

Research Material Shipment and Transport Manual

Table of Contents

Introduction	3
Material Transfer Agreements	5
Shipment and Transportation of Hazardous Research Materials	5
Training	7
Can I Be Trained to Ship My Own Research Material?	7
Requirements by Specific Research Material	8
Hazardous Chemicals	8
Hazardous Biological Materials	9
Hazardous Radioactive Materials or Radiation Generating Devices	9
Other Methods of Transport (When Shipment Via Carrier Is Not Feasible)	10
Self-Transport or Hand Carry to a Non-Harvard Destination	10
Local Transport of Research Materials	12
Intracampus	12
Intracampus Biological Materials	12
Intracampus Chemicals	14
Intracampus Radioactive Material or Radiation Generating Devices	16
Intercampus and within the Greater Boston Area	17
Materials of Trade	17
Domestic Transport or Exchange of Research Materials	17
Interstate Transport of Biologicals	18

Revision Date: 03/20/2024 Page 1 of 39



United States Department of Agriculture, Animal and Plant Health Inspection Service: Intersta	te Biological
Material Transport	18
United States Centers for Disease Control and Prevention	19
United States Fish and Wildlife Services	19
International Transport or Exchange of Research Materials	19
Import	19
Chemical Imports: Toxic Substances Control Act	19
Biological Import Permits	20
Centers for Disease Control and Prevention Import Permit Program	20
United States Department of Agriculture, Animal and Plant Health Inspection Service: Biologic	al Import
Permits	21
Fish & Wildlife Service and National Marine Fisheries Service	23
Export	23
Export Control	23
Chemical Exports: Toxic Substances Control Act	25
Biological Exports	25
Off-Campus, Domestic, or International Shipment of Animals (Including Native Animals)	25
Lithium Batteries and Equipment Containing Lithium Batteries	26
Self-Transport of Used Personal Biological Sharps	26
References	28
Harvard Policies	28
Federal Agency Regulations	28
International Regulations	29
Appendices	30
Appendix A – Who to Contact for Help by Keyword	31
Contact Information by Contact	31

Revision Date: 03/20/2024



Contacts by Keyword	31
Appendix B – Research Material Shipping Training Courses	33
Appendix C – Self-transport or Hand Carry (by air) Checklist	34
Appendix D – Options for Local Transport of Research Materials	36

Introduction

The purpose of this manual is to guide any member of the Harvard community who wishes to ship research material (regulated or otherwise) either between our campuses or to anywhere in the world.

Harvard is a world-class research institution, committed to serving as a model of quality in our safety practices as in our teaching and research. Integral to research discovery and advancement is collaboration across institutions, both domestically and internationally. Such collaboration often involves the sharing of research materials, including biological samples, chemicals, reagents, research prototypes, and research equipment, including laptops to lasers.

The transport and exchange of research materials may be subject to strict regulatory requirements related to the health and safety of shipping carriers and the public, international sanctions, protection of intellectual property, and export controls.

There are as many as ten different agencies imposing public health, safety, and security requirements on the transport and exchange of research materials.

For transporting or importing hazardous research materials (by hand or common carrier), researchers and research staff need to be aware of proper training, handling, labelling, and packaging requirements as well as the need to secure the appropriate federal safety and transport permits. This section describes the requirements and resources by material and mode of transport in more detail. Harvard Environmental Health and Safety (EH&S) provides assistance and guidance in these areas.

Revision Date: 03/20/2024 Page 3 of 39



For transporting or exporting research materials (by hand or common carrier) internationally, researchers and research staff must be aware that **the shipment of any research materials**, **whether hazardous or not, may be controlled for export by United States (U.S.) authorities**. Further detail on these requirements is detailed in the section on Export Controls. Your School or Institute Export Control Administrator provides assistance and guidance in this area.

It is important to note that the transport or shipment of chemicals, biologicals, radioactive materials, or radiation generating devices internationally may require guidance from both EH&S and your School or Institute Export Control Administrator.

Prior to sharing, shipping, or otherwise transporting research materials, ensure that proper controls are in place, including:

- Proper labelling to ensure safe shipping of hazardous materials and the prevention of waste or loss of perishable materials;
- Proper packaging and transport of hazardous materials to avoid accidental exposure of personnel who
 may handle or be exposed to the material during transport;
- Adequate training to handle, package and ship hazardous materials;
- Authorization to self-transport hazardous research materials;
- Execution of Material Transfer Agreements (MTA) to prevent theft of intellectual property when sharing items or information with third parties; and
- Securing applicable permits or export licenses prior to transport or exchange of research materials.

Failure to comply with health and safety and transportation regulations may result in significant delays in transport, confiscation of samples by agencies, loss of perishable research materials, fines, and other civil and criminal penalties, injury, and risks to public health and the environment.

Revision Date: 03/20/2024 Page 4 of 39



This manual outlines the applicable regulatory requirements and the resources available to Harvard researchers and staff to facilitate the transport and exchange of research materials safely, compliantly, and efficiently.

Material Transfer Agreements

When sharing research materials, MTAs specify the rights, obligations, and restrictions of both the providing and receiving parties with respect to issues such as ownership, publication, intellectual property and permitted use, and liability.

The Harvard Office of Technology Development (OTD) provides high-quality, expedited service while keeping Harvard investigators' interests protected, including the freedom to publish research results and to transfer modifications to other non-profits.

