R&D POLICY NUMBER: #014

TITLE: Material Transfer Agreements (MTAs)

1.0 PURPOSE

The purpose of this policy is to provide guidance on the VA Pittsburgh Healthcare System (VAPHS) requirements for acquisition or distribution of various research materials developed by VAPHS Principal Investigators, nonprofit, government, and private industry. A Material Transfer Agreement (MTA) (See Appendix A) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors are the most frequently transferred materials. However, MTAs may also be used for other types of materials such as chemical compounds and even some types of software.

2.0 REVISION HISTORY

R&D Approval Date	Revision #	Change	Reference Section(s)	Effective Date
February 23, 2016	2.0	Update contact information and wording of guidelines; update information on exempted material.	All	February 26, 2016
August 26, 2014	1.0	New format; updated contact information.	Section 5.0	August 29, 2014
February 22, 2011	N/A	New Policy		February 25, 2011

3.0 SCOPE

This policy applies to all Principal Investigators conducting laboratory research at or under the auspices of the VAPHS that want to send or receive research materials to/from other organizations.

4.0 COMPLIANCE REQUIREMENTS

- MTAs for animal tissues or custom antibodies must have protocol(s) reviewed and approved by the Institutional Animal Care and Use Committee (IACUC).
- MTAs for human tissue must have protocol(s) reviewed and approved by the Institutional Review Board (IRB).
- MTAs for recombinant or synthetic nucleic acid molecules, hazardous materials, and/or Select Agents must have protocol(s) reviewed and approved by the Institutional Biosafety Committee (IBC).
- MTAs for ionizing radiation must have project approval from the Radiation Safety Committee.
- Principal Investigators or their laboratory personnel must be current with applicable trainings if sending/receiving biohazardous materials (Bloodborne Pathogens and Saf-T-Pak training for shipping biological agents).

5.0 PROCEDURES

5.1 Incoming Materials

Whenever a VAPHS Principal Investigator wishes to obtain materials from a third party, the receiving researcher must follow the steps outlined below:

1. Complete the Incoming MTA Submission Form and sign it.
2. Attach any relevant compliance letters (i.e., IACUC, IRB, IBC) **AND** a research description/scope of work (SOW).
3. Send the Incoming MTA Submission Form, compliance letter(s), SOW and the MTA (signed by both parties) electronically to Dana Roolf at Dana.Roolf@va.gov.
4. The Principal Investigator will be contacted if there are any questions or additional information is needed. The Principal Investigator will also be contacted when the MTA is approved.
5. If the material is not listed on a currently approved protocol, then the Principal Investigator must submit an amendment to add the material to an approved study.

5.2 Outgoing Materials

Whenever a VAPHS Principal Investigator wishes to send materials to a third party, the sending researcher must follow the steps outlined below:

1. Complete the Outgoing MTA Submission Form and sign it.
2. Fill out the MTA form, and then send to the recipient for a signature.
3. Attach any relevant compliance letters (i.e., IACUC, IRB, IBC) **AND** a research description/scope of work (SOW).
4. Send the Outgoing MTA Submission Form, compliance letter(s), SOW and the MTA (signed by both parties) electronically to Dana Roolf at Dana.Roolf@va.gov.

5. The Principal Investigator will be contacted if there are any questions or additional information is needed. The Principal Investigator will also be contacted when the MTA is approved.

6.0 GUIDELINES FOR VAPHS INVESTIGATORS

MTA terms may vary on a case-by-case basis. Therefore, the VAPHS Department of Research and Development encourages Principal Investigators to seek legal review of each MTA by VA Office of General Counsel. . Researchers do not have the authority to bind VA and therefore do not have the authority to sign MTAs on behalf of VAPHS. All MTAs should be signed by the ACOS for Research. A Delegation Memo is in place at the VAPHS that allows the ACOS for Research to sign the MTA's at the approval of (and in lieu of) the Medical Center Director. Researchers may be required to sign an acknowledgement of the obligations and requirements of the MTA.

The Basic Material Transfer Agreement (MTA) provided in this policy is for use with non-profit or academic recipients only. It is not for use where the provider or recipient is a for profit organization or company. It is not for use when the research material will be used for screening, production or sale. The MTA may only be used when VA is the recipient or provider of material and no intellectual property (patent) rights are transferred. If VA is the recipient of a material and the provider would like a commitment of intellectual or patent rights, please use the MT CRADA.

MTAs are legally binding contracts between the VAPHS and the other party. A fully signed MTA requires that the VAPHS Principal Investigator and the lab personnel follow the terms and conditions as stated in the agreement. Breach of these terms could result in liability for VAPHS and could significantly affect the VAPHS Principal Investigator's research and the ability to publish.

