MEMO
Operating Guidance
No. 95-2
July 5, 1995

Subject: PHS Uniform Biological Material Transfer Agreement (UBMTA)

Background

The Uniform Biological Material Transfer Agreement (UBMTA) (Exhibit A-1) and related documents were published in the Federal Register on March 8, 1995 (Exhibit A-2). These documents are the result of a coordinated effort by the federal government and the university and nonprofit research communities nationwide to simplify and standardize the exchange of materials for research purposes. The broad use of such a national standard is anticipated to diminish current delays in sharing materials while conducting complex negotiations on such issues as publication restrictions and rights to inventions resulting from the use of the exchanged materials. The Public Health Service (PHS) recommended that the UBMTA "be considered for general use in the exchange of materials for research purposes among public and private nonprofit organizations." The consistent use of the UBMTA by public and nonprofit organizations is expected to reduce the administrative burden of sharing research materials as investigators rely on acceptance of its terms by cooperating institutions. The documents included in the Federal Register notice are described as follows:

i) The Uniform Biological Material Transfer Agreement (UBMTA):

The UBMTA is an agreement setting forth contractual provisions for transferring biological materials with potential commercial value for research purposes. It is intended for voluntarily use by the university and nonprofit research communities. The UBMTA provides uniform definitions for the exchanged materials and materials resulting from the research effort; discusses ownership, use, and re-distribution of such materials; establishes rights and restrictions on commercial access to intellectual property; addresses liability and distribution cost issues; requires adherence to PHS guidelines relating to recombinant DNA, protection of human subjects in research and the use of animals; and ensures the ability to publish research results. The UBMTA is intended to ensure that both the provider and recipient of the exchanged materials clearly understand their respective rights regarding the commercialization of the exchanged materials or materials resulting from the research use of the exchanged materials.
ii) Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement (Exhibit B):

PHS and the Association of University Technology Managers (AUTM) have proposed that the UBMTA be accepted as a master agreement by institutions in order to simplify the administrative handling of exchanges of biological materials. This "treaty" approach would allow participating institutions to effect individual materials exchanges by a simple reference to the UBMTA rather than by the negotiation and exchange of a full contract to address each transfer. Each institution would become part of the treaty arrangement by signing, on a one-time basis, a Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement. AUTM will maintain a list of those institutions that have agreed to accept the terms of the UBMTA and will publish that list on the Internet.

In support of the PHS objective of simplifying the exchange of research materials, and after coordination with University campus officials, Office of Technology Transfer (OTT) Executive Director Feuerborn has signed the Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement on behalf of the University of California for voluntary use systemwide. An executed copy of the Master Agreement was submitted to AUTM on June 30, 1995 (Exhibit B).

iii) UBMTA Implementing Letter (Exhibit C):

The terms of the UBMTA will be triggered for individual material exchanges into and out of the University upon the execution of a UBMTA Implementing Letter by the appropriate University official. Guidance on the appropriate use of the UBMTA Implementing Letter and on the authority to execute it is provided below.

iv) Simple Letter Agreement for Transfer of Non-Proprietary Biological Material (Exhibit D):

The Simple Letter Agreement has been developed for the transfer of non-proprietary materials upon execution by the appropriate University official. It incorporates some of the same principles as the UBMTA, but the terms of the UBMTA are not triggered by this Simple Letter Agreement. Guidance on the appropriate use of the Simple Letter Agreement and on the authority to execute it is provided below.
Materials Transferred In to the University

i) Transfers "in" using Simple Letter Agreement:

When scientists at other universities or nonprofit institutions transfer non-proprietary biological materials for teaching or academic research purposes to University faculty or scientific staff, use of the Simple Letter Agreement may be most appropriate. The Simple Letter Agreement as presented in the March 8, 1995 Federal Register may be accepted by University officials with formal authority to execute such agreements. Any changes to the wording of this Simple Letter Agreement should undergo the usual consideration by authorized University officials for conformance with University policy guidance.

ii) Transfers "in" using UBMTA Implementing Letter:

When scientists at other universities or nonprofit institutions transfer biological materials with potential commercial value for teaching or academic research purposes to University faculty or scientific staff, use of the UBMTA may be most efficient and appropriate. No institution, including signatories to the UBMTA Master Agreement, however, is required to use the UBMTA. Customized agreements may be more appropriate for transfers of materials with unusual commercial or research value.

