BEST PRACTICES FOR THE ALZHEIMER'S DISEASE RESEARCH CENTERS

MATERIAL TRANSFER GUIDELINES

The NIH has established principles and policies for the sharing of biospecimens in "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice"[1] in order to achieve the widest possible dissemination of "unique research resources" to promote research progress. The tissues obtained from carefully-characterized clinical populations, such as from ADCs, represent important resources to be considered in the same way. It is the obligation of the Principal Investigators to act as good stewards of these resources to ensure that they are used for the greatest good. NIH has also formally endorsed the use of material transfer documents known either as "material transfer agreements" (MTA) or "simple letters of agreement" (SLA).[2, 3] These documents, executed usually between institutions not individual scientists, define the terms and protections of the exchange. The SLA is a simpler, less detailed version of the MTA.

Why MTA/SLA? In the past, tissue samples were often exchanged without MTAs because they did not represent a unique resource that had been created, engineered or invented. The need for intellectual property and financial protections did not apply (e.g. an investigator would be unlikely to 'patent' blood samples). However, MTAs offer other protections and restrictions that make them useful. Most academic and government research institutions have technology management offices that govern/negotiate the material transfer agreements of their faculty and staff scientists. Such offices often have institutional templates, which usually can be customized for the individual material transfer (see Item L. below).

In addition to individual institutional documents, the NIH published the final version of the Uniform Biological Material Transfer Agreement (UBMTA) [4] and a Simple Letter Agreement for the Transfer of Non-Proprietary Biological Material in 1995. Institutions can sign the UBMTA Master Agreement and transfer materials under the terms of the UBMTA upon execution of an Implementing Letter for the particular transfer. The Association of University Technology Managers (AUTM) serves as the repository for the signed UBMTA Master Agreements from those institutions wishing to use the UBMTA for some or all of their exchanges of biological materials.

Regulatory Issues Related to Material Transfer: Compliance with federal, state and local laws regarding confidentiality of research participants can also be assured in MTAs. Some institutions routinely review the Institutional Review Board approvals under which tissue was collected to determine if the sharing is permitted. Other institutions require that the recipients' institution certify, in the MTA, that the study is compliant with all national and local regulations. Either approach is acceptable.

When providing data protected under the Health Insurance Portability and Accountability Act (HIPAA) and/or omic or other data which can be potentially used to identify individuals, a data use agreement should be put in place, i.e., these should not be considered de-identified datasets.

Recommendations: The following outline contains items/issues that are typically addressed in MTAs:

A. Identify the parties and specific material to be transferred – Formally identify the provider and recipient to ensure that there can be no accusations of misappropriation or misdirection of materials at a later date. Formally confirm provider has the authority to transfer material based on consent and authorization and how provider will notify the recipient of consent is withdrawn.

B. Protect intellectual property – Refer to Intellectual property section of the Best Practices for guidance.

C. Issues of academic freedom and integrity –

Few limitations should be placed on publication rights and conditions. Confidential review by the biospecimen provider of publications prior to submission (usually 30 days) can afford the opportunity to ensure that nothing confidential or proprietary is disclosed and that relevant grant support to generate the biospecimens are acknowledged. Scientific collaborations are encouraged when appropriate but should not be mandated as part of the agreement.

D. Protect against improper or unsafe use of the material – An MTA informs the recipient of their institution's responsibility if their handling of the material results in injury or damages. Indemnification may also be part of the MTA. It is recommended that both institutions be fully informed and aware of the assignment of responsibility and liability.

E. Provide and document explicit warnings – If the material requires special warnings they can be part of the MTA language (e.g., a warning should be included for tissue that has not been tested for infectious agents). However, the MTA need not be the only place such warnings are provided.

F. Restrict any further dissemination without permission – A recipient scientist cannot provide materials received under the MTA to a third party without written approval. The ADCs and NIH wish to account for the use and productivity of biospecimens they share. Unacknowledged third-party sharing of material thwarts such accountability and should be prohibited without explicit permission of the provider.

G. Restrict and define the scope of how the material may be used – An MTA can contain language that limits the use of the material. For example, the use and development of the material may be restricted to non-profit research or teaching uses. Material may also be restricted from use in research involving human subjects. However, it is recommended that the least restrictive language allowed by the consent be used in sharing tissue.

I. Agree to protect the confidentiality of research participants by not attempting to identify them.

J. Agree to follow cybersecurity best practices.

K. Agree to provide new data generated from the material to the Center and/or the NIA repository as agreed upon to be shared with the wider ADRD research community.

L. MTAs/SLAs can be modified for unique situations and requirements. If your Center has special requirements, they can be added. For example, the following items can be part of the MTA language:

a. Provide a copy of any publication that contains experimental results obtained from the use of the Material. Any publication using this Material must follow NIH Public Access Policies (e.g. a PubMed Central ID)

c. Provide a brief progress report XX months from the receipt of the requested tissue.

d. Acknowledge your Center grant in any presentation or publication that may result from this research:

1. Acknowledge the Center grant number (P30AGXXXXX) in all publications using the Material. Often the material is accompanied by other data generated from the material that require acknowledgements of additional grants

2. Adhere to NIH Public Access Policies and provide PubMed Central ID numbers for all publications.

3. Should funding result from this research now or in the future, please notify the Alzheimer's Disease Center with details so we may report productivity derived from our resources to NIA.

References

1. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf

2. The NIH Office of Technology Transfer (OTT): http://ott.od.nih.gov/

2a. Simple Letter of Agreement: https://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf

3. The NINDS Technology Transfer Office: http://tto.ninds.nih.gov/Mta.asp

4. Association of University Technology Managers: http://www.autm.net/Technology_Transfer_Resources/8395.htm

5. National Cancer Institute, NCI best practices for biospecimen resources:

5a. 2011 NCI Best Practices website: http://biospecimens.cancer.gov/practices/;

5b. PDF of the NCI Biospecimens Best Practice: http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf