Biological Material Transport & Transfer Documentation:

- Material Transfer Agreements
- Transport Permits (Import, Export, Domestic)
Instructions

Use the buttons at the bottom of the screen to navigate through this training tool.

Click on boxes like this to answer questions and learn more about a topic.

Click here to learn more.

Click this button to see a page full of external links.

Click this button to see the last slide you viewed.

Click the house to go back to the first slide.

Click on “Next Slide” to get started!

Click this button to exit the training tool.
This tool was developed to assist you in determining what documentation you need for sending or receiving biological material. Depending if you are sending or receiving material, this tool will guide you through the following topics:
Let’s go through a few questions to see what types of documentation / permits you need for your biological material...
Before we get started, have you or someone in your lab completed Shipping of Infectious Agents & Biological Materials Training within the past 2 years?

Click on one answer...

YES

NO
Are you sending or receiving biological material?

Click on one answer...

I’m sending it!

I’m receiving it!
If you are shipping infectious agents and/or biological material, you **MUST** be trained once every 2 years

- EHSO offers shipping training once a quarter
Great!

Let’s figure out what documentation and/or permits you need for your material!
Are you sending or receiving biological material?

Click on one answer...

I’m sending it!  
I’m receiving it!
Great!

You may need a Material Transfer Agreement.

Click here to learn more about MTAs and find out if you need one
Material Transfer Agreements (MTA)

- A contract between the owner of a material and the intended recipient governing the transfer and subsequent use of the material

- Used to transfer materials from one institution to another

- Examples:
  - Bacteria
  - Cultures
  - Nucleotides
  - Proteins
  - Plasmids
  - Cell Lines
  - Transgenic Animals
  - Pharmaceuticals
MTA - Outgoing

- **MTA does not** need to go through the Office of Technology Transfer (OTT) if all of the following apply:
  1. Material is provided to a non-profit institution
  2. Material was not developed using research funding (having intellectual property provisions) from an industrial sponsor, foundation, or other similar source
  3. Material has not been, nor is it expected to be, the subject of an invention disclosure or other potentially valuable intellectual property

- If **all** of the above conditions apply:
  - PI can use the Uniform Biological Transfer Agreement (**UBMTA**) Implementing Letter

- If **any** of the above conditions **do not** apply:
  - MTA must be handled through OTT
UBMTA Implementing Letter

- A simple letter agreement for the transfer of non-proprietary biological material
- Copies of the letter should be printed and signed by the provider of material and sent to the recipient
- The recipient should sign the letter and receive an institutional signature
- A list of all institutions that may sign a UBMTA letter are available on the Association of University Technology Managers (AUTM) website
  - If the receiving institution is not listed, notify OTT

Click here to link to the UBMTA Implementing Letter Template

Click here to link to the AUTM website
Providing PI should:
- Notify OTT
- Provide OTT with necessary information and documentation to ensure that OTT can negotiate a timely and suitable MTA

Click here to link to the OTT website
Now, let’s see if you need a transport permit.

Where are you sending the biological material?

Click on one location...

- Within the US
- Outside of the US
Great!

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Material Transfer Agreements (MTA)

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- Examples:
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  - Nucleotides
  - Proteins
  - Plasmids
  - Cell Lines
  - Transgenic Animals
  - Pharmaceuticals
All incoming MTAs must be forwarded to the Office of Technology Transfer (OTT) for approval along with a completed MTA questionnaire.
Now, let’s see if you need a transport permit.

Where are you receiving the biological material from?

Click on one location...

- Within the US
- Outside of the US
Great!

You may need an import permit.

Click here to learn more about import permits and find out if you need one
Who Regulates Importation?

- **Center for Disease Control and Prevention (CDC):**
  - Etiologic Agent Import Permit Program

- **United States Department of Agriculture (USDA) / Animal Plant and Health Inspection Service (APHIS) / Veterinary Service (VS):**
  - Plants Protection and Quarantine (PPQ) 526 Permit
  - Biotechnology permits
  - Live animal import permits
  - Animal product import permits

- **United States Fish and Wildlife Service**
USPHS 42 CFR - Part 71.54

Items requiring a CDC import permit:
- Etiologic Agents
  - Any infectious agent known or suspected to cause disease in humans
- Biological Materials
  - Unsterilized specimens of human and animal tissues containing an infectious or etiologic agent
- Hosts and Vectors
  - Any animal known or suspected of being infected with an organism capable of causing disease in humans
  - All live bats
  - Any living arthropod infected with an etiologic agent
  - Snail species capable of transmitting a human pathogen
What does not require a CDC import permit?