University officials with formal authority to execute such agreements, upon receipt from a university or nonprofit material provider of a UBMTA Implementing Letter, may execute Section 7 of the Letter, certifying that the University of California has signed the March 8, 1995 version of the UBMTA. These authorized officials should get the written concurrence of the Principal Investigator at Section 6 of the UBMTA Implementing Letter and return one signed copy to the provider of the materials. It is important to note that Principal Investigators or others who have not been delegated authority by their Chancellor or Laboratory Director are not authorized to accept the UBMTA Implementing Letter for incoming materials.

Materials Transferred Out of the University

i) Transfers "out" to universities and nonprofit institutions using Simple Letter Agreement:

When University faculty or scientific staff wish to transfer non-proprietary biological materials to colleagues for teaching or academic research purposes, the use of the Simple Letter Agreement generally is appropriate. The Simple Letter Agreement as presented in the March 8, 1995 Federal Register is hereby authorized for use by University of California
Principal Investigators or administrators only when sending non-proprietary biological materials to scientists at other universities or nonprofit institutions for teaching or academic research purposes.

If materials are being transferred to for-profit institutions or if commercial use of the materials is intended or if a patent application has been or will be filed for the materials, using the Simple Letter Agreement is not authorized. Instead, contact your campus technology transfer office or the systemwide OTT for guidance. Any changes to the wording of this Simple Letter Agreement must be reviewed by your campus technology transfer office or by the systemwide OTT.

Instructions for use of the Simple Letter Agreement by University Principal Investigators or administrators to transfer non-proprietary biological materials to universities or nonprofit institutions are included as Exhibit E. Please note that these instructions should be modified or supplemented at each campus/Laboratory to provide local guidance concerning: i) review of changes to the Simple Letter Agreement (Instruction B3), ii) transmittal fees (Instruction C4), and iii) record copies of executed agreements (Instruction C9).

ii) Transfers "out" to universities and nonprofits using UBMTA Implementing Letter:

When University faculty or scientific staff wish to transfer biological materials with potential commercial value to their colleagues for teaching and academic research purposes only, the use of the UBMTA may be most efficient and appropriate. The UBMTA Implementing Letter as presented in the March 8, 1995 Federal Register is hereby authorized for use by University of California Principal Investigators or administrators only when transferring University biological materials for teaching or academic research purposes to scientists at other universities and nonprofit institutions that have executed a Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement dated March 8, 1995. AUTM will maintain a list of those institutions that have agreed to accept the terms of the UBMTA and will publish that list on the Internet (Internet address not yet determined).

No institution, including signatories to the UBMTA Master Agreement, however, is required to use the UBMTA. Customized agreements may be more appropriate for transfers of materials with unusual commercial or research value. If materials are transferred to for-profit institutions or if commercial use of the materials is intended or if a patent application has been or will be filed for the material, using the UBMTA Implementing Letter may not be appropriate and is not authorized. Instead, contact your campus technology transfer office or the systemwide OTT for guidance. Any changes to the wording of this UBMTA Implementing Letter must be reviewed by your campus technology transfer office or by the systemwide OTT.
Instructions for use of the UBMTA Implementing Letter by University Principal Investigators or administrators to transfer biological materials to universities and nonprofit institutions are included as Exhibit F. Please note that these instructions should be modified or supplemented at each campus/Laboratory to provide local guidance concerning: i) review of changes to the Simple Letter Agreement (Instruction B3), ii) transmittal fees (Instruction C3), iii) campus address (Instruction C4), and iv) record copies of executed agreements (Instruction C10).

iii) Transfers "out" to industry:

If a for-profit institution is interested in using University biological materials, contact your campus technology transfer office or the systemwide OTT for guidance. In these circumstances, a commercial license and releases from University sponsors may be necessary.

Refer questions to: Joe Acanfora
(510) 748-6618
joe.acanfora@ucop.edu

Sincerely,

Terence A. Feuerborn
Executive Director

Exhibits:

A-1 Uniform Biological Material Transfer Agreement (UBMTA)
A-2 March 8, 1995 Federal Register Notice
B Master Agreement Regarding Use of the UBMTA
C UBMTA Implementing Letter
D Simple Letter Agreement for Transfer of Non-Proprietary Biological Material
E Instructions for Use of Simple Letter Agreement for Transfer of Non-Proprietary Biological Material (Outgoing Materials)
F Instructions for Use of UBMTA Implementing Letter (Outgoing Materials)