the substances are not destroyed, the recipient remains bound by the terms of the agreement in respect to those substances.[199]

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190. *Id.*

191. *Id.*

192. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. *Uniform Biological Material Transfer Agreement*, *available at* http://www.autm.net/ubmta/UBMTAWord.doc (last visited Nov. 4, 2002).

199. *Id.*

> "14. Paragraphs 6, 9, and 10 shall survive termination."[200]

Comment: Even following the effective date of termination, the provider and the recipient will be bound by the fact that the provider has made no express or implied licenses of any intellectual property rights for the original material, progeny, unmodified derivatives, substances created by the recipient that contain or incorporate the aforementioned substances.[201] The parties would also be bound by the clauses that the provider makes no warranties and accepts no liability other than that required by law.[202]

> "15. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested by the PROVIDER, the amount will be indicated in an implementing letter."[203]

Comment: In keeping with the NIH's goal of broad dissemination of research resources, any monetary fee over and above the costs of preparation and distribution would hinder the dissemination in comparison to the level that would occur at the lesser fee.[204]

The Implementing Letter that is executed and sent with individual transfers of material includes the names, organizations, addresses and signatures of the provider and recipient as well as a description of the original material and the amount of transmittal fee, if any, to cover preparation and distribution costs.[205] By signing the Implementing Letter, each party certifies that his institution is a signatory to the UBMTA.[206]

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200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.*

204. *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,091 (Dec. 23, 1999).

205. *Uniform Biological Material Transfer Agreement Finalized*, 24 NAT'L INST. OF HEALTH GUIDE No. 14 (1995), http://grants1.nih.gov/grants/guide/notice-files/not95-116.html(last visited Feb. 9, 2003).

206. *Id.*

IX. SIMPLE LETTER AGREEMENT

The PHS, through NIH, has also created a Simple Letter Agreement (SLA) for use when the biological materials to be transferred are nonproprietary.[207] It is also an alternative for institutions to use if they have not yet become a signatory to the UBMTA.[208] The SLA incorporates many of the clauses of the UBMTA.[209] However, the SLA does not contain a definitions section, allows for a description of the material to be inserted into the document, does not address ownership of any modifications by the recipient and does not contain clauses relating to termination.[210] The SLA requires an authorized signature from both the provider and the recipient.[211]

X. CONTRACT INTERPRETATION

Are the clauses of the UBMTA vague, ambiguous or both? If one wished to sue another for breach of contract, would he be able to prove whether the UBMTA prohibited using the substance in question in a particular manner? In other words, are the definitions in the UBMTA regarding "materials" so confusing that one would be able to define a given action with a given substance as being both prohibited and not being prohibited in the agreement? The "Discussion of Public Comments Received" mentioned that "respondents indicated that some of the UBMTA definitions were confusing" and that "as appropriate, clarifications have been made."[212] It was also stated "it was anticipated that the UBMTA would be a living document that would be further refined and streamlined over time."[213] That does not appear to have happened. In this author's opinion, further clarifications are necessary.

XI. CONCLUSION

UBMTAs are a good idea from a theoretical standpoint

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207. *Id.*

208. *Id.*

209. *See* ASS'N OF UNIV. TECH. MANAGERS, SIMPLE LETTER AGREEMENT FOR THE TRANSFER OF MATERIALS, http://www.autm.net/ubmta/SimpleLtrWord.doc (last visited Feb. 9, 2003).

210. *Id.*

211. *Id.*

212. Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771, 12,772 (Mar. 8, 1995), *available at* http://grants2.nih.gov/grants/guide/notice-files/not95-116a.html (last visited Nov. 24, 2002).

213. *Id.* at 12,772.

because they reduce many of the problems associated with the transfer of biological materials, while simultaneously improving public safety. The document can provide protection to researchers, institutions, and society. In order to increase UBMTA utilization, the document should be amended to clarify its definitions. While the current UBMTA is only for transfers between two non-profit institutions, a standardized agreement for transfers between industrial researchers and a non-profit institution has been drafted though not implemented.[214] To accommodate these situations, it has been suggested that multiple levels of material transfer agreements could be used.[215] These agreements could include "[a] standardized document for materials with a requirement of low exclusivity and a general document with negotiable clauses for materials with a requirement of high exclusivity."[216] Drafting these agreements promises to be more challenging than working with non-profit institutions because industrial researchers are driven primarily by commercial interests.[217] Unless researchers are required to use a uniform agreement, the agreement will likely continue to be underutilized by researchers regardless of its content. One researcher has been quoted as saying researchers don't like universal forms because they are too "rigid."[218] That researcher just wants everyone to be ethical and recommends this guideline, "don't ask anyone to sign an agreement you wouldn't sign yourself."[219] It may be necessary for NIH to create a regulation requiring the use of the UBMTA in any institution receiving NIH funds to adequately ensure the exchange of biological materials between research entities and public safety.[220]

Melissa Schwaller

214. ASS'N OF UNIV. TECH. MANAGERS, INTRODUCTION TO THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT, *at* http://www.autm.net/index_ie.html, (last visited Feb. 1, 2003).

215. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4, at 16.

216. *Id.*

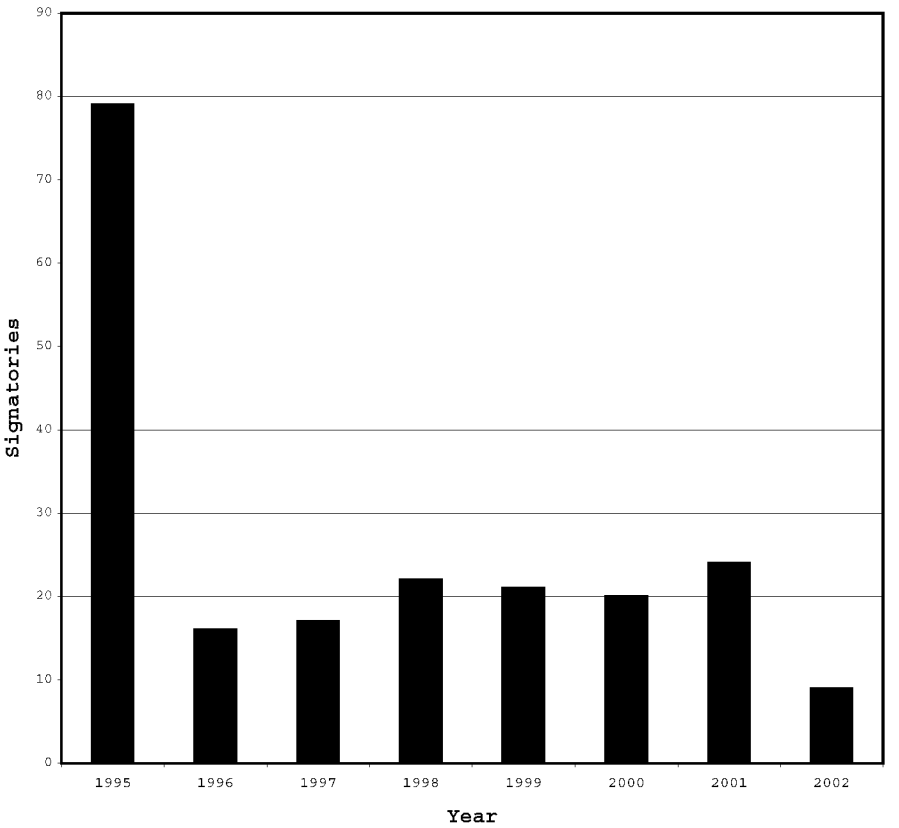
217. *Id.* at 1–2.

218. Eliot Marshall, *Need a Reagent? Just Sign Here . . .*, 278 SCI. MAG. 212, 213 (1997), http://www.sciencmag.org/cgi/content/full/278/5336/212 (last visited Oct. 1, 2003).

219. *Id.*

220. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999).

Appendix I[221]



221. THE ASS'N OF UNIV. TECH. MANAGERS, SIGNATORIES TO THE MARCH 8, 1995 MASTER UBMTA AGREEMENT, *at* http://www.autm.net/index_ie.html (last visited on Feb. 1, 2003)(Data analysis by the author using data compiled by The Association of University Technology Managers).

Appendix II

	Definition in UBMTA*	Interpretation	Example**
Original material	The description of the material being transferred will be specified in an implementing letter	The physical substance that is actually transferred from the provider to the recipient	Cell line sent to recipient
Material	Original material, progeny and unmodified derivatives. Does not include modifications or substances created by recipient by use of the material which are not modifications, progeny or unmodified derivatives	Doesn't include modifications or things created that are not modifications, progeny or unmodified derivatives	Cell line sent to recipient, unmodified descendant from cell line sent to recipient, subunit of or product expressed by the cell line sent to recipient
Progeny	Unmodified descendant from the material	Unmodified descendant from substance sent to recipient, subunit of or product expressed by the virus sent to recipient	Cells produced from the cell line sent to recipient
Unmodified derivatives	Substances created by the recipient which constitute an unmodified functional subunit or product expressed by the original material	Created from the substance transferred to the recipient	Subclones of the unmodified cell line, proteins expressed by cell line
Modifications	Substances created by recipient which contain/incorporate the material	Substance created by incorporating the transferred substance	Original DNA inserted in recipient's expression vector

*[222]

**[223]

222. *Uniform Biological Material Transfer Agreement Finalized*, 24 NAT'L INST. OF HEALTH GUIDE No. 14 (1995), http://grants1.nih.gov/grants/guide/notice-files/not95-116.html(last visited Feb. 9, 2003).

223. COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 4, at 9.