Visit the OTD MTA website for information on securing agreements for incoming and outgoing materials.

Shipment and Transportation of Hazardous Research Materials

The packaging, handling, and transport of hazardous materials is subject to strict local, state, federal and international regulations. This is particularly so if the material is transported through the "public domain," namely, those roadways, airways, and sea lanes accessible to the public.

Improper packaging of hazardous research materials can lead to leakage, hazardous material contamination of public areas, or injury to those handling the transported material or individuals and property nearby.

The regulations are usually applied based on the method of transport (for example, domestic ground or air).

Agency or Regulatory Body	Transport Mode	Responsibilities
International Air Transport	Air transport	Establish requirements for hazardous material
Association (IATA)		transport.

Revision Date: 03/20/2024 Page 5 of 39



Agency or Regulatory Body	Transport Mode	Responsibilities
U.S. Department of	Ground transport	Establish requirements for hazardous material
Transportation (DOT)		transport.
U.S. Departments of Commerce,	International export	Establish export requirements and impose trade
State and Treasury		restrictions on the shipment or transport of
		certain hazardous materials internationally.

Failure to comply with hazardous material transport requirements and export regulations (if applicable) can lead to fines, jail time, injury, loss of material, or delays in transport.

Harvard faculty, students, or staff who package, label, ship, prepare shipping documents, or self-transport hazardous research materials must complete appropriate training and comply with all federal, international, and local regulations.

EH&S assists lab researchers and staff in managing shipments and transportation of hazardous materials, including chemicals, radioactive materials, and biological materials, by ground, air, or sea. For EH&S assistance with hazardous research material transport, please contact EHS ResearchTransport@harvard.edu.

In addition to EH&S, <u>School or Institute Export Control Administrators</u> can advise lab researchers and staff on whether export controls apply to the shipment or hand-carry of hazardous research materials internationally.

Shipping hazardous research materials requires special attention and training, as each type of hazardous material will have specific requirements relating to:

- Training.
- Packaging.
- Labeling.
- Documentation.
- Mode of transport.

Revision Date: 03/20/2024 Page 6 of 39



For specific information about the shipment and transport of different types of hazardous research materials, please see <u>Training</u>.

Training

Federal regulations and the <u>Harvard University Laboratory Safety Policy</u> mandate training for all individuals involved in the shipment of hazardous materials including those who package, label, ship, prepare shipping documents, or otherwise transport hazardous materials.

Online training is available for the research community on the <u>Harvard Training Portal (HTP)</u> to enable researchers to ship or transport specific materials themselves.

The <u>Can I Be Trained to Ship My Own Research Material?</u> table outlines the options to ship or transport research materials. For more details, please review <u>Requirements by Specific Research Material</u>.

Can I Be Trained to Ship My Own Research Material?

Research Material	Description	Can I be trained to
		ship this material?
Chemical	Small volumes of flammables, corrosives, and common fixatives.	Yes.
Chemical	Non-hazardous chemicals.	Yes.
Chemical	All others.	No. Contact EH&S.
Biological	Infectious agents causing serious disease <u>Division 6.2 Infectious Substances</u> .	No. Contact EH&S. See <u>Biological</u> for more information.
Biological	All other infectious agents.	Yes.

Revision Date: 03/20/2024 Page 7 of 39



Research Material	Description	Can I be trained to
		ship this material?
<u>Biological</u>	Nucleic acids and proteins, human and animal	Yes.
	tissue samples, and non-infectious genetically	
	modified materials.	
Dry ice		Yes.
Radioactive material or radiation	Radioactive materials, lasers, and X-ray	No.
generating devices	devices.	

For a complete list of shipping and transport training courses available to you, please see Appendix B – Research Material Shipping Training Courses.

Requirements by Specific Research Material

Hazardous Chemicals

Trained faculty, staff, or students may ship specific small quantities of certain chemicals that are classified as flammables, corrosives, or common fixatives and are often used in biological research to fix or preserve biological samples (such as ethanol or formalin). Completion of the <a href="http://example.com/h

Other hazardous chemicals must be shipped by someone specially trained to ship chemical hazardous materials. Contact EH&S to arrange this type of shipment.

For the transport or shipment of chemicals internationally, whether hazardous or not, you must also consult your <u>School or Institute Export Control Administrator</u>.

Revision Date: 03/20/2024 Page 8 of 39

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Hazardous Biological Materials

There are five basic classifications for biological materials when it comes to transportation and shipping:

- Non-regulated biological material.
- Exempt Human or Animal Specimens.
- Genetically Modified Microorganism or Organism.
- Biological Substance, Category B.
- Infectious substance, affecting humans or Infectious substance, affecting animals (Category A).

Training is required for anyone that will prepare a shipment of biological material or transport material via ground or air. This training is available online through HTP and is called <u>Shipping Biological Materials and Dry Ice</u>. The training will provide you with all instructions for classifying, packaging, labeling, and documenting a shipment of biological material.

Trained faculty, staff, or students may ship all categories of biological material except for Category A materials.

To determine what constitutes a Category A shipment, please utilize the Preparing Biological Shipments

Flowchart. Contact EH&S to arrange shipments of Category A materials.

For the transport or shipment of biological materials internationally, whether hazardous or not, you must also consult your <u>School or Institute Export Control Administrator</u>.

