option to handle specific material with unusual commercial or research value on a customized basis. Thus, the use of the UBMTA would not be mandatory, even for signatory organizations. Administration of the signatory process also may be organization-specific. For example, organizational policies may require additional, or fewer, signatures.

For non-proprietary materials, a Simple Letter Agreement also has been developed, which incorporates many of the same principles as the UBMTA. This Simple Letter Agreement also could be used where the organizations have not

agreed to the UBMTA.

On behalf of PHS, NIH published the full text of the proposed version of the UBMTA, the draft Implementing Letter, and the draft Simple Letter Agreement in the **Federal Register** on June 21, 1994, and invited public comment. NIH received thirteen written comments from universities, research organizations, and various associations. The primary concerns raised by respondents and the NIH response to these comments are described in the comment section below.

## **Comments**

The vast majority of the respondents were extremely supportive of the UBMTA concept as a means of simplifying and expediting biological material transfers among public and nonprofit organizations. Several respondents suggested that a comparable agreement be developed for transfers between for-profit and nonprofit organizations. The PHS fully supports this idea and recognizes the importance of streamlining this type of agreement with industry. The NIH, in conjunction with the working group listed above, developed a proposed model for UBMTA transfers from industry to nonprofit organizations which was circulated to AUTM membership on December 31, 1992. This was an adaptation of the original UBMTA format which grants the industrial provider an option to negotiate a license agreement to inventions made through the use of the provided material. It should be noted that government agencies will not be able to use this format unless a Cooperative Research and Development Agreement ("CRADA") is negotiated because of limitations in statutory authority to provide licenses or options to license intellectual property in other types of agreements. No format was ultimately created by the working group for the transfer of material from nonprofit organizations to industry because it was viewed as being essentially a license negotiation. Most

organizations have license agreement formats for internal use of biological materials by commercial organizations, as well as for commercial sale of biological materials. The PHS will be soliciting further public commentary on the proposed model for UBMTA transfers from industry to nonprofit organizations.

Several respondents indicated that some of the UBMTA definitions were confusing. As appropriate, clarifications have been made. In particular, the definition relating to "Modifications" has been refined so that it is clear that Modifications are developed by the Recipient and contain or incorporate the Material. While the Modifications are owned by the Recipient who can license them for commercial use, this new use also may require a second commercial license or other evidence of agreement from the Provider since the Modifications incorporate the Material. The UBMTA also acknowledges that there may be other substances created by the Recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives of the Material, and are owned by the Recipient, who is free to license them. The UBMTA does not provide for any type of "reach-through" rights for the Provider of the Material, i.e. property rights in products developed by the Recipient through the use of the transferred material. Several definitions of "nonprofit organization" were proposed, and the final definition used was taken directly from the implementing regulations to the Bayh-Dole Act (37 CFR Part 401). We have also instituted a definition of Commercial Purposes to provide a clear distinction between academic research and activities which are considered commercial.

Other issues raised by respondents fell into two areas: issues regarding confidentiality with respect to protection of intellectual property rights, and issues regarding organizational policy variance on signature requirements from the suggested UBMTA signature requirements:

## (1) Confidentiality Issues

Some respondents were concerned that the requirement for the Provider to provide the Recipient with specific information regarding patent status of the Material might impair an organization's ability to obtain patent protection and questioned the necessity for the Recipient to obtain such information. The PHS agrees that the provision of such information is not necessary and would create an

additional administrative burden that would be inconsistent with the primary purpose of the UBMTA. We also agree that any commercial use or improper disclosure on the part of the Recipient could impair the Provider's ability to obtain suitable patent protection. Therefore, we have removed the requirement for the Provider to inform the Recipient about patent status and have included a provision that the Material may be the subject of a patent application. However, the Recipient is bound to inform the Provider upon filing patent applications which claim Modifications or method(s) of manufacture or use(s) of the Material so that the Provider may determine whether it believes joint inventorship is appropriate. The requirement to divulge the Provider's prior grant of rights to a third party (other than the customary rights granted to the federal government), that would substantially affect Recipient, has been eliminated since the agreement specifies that this transfer is for teaching and academic research purposes and that the Provider is under no obligation to widen the rights granted.

## (2) Signature Requirement Issues

Some respondents were concerned that their organizational polices with respect to signing MTAs are different than those suggested in the UBMTA Implementing Letter. An organization may require an additional signature of an authorized official of the Recipient organization if the signatory scientist is not legally authorized to bind the organization. In this case, the legally binding signature of the authorized official of the Recipient organization would provide assurance to the Provider organization that the Recipient organization is a signatory to the UBMTA. This assurance is critical because if the Recipient organization is not a party to the UBMTA, it may not be bound by the terms of the UBMTA. The signatures of the scientists provide a necessary record for both organizations of the transfer of the Material. Of course, organizations are free to develop their own signatory policies regarding the UBMTA

We hope to get practical guidance and constructive feedback from scientists and technology transfer professionals as they begin to use the UBMTA. It is anticipated that the UBMTA will be a "living" document which will be further refined and streamlined over time. Many of the definitions were intensively debated throughout the course of drafting the UBMTA and it is expected that they will be sharpened over time through use. We attempted to