

Time: 8:30 a.m.

Place: Hyatt Regency, Bethesda, Maryland.

Contact Person: Dr. Lynn Amende, 5333 Westbard Avenue, Room 5A10, Bethesda, Maryland 20892, (301) 594-7480.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Cytokine Effect on Hematopoiesis in AIDS Animal Models.

Date: May 1-2, 1995.

Time: 7 p.m.

Place: Holiday Inn, Chevy Chase, Maryland.

Contact Person: Dr. Deborah Beebe, 5333 Westbard Avenue, Room 555, Bethesda, Maryland 20892, (301) 594-7418.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: March 3, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-5643 Filed 3-7-95; 8:45 am]

BILLING CODE 4140-01-M

### Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement

AGENCY: National Institutes of Health (NIH), Public Health Service (PHS), DHHS.

ACTION: Notice.

**SUMMARY:** Following consideration of public comments, the NIH, as designated lead PHS agency for technology transfer activities, is issuing the final version of the Uniform Biological Material Transfer Agreement ("UBMTA") to be used by participating public and nonprofit organizations, an implementing letter to memorialize individual exchanges of biological material under the UBMTA, and a simple letter agreement for transferring nonproprietary biological materials among public and nonprofit organizations. For-profit organizations may also choose to adopt these agreements as well. The PHS recommends that the UBMTA be considered for general use in the exchange of biological material for

research purposes among public and nonprofit entities.

#### FOR FURTHER INFORMATION CONTACT:

Carol C. Lavrich, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804, phone: 301-496-7735 ext. 287, fax: 301-402-0220.

#### Background

Open access to the results of federally-funded research is a cornerstone of PHS's research policy. In the case of many research projects, this includes not only access to information provided through publications, but also access to biological research materials necessary to replicate or build on the initial results. Frequently, the exchange of research materials between scientists in separate organizations involves case-by-case negotiation of material transfer agreements ("MTAs"). In order to guide and facilitate the increasing number of such transfers, PHS issued in 1988, a "Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding" (NIH Guide for Grants and Contracts, Vol. 17, No. 29, September 16, 1988: pg. 1; also published at pp. 8-25-8-26 of the PHS Grants Policy Statement, DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994. This was followed in 1989 by adoption of a standard Material Transfer Agreement form for use by PHS scientists. MTAs are important because they require the recipient to exercise care in the handling of the materials, to maintain control over the distribution of the materials, to acknowledge the provider in publications, and to follow relevant PHS guidelines relating to recombinant DNA, protection of human subjects in research, and the use of animals. However, while most other organizations have adopted some standard material transfer agreement form, they are not all consistent.

#### Issue

Several issues have affected the sharing of research materials. These include delays in sharing of materials while conducting unnecessarily extensive negotiations on individual MTAs, required grants of invention rights to improvements to the materials or to inventions made using the materials, and required approval for publication. The negotiation of these complex issues has resulted in significant delays in sharing materials, undue administrative barriers to sharing, and in some cases, lack of availability of materials for further research by federal grantees. (For reports and discussion of these issues, please

refer to The New Biologist, Vol. 2, No. 6, June 1990: pp 495-497; and Science, Vol. 248, 25 May, 1990: pp 952-957).

#### Proposal

The PHS, in conjunction with representatives of academia and industry, has coordinated the development of a proposed uniform biological material transfer agreement ("UBMTA") to address concerns about contractual obligations imposed by some MTAs and to simplify the process of sharing proprietary materials among public and nonprofit organizations. Since 1990, the Association of University Technology Managers ("AUTM"), and many individuals representing universities, law firms, and industry, have played leadership roles in furthering the development of common materials sharing practices. The consistent use of the UBMTA by public and nonprofit organizations could reduce the administrative burden of sharing materials as investigators come to rely on common acceptance of its terms by cooperating organizations.

The PHS recommends that the UBMTA be considered for general use in the exchange of materials for research purposes among public and nonprofit organizations. For-profit organizations may also choose to adopt this agreement as well. While use of the UBMTA may not be appropriate for every material transfer, if used for the majority of transfers, it could set standards for materials sharing that would be of long-term benefit to the research enterprise and to the public health.

As a further suggestion to simplify the process of materials sharing, it is proposed that the UBMTA be approved at the organizational level, and handled in a master agreement or treaty format, so that individual transfers could be made with reference to the UBMTA, without the need for separate negotiation of an individual document to cover each transfer. As a result, transfers of biological materials would be accomplished by an Implementing Letter (see sample) containing a description of the material and a statement indicating that the material was being transferred in accordance with the terms of the UBMTA. The Implementing Letter would be executed by the provider scientist, the recipient scientist, and any other authorized official(s) of the provider or recipient organization who might be required to sign on behalf of the organization. Thus, sharing of materials between organizations, each of which had executed the UBMTA, would be significantly simplified. At the same time, any organization would retain the

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 policies 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

emphasize a fair allocation of rights between the Provider and the Recipient and had to draw lines especially in the definitions of Modifications and Commercial Purposes. The use of the UBMTA over time will ultimately determine whether the right decisions were made.