Hazardous Radioactive Materials or Radiation Generating Devices

No one may use, acquire, or remove from the University any radioactive materials or radiation generating devices (such as irradiators, X-rays, and lasers) without obtaining written authorization from the <u>Radiation</u>

<u>Protection Office (RPO)</u> in EH&S. This includes registration of radioactive materials in consumer products that are licensed for sale to the general public and do not require any registration with governmental agencies.

For complete requirements governing the transport and exchange of radioactive materials or radiation generating devices, please reference <u>Harvard's Radiation Safety Manual</u>.

Revision Date: 03/20/2024 Page 9 of 39



For the transport or shipment of radioactive materials or radiation generating devices internationally, whether hazardous or not, you must also consult your <u>School or Institute Export Control Administrator</u>.

Other Methods of Transport (When Shipment Via Carrier Is Not Feasible)

Self-Transport or Hand Carry to a Non-Harvard Destination

Self-transport or hand carry of research materials via ground or air is strongly discouraged.

Self-transport of research materials, especially hazardous research materials, may incur increased scrutiny of material identity and packaging by authorities, and complex documentation requirements.

In rare instances where use of a carrier or courier service may be limited (such as a remote field site), hand carry or self-transport may be considered.

Examples of self-transport or hand carry include:

- Carrying research materials in airline checked or carry-on luggage.
- Using a Harvard owned or leased vehicle to transport research materials.

In these cases, you must notify EH&S at EHS ResearchTransport@harvard.edu and meet all requirements outlined in this section in order to perform self-transport.

Additionally, if you are planning to hand-carry research materials internationally, you must notify your <u>School or Institute Export Control Administrator</u> so that they can review the items and determine whether an export license is required.

Note that arranging all required paperwork may take weeks to months depending on the nature of the material and where it will be transported. Be sure to reach out to EH&S and your <u>School or Institute Export</u> <u>Control Administrator</u> (if international) as soon as you suspect that self-transport may be needed to move

Revision Date: 03/20/2024 Page 10 of 39



research materials. Unauthorized self-transport, improperly packaged items, or items with inadequate documentation may subject you to detention or other enforcement action by Customs and Boarder Protection (CBP). These requirements are found in a checklist format in Appendix C - Self-Transport or Hand Carry (by Air) Checklist.

Requirements for self-transport or hand carry of research materials:

- Obtain and carry documentation that proves you have authority to transport and exchange the research materials.
 - An MTA is the recommended mechanism of documentation. If an MTA is not established, a letter signed by the Principal Investigator (PI) must be obtained.
- Receive authorization from any and all airlines that you may use to arrive at your destination with your material.
- Obtain and carry all permits relevant to public, agricultural, and environmental health. See <u>Domestic</u>
 <u>Transport or Exchange of Research Materials</u> and <u>International Transport or Exchange of Research</u>
 <u>Materials</u>. These may include import permits for the destination country or export licenses for materials leaving the U.S.
- For international self-transport or hand carry, have the material reviewed by your <u>Export Control</u>
 <u>Administrator</u> who could review the materials being transported and determine if an export license if needed.
- Obtain and carry documentation that accurately identifies the material to be transported and ensures it is allowable for self-transport or hand carry via ground or air.

The documentation must also outline that the packaging and labelling meets regulatory requirements. This documentation must include references to the regulation or regulations that govern the transport of materials via these modes.

EH&S can review your hand carry plans and provide this documentation.

Revision Date: 03/20/2024 Page 11 of 39



- Package and label research materials appropriately per regulations cited in this section.
- Arrange for notification of relevant authorities before you self-transport research materials. This may
 include the Transportation Security Administration (TSA), CBP, U.S. Department of Agriculture (USDA), and
 others.

EH&S can make these notification arrangements for you.

- Declare all research materials to customs and border authorities. Present all paperwork to justify legitimate self-transport of research materials.
- Carry a list of institutional contacts if questions arise during transport. This list should include contact
 information for the PI, EH&S, <u>School or Institute Export Control Administrator</u>, lab manager, or other
 pertinent lab contact.

Local Transport of Research Materials

Intracampus

Intracampus Biological Materials

When transporting biohazardous materials by foot within a Harvard campus, take precautions to prevent accidental spills, particularly in public areas of campus buildings and exterior walkways.

The following requirements must be observed during the transportation of biological materials or hazardous chemicals within a campus (for example, between two labs or buildings on the same campus):

• Place the primary container or containers in a secondary transport container that is also secured.

The secondary container must be closeable, shatterproof, leak-proof, and sturdy enough to remain closed in case the container is dropped.

Revision Date: 03/20/2024 Page 12 of 39



Never place dry ice or other chemical that requires venting and/or pressure release into a sealed container. Seal the primary and secondary containers and then place them into dry ice.

- Add sufficient, compatible absorbent material to the secondary container to absorb the entire contents of the primary container in case of a spill or leakage.
- Decontaminate the outside of the primary container before placing it into the secondary container.
 Decontaminate the secondary container before leaving the lab.
- Clearly label the primary container, including the identity of the research material, the universal biohazard symbol (if the biological material has been assigned biosafety level 2 (BL2) by the Committee on Microbiological Safety) and the name and phone number of the person carrying the material or the lab the material belongs to.
- Carry a pair of clean disposable exam gloves with you when transporting biohazardous materials. Do not wear gloves while moving materials around campus.
- Avoid transporting materials through eating areas or break rooms.