When entering into an MTA, the VAPHS Principal Investigator should understand that he or she will not own the incoming material. Ownership will most likely remain with the Provider Institution. Therefore, if the VAPHS Principal Investigator or a lab member decides to leave the VAPHS, he or she will need to obtain explicit written permission before transferring the material. As part of closure approval, the request for permission to transfer material must be submitted to the Associate Chief of Staff (ACOS) at least 90 days before personnel leave the VAPHS. Approval must be granted by the Research and Development Committee before the material can be transferred.

7.0 IMPORT REGULATIONS

In addition to the MTA, there are additional requirements that Principal Investigators must consider before either receiving or sending materials. Depending on the material that is transferred, a permit may be required (this includes inter-state transport). The sections below provide guidance in regards to regulations that may apply to the MTA.

7.1 Factors to Consider When Importing Materials

There are several regulations that Principal Investigators must consider before importing materials. These regulations are obtained from the United States Department of Agriculture (USDA) or the United States Fish and Wildlife Service. The following items may require an import permit:

- Any microorganisms that can cause infectious, contagious, or communicable diseases of livestock and poultry
- Highly pathogenic agents such as CDC/USDA Select Agents (also require registration for Select Agent program)
- Live animals such as livestock, dogs, sheep, birds, and fish including their reproductive fluids and fertilized embryos
- Animal trophies

For additional information on import permits, contact the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services division, National Center for Import and Export. Information is available at http://www.aphis.usda.gov/import_export/.

The U.S. Fish and Wildlife Service are concerned with timber, endangered plants, animal furs, endangered animals, injurious wildlife, marine mammals, exotic birds, and trophy animals. Information on their requirements can be found at http://www.fws.gov/permits/ImportExport/ImportExport.html.

7.2 Exempted Materials

There is also a specific list of exempted materials that do not require a permit.

- Human pharmaceuticals and human vaccines containing animal derived components that are in final dosage form and approved by the Food and Drug Administration (FDA).
- Non-human primate material/specimens including tissues, blood/blood fractions, proteins, DNA, enzymes, feces, fluids, hormones, peptides, etc.
- Feline and canine materials including blood, tissues, serum, extracts, etc.
- Live laboratory mammals and their material including transgenic/knock-out mice and rats, hamsters, rabbits, and their blood, tissue, DNA, extracts, antibodies, feces, sera, and antisera for research purposes.
- Chemically synthesized materials including biochemical and materials not containing or derived from animal products including cell culture derived products.
- Microbially produced materials including enzymes, plasmids, proteins, hormones, extracts, phages and/or DNA.

- Recombinant microbes and their products including microbes (bacteria, viruses, yeasts/fungi), proteins, hormones, extracts, plasmids, DNA, and RNA.
- Non-pathogenic microorganisms and extracted non-infectious genomic material including environmental or water organisms such as algae.
- Cell cultures/line, recombinant cell cultures/lines, and their products (for in vitro use) including monoclonal antibodies, cell culture supernatants, ascetic fluid, cell extracts, hybridomas, cell cultures/lines which are not derived from livestock or avian species.
- Self-contained test kits containing animal-derived ingredients
- Most commercially derived vitamins and minerals synthetically produced from non-animal origin ingredients.

8.0 EXPORT REGULATIONS

8.1 Factors to Consider When Exporting Materials

There are also export regulations that Principal Investigators must be familiar with when sending items. Important things to remember include the following:

- Often, items of concern for VAPHS researchers are biological and chemical agents. However, electronics and technology such as GPS systems have come under increasing regulation due to their potential for use in satellites and other "spy ware".

- Intellectual property and software are also of concern, particularly those which may be used for chemical and/or biological weapons design. If an MTA involves the exchange of this kind, the Information Security Officer must review the material.

- Common biological reagents used in labs, such as antibodies, DNA, proteins, established mammalian cell lines such as rat and mouse cell lines, and established human cell lines, do not usually require an export permit to be shipped to another country.

- Common chemical reagents used in labs, such as bacteria and viruses pathogenic to animals or plants, may be listed as CDC/USDA Select Agents and therefore a permit may be required to export these agents.

- Genetic elements that code for certain biological agents, mainly CDC/USDA Select Agents, are also regulated.

8.2 USDA Export Regulations

For additional information on export permits, contact the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services division, National Center for Import and Export. Information is available at http://www.aphis.usda.gov/import_export/index.shtml.

- Export regulations are related to animal products for human consumption, such as dairy, meat, aquaculture/fish products, and eggs
- For live animal exports, investigators must have an accredited veterinarian sign off on an international health certificate. A USDA health certificate for small animals can be found at http://www.aphis.usda.gov/library/forms/pdf/APHIS7001.pdf.
- Animal research products such as animal cell lines are not covered in these regulations and therefore a permit is not required to export animal cell lines such as established rat, mouse, or hamster cell lines.
- The destination country may have its own regulations for animal and plant materials.