The Association of University Technology Managers ("AUTM") will be providing assistance in implementation of the UBMTA among its members and nonprofit organizations by notifying members of its availability in its newsletter, providing signature copies of the agreement at its annual meeting, assisting with training regarding material transfers, and maintaining a master list of signatories to the UBMTA. We anticipate that the master list of signatories will be published in the **Federal Register** annually. In order for AUTM to compile a master list of signatories, organizations should return an executed copy of the UBMTA Master Agreement to: The UBMTA Project, AUTM Headquarters, 71 East Avenue, Suite S, Norwalk, CT 06851-4903. A read only version of the signatory list will be made available on the Internet. A copy of this announcement also will be appearing in the NIH Guide For Grants and Contracts.

Complete texts of the final version of the UBMTA, the Implementing Letter, and the Simple Letter Agreement follow in the Appendix.

Dated: February 18, 1995.

**Barbara M. McGarey,**

*Deputy Director, Office of Technology Transfer.*

**Appendix—Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement March 8, 1995**

Upon execution of an Implementing Letter in the form attached which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement ("UBMTA") published in the **Federal Register** on March 8, 1995.

Attachments:

UBMTA

Implementing Letter

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Authorized Official: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Please return an executed copy of this Master Agreement to: The UBMTA Project, Association of University Technology Managers (AUTM), 71 East

Avenue, Suite S, Norwalk, CT 06851-4903. AUTM will be maintaining signed originals and the official list of signatory organizations.

**The Uniform Biological Material Transfer Agreement**

March 8, 1995

*I. Definitions:*

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

2. PROVIDER SCIENTIST: The name and address of this party will be specified in an implementing letter.

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

4. RECIPIENT SCIENTIST: The name and address of this party will be specified in an implementing letter.

5. ORIGINAL MATERIAL: The description of the material being transferred will be specified in an implementing letter.

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

7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

8. UNMODIFIED DERIVATIVES: Substances 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.

9. MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.

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.

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.

*II. Terms and Conditions of this Agreement*

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

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

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 within the RECIPIENT organization without the prior written consent of the PROVIDER.

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.

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 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.

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 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.

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.

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 manufacture or use(s) of the 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.

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.

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.

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.

13. This Agreement will terminate on the earliest of the following dates: (a) When the MATERIAL becomes generally available from third parties, for example, through 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 sources; 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 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.

14. Paragraphs 6, 9, and 10 shall survive termination.

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.

#### **Implementing Letter**

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer

Agreement ("UBMTA") March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL:

Organization: \_\_\_\_\_  
Address: \_\_\_\_\_

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL:

Organization: \_\_\_\_\_  
Address: \_\_\_\_\_

3. ORIGINAL MATERIAL (Enter description):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. Termination date for this letter (optional):

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional).

Amount: \_\_\_\_\_

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Address: \_\_\_\_\_

Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

RECIPIENT SCIENTIST

Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Address: \_\_\_\_\_

Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

RECIPIENT ORGANIZATION  
CERTIFICATION

Certification: I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA

(May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized Official: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Simple Letter Agreement for Transfer of  
Non-Proprietary Biological Material**

PROVIDER

Authorized Official: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

RECIPIENT

Authorized Official: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

In response to the RECIPIENT's request for the BIOLOGICAL MATERIAL identified as

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the BIOLOGICAL MATERIAL:

1. The above BIOLOGICAL MATERIAL is the property of the PROVIDER and is made available as a service to the research community.

2. The BIOLOGICAL MATERIAL will be used for teaching and academic research purposes only.

3. The BIOLOGICAL MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the BIOLOGICAL MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the BIOLOGICAL MATERIAL available, under a separate Simple Letter Agreement, to other scientists (at least those at nonprofit organizations or government agencies) who wish to replicate the RECIPIENT SCIENTIST's research.

4. The RECIPIENT agrees to acknowledge the source of the BIOLOGICAL MATERIAL in any publications reporting use of it.

5. Any BIOLOGICAL MATERIAL delivered pursuant to this Simple Letter 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 BIOLOGICAL MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. 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

BIOLOGICAL 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.

6. The RECIPIENT agrees to use the BIOLOGICAL MATERIAL in compliance with all applicable statutes and regulations, including, for example, those relating to research involving the use of human and animal subjects or recombinant DNA.

7. The BIOLOGICAL MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: \_\_\_\_\_

The RECIPIENT and the RECIPIENT SCIENTIST should sign both copies of this letter and return one signed copy to the PROVIDER SCIENTIST. The PROVIDER will then forward the BIOLOGICAL MATERIAL. PROVIDER SCIENTIST

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

RECIPIENT SCIENTIST

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

RECIPIENT ORGANIZATION APPROVAL

Authorized Official: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

[FR Doc. 95-5644 Filed 3-7-95; 8:45 am]

BILLING CODE 4140-01-P

**Office of Refugee Resettlement**

**Refugee Resettlement Program:  
Proposed Allocations to States of FY  
1995 Funds for Refugee Social  
Services and for Refugees Who Are  
Former Political Prisoners From  
Vietnam**

**AGENCY:** Office of Refugee Resettlement (ORR), ACF, HHS.

**ACTION:** Notice of proposed allocations to States of FY 1995 funds for refugee <sup>1</sup>

<sup>1</sup> In addition to persons who meet all requirements of 45 CFR 400.43, "Requirements for documentation of refugee status," eligibility for