The container should be carried directly to the intended lab, avoiding all unnecessary stops, and not taken to bathrooms, offices, cafeterias, or other public or inappropriate locations.

- Secure Institutional Animal Care and Use Committee (IACUC) approval prior to transport of any experimentally-infected animals.
- Recommended secondary container for test tubes and vials:
 - Nalgene Biotransport Carrier.
 - Less expensive options include Plano tackle, field boxes with O-ring seals, available at various sporting goods stores and through Amazon.

Revision Date: 03/20/2024 Page 13 of 39



Intracampus Chemicals

When transporting chemicals (regardless of hazard) by foot within a Harvard campus, take precautions to prevent accidental spills, particularly in public areas of campus buildings and exterior walkways.

- If your sample also contains biological or radiological materials, please consult <u>Intracampus Biological</u>
 <u>Materials</u> and <u>Intracampus Radioactive Material or Radiation Generating Devices</u> for further guidance on the transportation requirements for those hazards.
- The label on primary container or containers should be understandable to trained lab personnel and members of emergency response teams.
- If you are transporting a material in the original, manufacturer-provided container, you may rely on the existing manufacturer label to provide the necessary information, as long as it includes:
 - Lab name.
 - Full chemical name.
 - Globally Harmonized System (GHS) hazard identification.
 - Chemical Abstracts Service (CAS) number.
- If you are transporting a lab-made, experimental material, the container or containers should be labeled with:
 - Researcher's name.
 - Material identification (name of the chemical compound or compounds in the sample container and the quantity and/or concentration of each).
 - Appropriate hazard warnings (for example, GHS hazard classification).
 If hazards for multiple containers are similar, a single label on the secondary container is sufficient.
 - If applicable, specify that the sample is dry nanomaterials or nanomaterials in solution, as nanomaterials may exhibit unusual reactivity and toxicity from their parent compounds.

Revision Date: 03/20/2024 Page 14 of 39



- The primary container should be labeled appropriately and tightly sealed, with a threaded cap closure, a
 tape seal, or a wire tie, parafilm to prevent a removable closure from inadvertently opening during
 transport.
- Primary containers should be placed within secondary containment, which is meant to prevent the primary container from breaking and prevent release of the material should the primary container break.
 - A bottle carrier may be used as secondary containment.
 - If transporting multiple bottles of liquids, ensure they are secure.

Glass bottles should be separated with cushioning (such as absorbent pads) to avoid breakage and spills.

- Use carts with attached side rails or lips to contain a spill that may occur.
- Consider having a spill kit on the cart or know where the spill kits on your travel route are.
- Using a cart or bottle carrier avoids the need to wear gloves for your own protection and avoids potential contamination of public surfaces.

If a glove must be worn, remember to use the one-handed glove technique.

- For sample tubes, the secondary container must be gasket-sealed, shatterproof, leak-proof, and sturdy enough to remain closed in case the container is dropped.
 - Closed sample tubes should be placed upright in a sealed container ideally with absorbent materials absorb liquids that might leak from the inner container or containers during normal events in transport.
 - Recommended secondary container for sample tubes and/or vials:
 - Nalgene Biotransport Carrier.
 - Less expensive options include Plano tackle, field boxes with O-ring seals, available at various sporting goods stores and through Amazon.

Revision Date: 03/20/2024 Page 15 of 39



Never place dry ice or other chemical that requires venting and/or pressure release into a sealed container. Seal the primary and secondary containers and then place them into dry ice.

Avoid transporting materials through eating areas or break rooms.

The container should be carried directly to the intended lab, avoiding all unnecessary stops, and not taken to bathrooms, offices, cafeterias, or other public or inappropriate locations.

- When possible, use freight elevators when transporting research materials and disclose to non-lab
 passengers that you are transporting lab research materials and encourage them to wait for another
 elevator.
- If transporting via stairs, use the fire-rated emergency stairwells typically at the end or ends of the floor.
- The indoor transport of cylinders and cryogenic materials is building specific, please consult with someone like your Lab Safety Adviser, Facilities Manager, or a Research Operations Manager (ROMS) as applicable.

Intracampus Radioactive Material or Radiation Generating Devices

Transportation of radioactive materials is regulated by the Massachusetts Radiation Control Program, U.S. DOT, U.S. Postal Service, the License of the destination facility, as well as other local regulations.

To ensure the transportation of radioactive materials meets these regulatory requirements, all transportation for radioactive materials must first be approved by the RPO.

Review <u>Harvard's Radiation Safety Manual</u> for complete instructions on how to transport such materials on campus.

Revision Date: 03/20/2024 Page 16 of 39



Intercampus and within the Greater Boston Area

Transporting materials considered to be hazardous materials between Harvard campuses (for example, Longwood, Cambridge, or Allston) and neighboring institutions using public roadways must be done in compliance with U.S. DOT requirements.

A guide for transportation of biological materials with the greater Boston area can be found in <u>Biological Materials</u>, <u>Infectious Substances</u>, <u>and Dry Ice Local Transport Guidance</u> and a table of options for local transport of biological materials can be found in <u>Appendix D – Options for Local Transport of Research Materials</u>.