8.3 Department of Commerce Regulations

There are Export Administration Regulations (EAR) administered by the Department of Commerce, Bureau of Industry and Security. Regulations are found in 15 CFR Part 774 Supplement No. 1 which contains the "Commerce Control List" (CCL).

- CCL, Section 1C350: Chemical precursors for highly toxic chemicals. Specific chemicals are listed.
- CCL, Section 1C351: Human and zoonotic pathogens and toxins of biological origin. Specific viruses, rickettsiae, bacteria, and toxins are listed. Most of these are CDC/USDA Select Agents.
- CCL, Section 1C352: Animal pathogens. Specific viruses and bacteria are listed. Most of these are CDC/USDA Select Agents.
- CCL, Section 1C353: Genetic elements and genetically-modified organisms of the preceding sections.
- CCL, Section 1C354: Plant pathogens. Specific bacteria, fungi, and viruses are listed. Some of these are CDC/USDA Select Agents.
- CCL, Section 1C355: Chemicals listed as part of the Chemical Weapons Convention (not in Section 1C350). Specific chemicals and chemical families are listed.
- CCL, Section 1C360: Select Agents and toxins not listed in preceding sections. Specific viruses, fungi, toxins, rickettsiae, etc. are listed.

8.4 International Traffic in Arms Regulations

International Traffic in Arms (ITAR) regulations required by the Department of State are listed in 22 CFR Parts 120-130 (Subchapter M). Part 121 is the "U.S. Munitions List". This regulation states that information and materials related to military and defensive technologies cannot be exported unless an exemption is granted by the Department of State. Information is available at http://www.access.gpo.gov/nara/cfr/waisidx_99/22cfr121_99.html.

- Main issue for researchers is chemical agents or toxicological agents of biological origin or derivation.

- Category 5: Explosives, propellants, incendiary agents and their constituents. Includes hydrazine and perchlorates.
- Category 14: Toxicological agents and equipment and radiological equipment (including chemical and biological agents). Includes nerve agents such as sarin, VX gas, sulfur mustards, cyanides, etc.

8.5 Office of Foreign Assets Control Regulations
Regulations for the Office of Foreign Assets Control (OFAC) are enforced through the U.S. Department of Treasury. Everything that is exported is of concern (not just specific research items, technology, etc.).

Nothing of value should go to boycotted, sanctioned, or embargoed countries. Additional information is available at http://www.treas.gov/offices/enforcement/ofac/.

8.6 U.S. Fish and Wildlife Service Regulations
The U.S. Fish and Wildlife Service are concerned with the export of timber, endangered plants and animals, animal furs, marine mammals, and trophy animals. Animal research products such as animal cell lines are not covered under these regulations and therefore, a permit is not required to export animal cell lines such as established rat, mouse, or hamster cell lines. Information is available at http://www.fws.gov/permits/ImportExport/ImportExport.html.

//signed copy on file //
Gretchen L. Haas, PhD
Research and Development Committee Chair

//signed copy on file //
Steven H. Graham, MD, PhD
Associate Chief of Staff for Research and Development

Department of Veterans Affairs

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("**MTA**") has been adopted for use by the Department of Veterans Affairs ("VA"), in all transfers of research material ("**Research Material**") whether **VA** is identified as a **Provider** or **Recipient**. This MTA is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a, *et seq*., and shall be effective on the date of the last signature of the parties.

Provider:

_____

Recipient:

_____

1. Provider agrees to transfer to Recipient's Investigator named below the following Research Material:

_____

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for teaching and not for profit research purposes by Recipient's investigator in his/her laboratory, for the research project described below, under suitable containment conditions. **This Research Material will not be used by for-profit recipients for screening, production or sale, for which a commercialization license may be required.** Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

2(a). Were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

☐ Yes (Please provide Assurance Number:_____)
☐ No
☐ Not Applicable (Materials not collected from humans)

3. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

_____

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project. However, if Provider has provided CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when there is a shortened time period under court order or the Freedom of Information Act.

5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, the Research Material will be disposed of, if directed by Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. <u>When Provider is the VA</u>: Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s).

8. When Recipient is the VA: VA shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. VA is not authorized to promise rights in advance for inventions developed under this Agreement. Provider acquires no intellectual property rights under this MTA, but may apply for license rights to any patentable invention that might result from this Research Project.

9. Indemnification- Neither Provider nor Recipient provides for any indemnification under this MTA. VA's indemnification is only within the requirements of the Federal Torts Claims Act.

10. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

11. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

Signature Page Follows

Click here to enter text.	Click here to enter text.
Date	Recipient's Investigator and Title

Click here to enter text.	Click here to enter text.
Date	Authorized Signature for Recipient and Title

Recipient's Official Mailing Address:

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Click here to enter text.	Click here to enter text.
Date	Provider’s Investigator and Title

Click here to enter text.	Click here to enter text.
Date	Authorized Signature for Provider and Title

Provider's Official and Mailing Address:

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Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).