

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 505A

NIH Model Material Transfer Agreement For The Transfer Of Human Materials For Non-Profit Research Purposes

A. PURPOSE:

This Manual Chapter describes the purpose and use of the National Institutes of Health (NIH) Model Material Transfer Agreement for the Transfer of Human Materials for Non-Profit Research Uses. (hm-MTA)

B. BACKGROUND:

Open access to the results of federally-funded research is a cornerstone of the PHS research policy. For many research projects, this includes not only access to information provided through publications, but also access to materials, human or human derived samples (Materials) necessary to replicate or build on initial research results. Model material transfer agreements (MTAs) that are approved by NIH assist to facilitate access to Materials that were developed from NIH-funded Materials as well as reduce the administrative burden in such transfers. The majority of transfers to non-profit entities should be implemented under terms no more restrictive than the Uniform Biological Material Transfer Agreement. (See PHS Policy Chapter 502.) Unique research Materials that arise from biomedical research are often essential resources to other researchers. As a valuable resource, these Materials must be managed in a way that promotes their responsible and fair distribution.

C. TRANSFER OF HUMAN MATERIALS

The transfer of human and human derived Materials require special attention and transfers must be made consistent with The Privacy Act of 1974, as amended at 5 U.S.C. § 522a, human subjects relations and guidance found at 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1977)). In order to guide and facilitate the increasing number of MTAs between scientists in separate organizations, the NIH hm-MTA ensures that unique research resources arising from NIH-funded intramural research are made available to the scientific research community consistent with federal statutes and regulations for the transfer of human material.

D. EFFECTIVE DATE:

The NIH Model Transfer Agreement for the Transfer of Human Materials for Non-Profit Research Purposes was approved by the PHS Technology Transfer Board on January 26, 2010. This Manual Chapter was approved by the PHS Technology Transfer Board on March 8, 2012.

E. ADDITIONAL INFORMATION

For further information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301)496-7057 or http://www.ott.nih.gov/contactus/contact_us.aspx.

A copy of the hm-MTA can be found at:

http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx#MTACTA