Materials of Trade

Harvard University Mail Services (HUMS) can transport eligible research materials to local Harvard or affiliate sites under the DOT Materials of Trade (MOT) exception.

MOT are hazardous materials that are transported via Harvard owned or leased motor vehicles for the purpose of directly support academic and lab research.

To utilize this method, first contact EHS ResearchTransport@harvard.edu to confirm that the materials you'd like to ship are eligible and to receive a brief training.

The <u>Transport of Research Materials form</u> must be provided to the HUMS courier along with each package.

Domestic Transport or Exchange of Research Materials

Within the U.S., the DOT regulates all activities related to the shipment and transport of hazardous materials (for example, chemicals or gases).

The Hazardous Materials Regulations apply to each person who performs functions related to the transportation of hazardous materials. U.S. DOT oversees the <u>Hazardous Materials Regulations</u> (49 CFR Parts

Revision Date: 03/20/2024 Page 17 of 39

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<u>100-185</u>) that regulate all activities involved with the shipment and transport of hazardous materials (for example, chemicals or gases).

This includes shipping hazardous materials:

- Interstate.
- Intrastate.
- Through commerce by rail car, aircraft, motor vehicle, and vessel.

These comprehensive regulations govern transportation-related activities by:

- Offerors, such as shippers, shipping and receiving departments, brokers, forwarding agents, and freight forwarders.
- Carriers, that is common, contract, and private trucking and other transport companies.

In most cases Harvard acts as an offeror of hazardous materials.

Interstate Transport of Biologicals

United States Department of Agriculture, Animal and Plant Health Inspection Service: Interstate Biological Material Transport

The USDA, Animal and Plant Health Inspection Service (USDA APHIS) regulates the interstate movement of agricultural products to prevent pests and agricultural disease agents from spreading within the U.S.

Examples of regulated items include:

- Livestock disease agents (naturally occurring or engineered).
- Material known or reasonably expected to contain livestock disease agents.
- Vectors of livestock diseases.
- Naturally occurring or engineered organisms that impact plants directly or indirectly.

Revision Date: 03/20/2024 Page 18 of 39



- Plant pests.
- Noxious weeds, soil, or plants.

More detailed information about USDA APHIS permits can be found in the Biological Import Permits section.

Contact EH&S as soon as possible when you suspect the need for an USDA intrastate transfer permit.

United States Centers for Disease Control and Prevention

Generally, the U.S. Centers for Disease Control and Prevention (CDC) only regulates the importation of:

- Infectious biological agents capable of causing illness in humans.
- Materials known or reasonably expected to contain an infectious biological agent, and vectors of human disease (such as insects or bats).

However, if noted as a <u>condition of an issued import permit</u>, subsequent transfers of any infectious biological agent, infectious substance or vector within the U.S. will require an additional permit issued by the CDC.

United States Fish and Wildlife Services

U.S. Fish and Wildlife Services (FWS) may regulate the <u>interstate transport of certain animal species</u>. Please reach out to your <u>Biosafety Officer</u> with questions.

International Transport or Exchange of Research Materials

Import

Chemical Imports: Toxic Substances Control Act

Labs engaged in research must consider the applicability of the Toxic Substances Control Act (TSCA) to their operation.

Revision Date: 03/20/2024 Page 19 of 39



The TSCA, administered by the U.S. Environmental Protection Agency (EPA), is intended to ensure that the human health and environmental effects of chemical substances are identified and adequately addressed prior to production or transport.

Visit the EH&S TSCA website for more information and import certification form.

Biological Import Permits

Harvard EH&S Biosafety can help you determine if you need an import permit for biological materials, assist you in the application process, and support you in preparing for import permit inspections.

Permits must be applied for in the name of the faculty member who is the PI overseeing the use of the imported biological material. EH&S does not maintain an umbrella permit.

You must notify the EH&S Biosafety team at EHS ResearchTransport@harvard.edu as soon as you identify the need to obtain a permit.

Centers for Disease Control and Prevention Import Permit Program

The <u>CDC Import Permit Program (IPP)</u> regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S. The program ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents.

Items requiring CDC import permits (contact EH&S or utilize the <u>CDC IPP e-Tool</u> for help determining if a permit is needed):

- Any infectious (etiologic) agent known or suspected to cause disease in humans.
- Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions, or similar material) containing an infectious or etiologic agent.
- Hosts and vectors:

Revision Date: 03/20/2024 Page 20 of 39



- Any animal known or suspected of being infected with an organism capable of causing disease in humans may require an import permit.
 - Importation of live turtles of less than 4 inches in shell length and live nonhuman primates is regulated by the CDC Division of Global Migration and Quarantine (DGMQ).
- All live bats require an import permit from the CDC and the U.S. Department of Interior, FWS.
- Any living insect or other arthropod that is known or suspected of containing an etiologic agent (human pathogen).
- Snail species capable of transmitting a human pathogen.

To obtain a CDC import permit:

- Notify EH&S at EHS ResearchTransport@harvard.edu.
- Importation permits are issued only to the importer, who must be located in the U.S..
- The permittee must be the PI of the lab. Exceptions must be reviewed by EH&S.
- EH&S will assist you in applying for your permit online through the CDC eIPP System.