- Non-infectious material (formalin fixed specimens, non-infectious human stem cells or organs for transplantation)
- Human and animal diagnostic specimens (blood, urine, tissues) where there is no evidence of an etiologic agent
- Laboratory rats, mice, and hamsters reared under specific pathogen-free conditions
- Genetically modified animals provided that they are not infectious to humans
- Full taxidermied or treated non-human primate trophies, skins, or skulls
• If you need a CDC import permit complete the import application form
  ○ Link to CDC Import Application Form

• If you are importing material that **does not** require a CDC import permit, CDC advises to include a signed statement, on official letterhead, from the person responsible for the shipment of this material with the following information:
  ○ A description of the material
  ○ A statement that this material meets one of the previously listed criteria
  ○ Verification that the material has been packaged, labeled, and transported in accordance with all applicable regulations
USDA/APHIS/VS: PPQ 526 Permit

- Required for the importation of:
  - Plant pests
    - Plant feeding insects, mites, snails, slugs, and plant pathogenic bacteria, viruses, fungi, etc.
  - Biological control organisms of plant pests and weeds
  - Bees
  - Parasitic plants
  - Federally listed noxious weeds
  - Soil for the purpose of isolating or culturing microorganisms from the soil

- See the USDA website for more information and instructions on how to obtain a permit

Click here to link to the USDA/APHIS/VS Biotechnology Permit Program website
A Biotechnology Permit is required for the importation of genetically engineered organisms that pose a plant pest risk, including plants, insects, or microbes.
USDA/APHIS/VS: Animal Product Import Permits

- **USDA veterinary permit** is needed for materials derived from animals or exposed to animal-source materials

- **Materials which require a permit include:**
  - Animal tissues, blood, cells or cell lines of livestock or poultry origin
  - RNA/DNA extracts, hormones, enzymes, monoclonal antibodies for IN VIVO use in non-human species
  - Certain polyclonal antibodies and antisera
  - Bulk shipments of test kit reagents
  - Microorganisms including bacteria, viruses, protozoa, and fungi

- **Exceptions to this requirement are human and non-human primate tissues, serum, and blood**

Click here to link to the USDA/APHIS/VS Animal Product Permit Program website
Due to the vast variety of animals, go directly to the USDA/APHIS website for animal specific regulations, guidelines, and protocols pertaining to importation.

Click here to link to the USDA/APHIS/VS Live Animal Permit Program website.
The US Fish and Wildlife Service regulates the importation of animals and plants. The following laws and treaties require permits for importation:

- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- Endangered Species Act
- Injurious Wildlife (Lacey Act)
- Marine Mammal Protection Act
- Migratory Bird Treaty Act
- Wild Bird Conservation Act
To determine if a US Fish and Wildlife Service import permit is required and how to obtain a permit, see the US Fish and Wildlife Service website.
Now you should have a better idea about what documents/permits you need!

Click here for links to more resources

Click here to exit
Shipping outside the US?

You may need an export controls license.

Click here to learn more about export controls
Export Controls

- Exports are regulated in the US by:
  - US Department of State - Directorate of Defense Trade Controls:
    - International Traffic in Arms Regulations (ITAR)
  - US Department of Commerce - Bureau of Industry and Security:
    - Export Administration Regulations (EAR)
  - US Department of Treasury - Office of Foreign Assets Controls
    - OFAC

- The export regulations are intended to control access to certain technology, agents, military equipment, etc. that could be used by terrorists, drug cartels, rogue regimes, and others who may want to harm the U.S. or violate its laws and treaties

- Export restrictions under ITAR, EAR, and OFAC may apply to research activities and may require an export license
What falls under the fundamental research exclusion?
- “Basic and applied research in science and engineering when the resulting information is *ordinarily published* and *broadly shared* within the scientific community”
- EAR 734.8

What **does not** fall under the fundamental research exclusion?
- Research that is “proprietary”, i.e., restricts publication and other forms of sharing research results
- Industrial development, design production, and product utilization
- Such activities usually restrict dissemination of research results for proprietary or national security reasons.

**NOTE:** The fundamental research exclusion only applies to technical data/information; it does not apply to equipment or commodities.
Will I need a license?

- In most cases, an export license will not be required. There are a number of license exceptions that may apply to the shipment of many biological and chemical agents outside of the US.

- BUT, we have to be able to show that we have screened the specific agent being shipped outside the US for compliance with US export controls laws and regulations.

- And, we have to document our use of any of the available license exceptions.
If it is determined that a license will be required, substantial time should be built into the project plan to accommodate the license application process.

- This process can take several weeks, even months, depending upon the agency and the nature of the export.

If a license is granted, the conditions of the license for the export activity must be carefully observed.

If a license application is denied, that activity, export or deemed export, is prohibited.
The penalties for noncompliance are quite severe:

- The civil penalty fines for violation of these regulations is $250,000 *per occurrence*
- The criminal penalty amounts are $1,000,000 *per occurrence* and/or imprisonment

Click here to link to the ORC website for more information on export permits
Who do I contact about export controls?

Click here to find the export controls coordinator for your school or unit

Scroll down to the bottom of the web page
Now you should have a better idea about what documents/permits you need!

Click here for links to more resources

Click here to exit
Great!

You may need a domestic transport permit.

Click here to learn more about domestic transport permits and find out if you need one
Who regulates domestic transport?

- United States Department of Agriculture (USDA) / Animal Plant and Health Inspection Service (APHIS) / Veterinary Service (VS):
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More Information

Emory Links:
- Environmental Health and Safety Office
- Office of Technology Transfer (MTAs)
- Office of Research Compliance (Export Permits)

External Links:
- CDC: Etiologic Agent Import Permit Program
- USDA/APHIS/VS: PPQ 546 Permit Program
- USDA/APHIS/VS: Biotechnology Permit Program
- USDA/APHIS/VS: Animal Product Permit Program
- USDA/APHIS/VS: Live Animal Permit Program
- US Fish and Wildlife Service Permit Program