

Chapter 7 – BIOHAZARDOUS MATERIAL TRANSPORTATION AND SHIPPING

Many biological materials are recognized by federal, state, and local governments as hazardous materials and their transportation is subject to regulatory control. Shipments involving dry ice are also subject to regulatory control through EHS Hazardous Materials Services. This chapter describes MU procedures for maintaining compliance with government regulations with biological materials transportation and shipping.

7.1 Biohazardous Materials Transfers Description

Guidance on **transfers ON MU campus** is covered under [Section 7.3](#). Transfers using MU vehicles may also be subject to DOT regulation. EHS recommends that private vehicles not be used for transferring biohazardous materials between buildings.

Guidance on **transfers OFF MU campus** is covered under [Section 7.4](#) and as per MU Business Policy and Procedure Manual Section 7:040. All persons wishing to ship potentially hazardous and/or biohazardous materials off campus are required to contact EHS to determine if the material is subject to DOT hazardous materials shipping regulations. If DOT regulations are found to apply, then EHS will determine proper packaging, marking, and labeling requirements. EHS will also provide the required DOT documentation.

7.2 Biohazardous Material Transportation and Transfer Resources

Controls on biohazardous material transportation are aimed at ensuring public and workers are protected from exposure to any infectious material. Control is maintained through rigorous packaging, appropriate labeling to alert transportation workers, documentation on biohazardous contents, emergency contact information, and worker training in the transportation chain. Regulations include, but are not limited to:

- Public Health Service 42 CFR Part 72: Interstate Transportation of Etiologic Agents
- Department of Transportation 49 CFR Parts 171-178: Hazardous Materials Regulations
- United States Postal Service 39 CFR Part 111: Mailability of Etiologic Agents
- Occupational Safety and Health Administration 29 CFR Part 1910.1030
- International Civil Aviation Organization (ICAO): Technical Instructions on Safe Transport by Air
- International Air Transport Association (IATA): Dangerous Goods Regulations.

Requirements on the transfer of biohazardous materials are aimed at ensuring the change of possession is within the best interest of the public and nation. Controls require documentation on personnel, facilities, and justification of need for the transfer process with approval by the federal authority. Regulations include, but are not limited to:

- Public Health Service 42 CFR Part 71.54: Foreign Quarantine, Etiologic Agents, Hosts and Vectors
- USDA & APHIS 9 CFR Parts 92, 94, 95, 96, 122 & 130: Import or Domestic Transfer of Etiologic Agents
- Federal Plant Pest Regulation 7 CFR Part 330: Importation of Plant Pests
- Center of Disease Control 42 CFR Part 72.6: Transfer of Select Agents of Human Disease
- Department of Commerce 15 CFR Part 730 – 799: Export of Etiologic Agents

7.3 Transportation of Biohazardous Materials on MU Campus

Before you pack biohazardous materials to transfer from your laboratory to another laboratory within your building or another building on the MU campus you must consider the following items:

7.3.1 Transfer of RG1 Agents on MU Campus

If you will transport biological materials that are considered RG1 ([Section 4.2.9](#)) (agents that pose no potential hazard to humans, animals, plants, or the environment) and the material has not been genetically modified, you may transport the material without restrictions either on foot or by car on the MU campus.

NOTE: If dry ice or other hazardous material (i.e., liquid nitrogen) is required for transport by motorized vehicle then contact EHS Hazardous Materials Services for regulatory control guidance.

7.3.2 Transfer of Risk Group 2 or 3 Agents and/or Genetically Modified Material on MU Campus

If you are transporting material that is Risk Group 2 or above (with the potential to cause harm to human, animals, plants or the environment) or if the materials has been modified using recombinant techniques you must:

First, assure the PI and laboratory may safely receive and work with the material. You may do this by contacting the PI and requesting their IBC approval letter or by contacting the MU Biosafety Office at 882-7018 to ask a Biosafety staff member about the transfer.