United States Department of Agriculture, Animal and Plant Health Inspection Service: Biological Import Permits

<u>USDA APHIS</u> regulates the import, transit and release of regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil, and genetically engineered organisms, and all agricultural products to ensure U.S. agricultural industries are kept free from pests and diseases. APHIS makes sure that all imported agricultural products shipped to the U.S. from abroad meet the Agency's entry requirements to prevent pests and diseases impacting U.S. agriculture. APHIS regulates the importation of plants and plant products, organisms/microorganisms, soil, animals and animal products, and vectors.

USDA also regulates the interstate movement of agricultural products to prevent pests and agricultural disease agents from spreading within the U.S.

Revision Date: 03/20/2024 Page 21 of 39



USDA APHIS requirements for import permits is complex. Contact <u>EH&S Biosafety</u> for help determining if a permit is required.

Items Requiring USDA APHIS Import Permits:

- Animal pathogens and biological materials of animal origin
 - USDA APHIS requires permits for the importation of animal pathogens and biological materials that
 contain animal material. Materials such as cell culture-grown pathogens containing animal
 components (e.g. bovine serum albumin, blood agar, etc.) require permits due to the potential for the
 presence of organisms/viruses that may be dangerous to animals.
 - Some animal products may not need a USDA import permit but are still subject to review at the port of entry by USDA inspectors
 - Visit the <u>USDA website</u> or contact EH&S for a list of items that do not require an import permit. While a
 permit may not be required, there may be documentation requirements to successfully import the
 materials into the U.S.
 - Permits related to animal health must remain active for the entire duration importation/interstate transport is occurring.
- Soil, plant material, plant pests and plant pathogens
 - If you plan to import soil, plant material, plant pests or plant pathogens from a country outside of the U.S., or from certain areas within the U.S., you must be authorized by APHIS through their permitting system. These permits will stipulate handling precautions, storage conditions, and disposal requirements, designed to prevent the release or spread of pathogens that may be present in the samples. These types of permits must remain active for the entire duration of material possession, use, storage, and transport.

To Obtain a USDA Import Permit:

Notify EH&S at EHS ResearchTransport@harvard.edu.

Revision Date: 03/20/2024 Page 22 of 39



- The permittee must be the PI of the lab. Exceptions must be reviewed by EH&S.
- EH&S will assist you in applying for your permit on-line using the <u>USDA ePermits</u> system.

Fish & Wildlife Service and National Marine Fisheries Service

Fish and Wildlife Service permits are required for marine mammals, certain fish, and certain live animals, including bats as well as species covered by the Convention on International Trade in Endangered Species (CITES). Contact EH&S and review the <u>U.S. FWS website</u> on import and export to determine if you need a permit.

Export

Export Control

The U.S. government actively regulates, and in some cases, restricts the export of certain items and information, including technologies that it deems critical to the interests of national security, the economy, and foreign policy.

The Departments of State, Commerce, and Treasury administer the primary controls on exports of goods, commodities and information:

- The Department of State Directorate of Defense Trade Controls (DDTC) administers export controls of defense items.
- The Department of Commerce Bureau of Industry and Security (BIS) administers export control of items that have both commercial and possible military applications.
- The U.S. Department of the Treasury Office of Foreign Assets Control (OFAC) enforces country-specific embargoes and financial sanctions on individuals, organizations and countries.

For more information on Comprehensively Sanctioned Countries or Targeted Sanctions Countries, see <u>Harvard</u>
<u>Screening Process and Monitoring Guidance: Appendix II</u>.

Revision Date: 03/20/2024 Page 23 of 39



Controlled items may include certain:

- Pathogens.
- Genetically modified organisms.
- Toxins.
- Chemicals.
- Lasers.
- Software.
- Robotics.
- Other research items and equipment.

The export of controlled items, information or software may require approval from the U.S. government in the form of an export license. An export license permits controlled tangible items or software to be sent outside the U.S. or controlled information or software to be shared with foreign persons in the U.S. or abroad. Before carrying, shipping, sharing, or otherwise sending any materials outside of the U.S., consult the International Shipping Guidance.

Additionally, contact your <u>School or Institute Export Control Administrator</u> when:

- Shipping or hand-carrying research samples, models, equipment, or other items internationally.
- The shipment of research materials involves a <u>Restricted Party on a U.S. government export or trade</u>
 sanctions list.
- The shipment involves items, information or software on the <u>U.S. Commerce Control List</u> or the <u>U.S.</u>
 Munitions List.

School or Institute Export Control Administrators can help determine if an export license is required.

All license applications must be reviewed and approved by the Office of the Vice Provost for Research (OVPR) prior to submission.

Revision Date: 03/20/2024 Page 24 of 39



Export Licenses must be applied for in the name of the faculty member who is the PI overseeing the research and transport of the material.

In the event of a violation of U.S. export controls, both the individual shipping or transporting the item, as well as the University, may be held liable. The individual shipper may be subject to criminal and civil penalties, as well as denial of export privileges and debarment from contracting with the federal government.

Chemical Exports: Toxic Substances Control Act

See <u>Chemical Imports: Toxic Substances Control Act</u> and visit the <u>EH&S TSCA webpage</u> for more information and the export notification form.

Biological Exports

Exportation of biological materials usually does not require a USDA or CDC export permit. Export permits and certification are available through USDA, however, in the case that the destination country requires documentation of the health status or disease risk of agricultural products.

Contact EH&S or visit USDA Imports and Exports for more information.

The external recipient may also need to have an import permit to allow entry into their country.

All permits must be included with the other documentation for the shipment.

Off-Campus, Domestic, or International Shipment of Animals (Including Native Animals)

Shipments of animals to other institutions or another Harvard campus are complicated transactions for the investigator's lab, veterinary services, and receiving institutions. Sending labs, veterinary staff, and IACUCs must work together to coordinate animal shipments with the recipient institution and all intermediary authorities (such as national veterinary authorities or Customs).

Revision Date: 03/20/2024 Page 25 of 39



Some receiving institutions may need additional assurances regarding health status, required additional diagnostic testing results, or documentation of various aspects of animal care or husbandry. These may require extensive communication and time. Under IATA, <u>shipments of infected animals are strictly controlled</u>.

For animals originating at or transported to the Harvard Longwood campus, contact the <u>Harvard Center for</u> Comparative Medicine.

For animals originating at or transported to the Cambridge campus, Allston campus, or Concord Field Station, contact the Faculty of Arts and Sciences (FAS) Office of Animal Resources.

Lithium Batteries and Equipment Containing Lithium Batteries

Shipping lithium batteries (both cell and ion) can be complicated and is highly regulated. Fortunately, there is some relief for equipment (such as laptops and drones) containing lithium-ion batteries.

If your shipment meets the following conditions, you do not need any special labeling or marking and the shipment is not considered hazardous:

- There are no more than two items containing batteries in your package.
- Each battery Watt-hour rating is not more than 100 Wh.
- The total weight of the batteries does not exceed 5 kg.
- The equipment containing the batteries is secured against movement within your package and accidental activation cannot happen.

Please contact EHS ResearchTransport@harvard.edu if you have any questions.

Self-Transport of Used Personal Biological Sharps

If you need to transport used needles and syringes that you yourself used for personal medical reasons you can do so as long as the following criteria are met:

Revision Date: 03/20/2024 Page 26 of 39

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- There is not a more restrictive provision imposed by a board of health or the Massachusetts Department of Environmental Protection that would prevent the transport. At the moment there are none.
- You do not transport more than 50 pounds every 30 days.
- Your container is sealed, not leaking, or damaged.
- It remains in your possession at all times while transporting the waste.

It is advised that your personal sharps container be kept within another container at all times for the personal comfort of people you may be around during your travels.

Revision Date: 03/20/2024 Page 27 of 39



References

Harvard Policies

EH&S:

- EH&S Policy.
- Laboratory Safety Policy.
- Biosafety Manual.
- Radiation Safety Manual.

OVPR:

- Export Controls Policies and Procedures.
- Export Control Policy Statement.
- Export License Review and Approval Policy.
- International Shipping Guidance.
- Specially Designated National List Screening Process and Monitoring Guidance.

Federal Agency Regulations

- International Traffic in Arms Regulations.
- Export Administration Regulations.
- OFAC Sanctions Lists.
- U.S. DOT Hazardous Materials Regulations (49 CFR Parts 100-185).
- USDA Animal and Plant Health Inspection Service Imports and Exports.
- CDC Import Regulations (42 CFR Part 71.54).

Revision Date: 03/20/2024 Page 28 of 39



International Regulations

• IATA Dangerous Goods Regulations.

Revision Date: 03/20/2024 Page 29 of 39



Appendices

Revision Date: 03/20/2024 Page 30 of 39



Appendix A – Who to Contact for Help by Keyword

Contact Information by Contact

Group	Contact
EH&S	EHS ResearchTransport@harvard.edu
Export Control	Export Control Officer
OTD	OTD contacts by school

Contacts by Keyword

Keyword	Contacts
Chemical (hazardous)	EH&S
Biological pathogen	EH&S
Biological genetically modified organisms and micro-organisms (GMO/GMMO)	EH&S
Biological human and animal samples	EH&S
Animal pathogens	EH&S
Soil, plant material, plant pests, and plant pathogens	EH&S
USDA permits	EH&S
CDC permits	EH&S
U.S. FWS permits	EH&S
Import	EH&S

Revision Date: 03/20/2024 Page 31 of 39



Keyword	Contacts
Export	Export Control
Self-transport or hand carry of hazardous research materials	EH&S and Export Control
Restricted party	Export Control
Trade sanction	Export Control
U.S. Commerce Control or Munitions list	Export Control
TSCA	EH&S
International	EH&S and Export Control
Intrastate	EH&S
Intellectual property (IP)	OTD
MTA	OTD
U.S. DOT	EH&S
IATA	EH&S
Domestic transport	EH&S
Radioactive materials and radiation-generating devices (such as lasers and X-	EH&S
rays)	
Live animals	Local Harvard Animal
	Facility

Revision Date: 03/20/2024 Page 32 of 39



Appendix B – Research Material Shipping Training Courses

Research Material	Description	HTP Training Available
Chemical	Small volumes of flammables,	Shipping Excepted Quantities:
	corrosives, and common fixatives	Flammables, Corrosives, and Common
		<u>Fixatives</u> .
Chemical	All others	None. Shipment must be coordinated by
		EH&S.
Biological	Category B, GMO/GMMO, and	Shipping Biological Materials and Dry
	exempt specimens	<u>lce</u> .
Biological	Category A	None. Contact EH&S for guidance.
Dry ice		Shipping Non-regulated Materials and
		Dry Ice.
Radioactive material or		None. Shipment must be coordinated by
radiation generating devices		EH&S.

