UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 500

PHS Policy for Material Transfer Agreements

A. PURPOSE

This Manual Chapter sets forth the policy for the use of Material Transfer Agreements (MTAs) by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and each of the Institutes and Centers (ICs) of the National Institutes of Health (NIH), all of which are component agencies of the Public Health Service (PHS).

B. BACKGROUND

Access to the materials that result from federally-funded research is a cornerstone of the research policy of the PHS. Unique research materials that arise from federally-funded biomedical research are often essential and valuable resources to other researchers. Some materials are capable of self-replication (*e.g.* cell line) or are able to be produced in large quantities, while others may be limited in quantity due to expense, nature, or source (*e.g.* from humans). As a valuable resource, these materials must be managed in a way that promotes their responsible and fair distribution. The PHS and its components utilize several mechanisms to authorize and document the transfer of materials consistent with the NIH Research Tools Policy (https://www.govinfo.gov/content/pkg/FR-1999-12-23/pdf/99-33292.pdf).

A Material Transfer Agreement (MTA) is a written document that authorizes the exchange of tangible research materials between separate institutions and is signed by respective authorized institution officials. MTAs typically include terms that specify the allowable uses and distribution of the materials, how to acknowledge the provider in publications, and other relevant PHS guidelines relating to recombinant DNA, stem cells, the protection of human subjects in research, or the use of animals, as applicable.

C. POLICY

To the extent cost and availability allows, PHS materials will be distributed in a fair manner and without bias to qualified recipients. The shipment of materials to qualified recipients will be in accordance with applicable laws, regulations, policies, guidelines, and best practices. The type of the materials to be transferred (*e.g.*, human materials, genetically modified organisms, infectious materials) and other considerations will determine which regulations and policies are applicable and informs the type of MTA used and its terms. Other considerations may include the purpose of the transfer, the type of institution receiving the PHS materials (*e.g.* university or for-profit company), project funding, the management of publications, the protection of confidential information and/or intellectual property, or use in a public health

emergency-use case. This policy chapter does not apply to the outgoing transfer of materials for fee-for-service analysis, clinical use, or diagnostic use.

For purposes of this policy, human materials include a) human biospecimens obtained directly from humans and b) derivatives of human biospecimens. Human biospecimens include, but are not limited to, blood and other body fluids, tissues, and other biological materials obtained directly from humans. Derivatives of human biospecimens include, but are not limited to, human cell lines, recombinant DNA clones of human genes, and isolated infectious agents from humans. Human materials can be identifiable, coded, or unlinked from identifiers. The transfer of any human materials requires careful review and is conducted in accordance with 45 C.F.R. Part 46, when applicable, and other applicable federal regulations and policies. PHS must abide by the highest scientific and ethical standards when transferring human materials to external institutions to preserve the public's trust and the substantial investment these resources represent.

Unique non-human research materials that arise from PHS research, including, but not limited to, plasmids, bacterial and yeast strains, non-human cell lines, genetically modified alleles contained within mice, and compounds, are also essential resources to other researchers. PHS recognizes the importance of appropriate distribution of research materials as part of its commitment to public health.[1]

PHS agency researchers planning to transfer PHS materials, or to receive materials, should contact their agency technology transfer office for guidance. The technology transfer office will determine if an MTA is appropriate for the transfer of particular materials for the stated purpose, and if so, PHS agency researchers must provide their technology transfer office with any information requested so the office can properly draft, negotiate, and execute an MTA.

Publicly accessible, PHS-approved model agreement templates can be found at https://www.techtransfer.nih.gov/resources. Agency-specific model agreement templates may also be utilized. If revisions to standard MTA terms are made, the PHS agency technology transfer office may have the terms reviewed by the HHS Office of General Counsel (OGC) or other relevant HHS offices concerning procurement, records retention, data security, data privacy, ethics, or the protection of human subjects, if applicable.

[1] Several policies govern the distribution of PHS federally-funded research materials i.e., Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice (otherwise known as the "NIH Research Tools Policy" and referenced in the Background of this chapter) https://www.govinfo.gov/content/pkg/FR-1999-12-23/pdf/99-33292.pdf, PHS Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding https://www.ncbi.nlm.nih.gov/books/NBK236190/ and Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement (https://www.govinfo.gov/content/pkg/FR-1995-03-08/pdf/95-5644.pdf.

PHS agencies are responsible for maintaining good recordkeeping practices of materials transferred under agreements, the agreement(s) used to transfer them, and associated information related to those agreements.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective on June 15, 2023 when it was approved by the PHS Technology Transfer Policy Board.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, nihott@mail.nih.gov or the Division of Technology Transfer and Innovation Policy, Office of Science Policy National Institutes of Health, NIH, SciencePolicy@od.nih.gov. For CDC contact tto@cdc.gov. For FDA contact techtransfer@fda.hhs.gov.