Revision Date: 03/20/2024 Page 33 of 39



Appendix C – Self-transport or Hand Carry (by air) Checklist

Complete?	Task
	Obtain and carry documentation that proves you have authority to transport and/or exchange the research materials. An MTA is the recommended mechanism of documentation. If an MTA is not established, a letter signed by the PI must be obtained.
	Obtain and carry all permits relevant to public, agricultural, and environmental health. See <u>Domestic Transport or Exchange of Research Materials</u> and <u>International Transport or Exchange of Research Materials</u> .
	For international self-transport or hand carry, have the material reviewed by your Export Control Administrator and obtain and license if needed.
	Obtain and carry all import and export authorizations for international self-transport. These may include import permits for the destination country or export licenses for materials leaving the U.S.
	Obtain and carry documentation that accurately identifies the material to be transported and ensures it is allowable for self-transport or hand carry via ground or air. The documentation must also outline that the packaging and labelling meets regulatory requirements. This documentation must include references to the regulation or regulations that govern the transport of materials via these modes. EH&S can review your hand carry plans and provide this documentation.
	Package and label research materials appropriately per regulations cited in this checklist.

Revision Date: 03/20/2024 Page 34 of 39



Complete?	Task
	Arrange for prior notification of relevant authorities before you self-transport research
	materials. This may include the TSA, CBP, USDA, and others. EH&S can make these notification
	arrangements for you.
	Declare all research materials to CBP authorities. Present all paperwork to justify legitimate
	self-transport of research materials.
	Carry a list of institutional contacts if questions arise during transport. This list should include
	contact information for the PI, EH&S, School or Institute Export Control Administrator, lab
	manager, or other pertinent lab contact.

Revision Date: 03/20/2024 Page 35 of 39



Appendix D – Options for Local Transport of Research Materials

Type of Shipment	Non-Regulated	Non-Regulated Biological on Dry Ice,	Excepted Quantities of Chemical Fixatives
	Materials (May Include	GMMO, Exempt Patient or Animal	or Preservatives (Less Than 30 ml)
	Ice or Ice Packs)	Specimen, and Category B Biological	
		Substances	
Considered DOT-	No.	Yes.	Yes, with less stringent requirements than
Hazmat by ground?			fully regulated hazmat.
Required training	No IATA or DOT	Shipper and transporter must be IATA and	Shipper and transporter must be IATA and
	training required.	DOT trained if a vehicle is used to transport	DOT trained if a vehicle is used to transport
		the material. Training is offered in HTP.	the material. Training is offered in HTP.
Packing and labeling	To and from	Fully DOT compliant packing and labeled	Fully DOT compliant packing and labeled
	information.	required if transported via vehicle.	required if transported via vehicle.

Revision Date: 03/20/2024 Page 36 of 39



Type of Shipment	Non-Regulated Materials (May Include Ice or Ice Packs)	Non-Regulated Biological on Dry Ice, GMMO, Exempt Patient or Animal Specimen, and Category B Biological Substances	Excepted Quantities of Chemical Fixatives or Preservatives (Less Than 30 ml)
HUMS courier service	Yes.	Yes. ¹	Yes. ²
Walking, bicycling, or e- scooting	Yes.	Yes.	Yes.
Personal vehicle	Yes.	Not recommended. ^{1,3}	Not recommended. ³

Revision Date: 03/20/2024 Page 37 of 39

¹ Avoid transporting dry ice packages in a poorly ventilated vehicle due to suffocation hazard.

² Larger quantities of regulated chemicals may be acceptable under the DOT MOT exception. Contact EHS ResearchTransport@harvard.edu.

³ Transporting regulated shipments may null or void your auto insurance in case of an accident.



Type of Shipment	Non-Regulated Materials (May Include Ice or Ice Packs)	Non-Regulated Biological on Dry Ice, GMMO, Exempt Patient or Animal Specimen, and Category B Biological Substances	Excepted Quantities of Chemical Fixatives or Preservatives (Less Than 30 ml)
Taxicab	Yes. ⁴	Yes. ^{1,4}	No.
Medical Courier	Yes. ⁵	Yes. ⁵	No.
Mass transit (that is MBTA trains, busses, or commuter rail)	Yes.	No.	No.

Revision Date: 03/20/2024 Page 38 of 39

⁴ Call ahead to ensure the company will take biomedical packages and dry ice. Metro Cab is a suggested taxi company. Individual drivers have the right to refuse any package. You may be required to ride with your package.

⁵ Examples of couriers are Deliv and Skycom. Your school or department may already have an agreement with a courier service.



Type of Shipment	Non-Regulated Materials (May Include Ice or Ice Packs)	Non-Regulated Biological on Dry Ice, GMMO, Exempt Patient or Animal Specimen, and Category B Biological Substances	Excepted Quantities of Chemical Fixatives or Preservatives (Less Than 30 ml)
Local shuttles, such as MASCO shuttle or Harvard shuttles	Yes.	No.	No.
Car for hire, that is UBER or Lyft	Yes.	No.	No.

If you are unsure about any aspect of shipping biological materials (hazardous or non-hazardous), contact EH&S at EHS_ResearchTransport@harvard.edu.

Revision Date: 03/20/2024 Page 39 of 39