Second, Prepare for transport (hand-carry) agents between University labs or buildings through public areas. Infectious and/or genetically modified materials must be transported or moved between laboratories in way as to prevent spills and accidental exposure or release including the Packaging Checklist – [Appendix K](#) and the guidance below:

Checklist

- Place material in a primary (specimen) container that is leak-proof and secured with a tight-fitting cap, parafilm, or lab tape.
- Place absorbent material (diapers, absorbent towels, pads) around the primary containers for transport of liquids.
- Place the primary containers in a secondary transport container that is also sealed and labeled with a biohazard symbol. These materials may be moved on a cart or other device between rooms or buildings.
- Wear PPE that is appropriate for movement through public areas. Place the specimen within a suitable secondary container that can be carried without nitrile gloves. Lab coat should never be worn in public areas.
- If dry ice or other hazardous material (i.e. liquid nitrogen) is required for transport in vehicle then contact EHS Hazardous Materials Services for regulatory control guidance.
- Always use freight or non-public access to buildings as you are making your way from your laboratory to another.
- You must carry a small biohazardous spill kit ([Appendix K](#) for spill kit contents) and some type of communication device (cellular phone) with emergency contact numbers in case of incident.
- A single nitrile gloves or two nitrile gloves should be strongly discouraged during transport of biological material through public hallways, elevators, etc. The material you are transporting should be properly packaged prior to exiting the laboratory so that you are comfortable transporting the material without nitrile gloves. Perception of a lab staff member in a public hallway with lab coat and nitrile gloves gives visitors the impression that you are transporting material that is somehow dangerous.

For any additional hazardous materials, check with the Hazardous Materials office on regulations.

7.4 Transportation of Materials Off MU Campus

The University of Missouri-Columbia Biosafety Staff have developed a *Biological Materials Shipping and Transportation Policy (information below)* to provide information regarding the process of shipping Department of Transportation (DOT)/International Air Transport Association (IATA) Class 6.2 infectious materials, diagnostic samples, human blood and/or tissues, and genetically modified organisms from the University of Missouri campus. The University of Missouri is responsible for compliant packaging for all potentially infectious materials or genetically modified organism transported on public roadways and airways. Contact the EHS Biosafety Professional (882-7018) if you wish to transfer biohazardous materials to another facility off the MU Columbia campus.

7.4.1 Overview of Biological Shipping

When biological materials are transported, the U.S. Department of Transportation (DOT) Hazardous Materials Regulations may apply and are extremely complex in nature. Laboratory employees must properly package, transport, and handle any biohazardous substances which are used in their research. Labeling using the universal biohazard symbol is also required for any infectious biological materials to prevent accidental exposure to unsuspecting employees who may be exposed to the biological material (e.g., other laboratory staff, Shipping and Receiving employees).

There are nine DOT classes of dangerous goods:

- Class 1: Explosives.
- Class 2: Compressed gasses (flammable, non-flammable, toxic).
- Class 3: Flammable liquids.
- Class 4: Flammable solids.
- Class 5: Oxidizers and organic peroxides.
- **Class 6: Poisons and toxins (Division 6.1), and infectious materials (Division 6.2)**
- Class 7: Radioactive Materials (RAM)
- Class 8: Corrosives
- **Class 9: Miscellaneous (includes dry ice and genetically modified organisms).**

This document only addresses shipping requirements for packages containing infectious materials (Class 6.2), biological products, genetically modified organisms (Class 9), and dry ice (Class 9). For assistance on shipments involving other types of dangerous goods, contact Environmental Health and Safety (EH&S) at 882-7018 or at biosafety@missouri.edu. General definitions of infectious substances, biological products, genetically modified organisms, and dry ice are provided in this policy.

7.4.2 Biological Shipping Regulations

The following is a summary of the regulatory authorities that control and provide guidelines for the transport of biological materials, infectious agents, and recombinant or synthetic nucleic acid molecules in the United States.

Packaging, shipment, and transportation requirements for biological materials are addressed in the following regulations, rules, and guidelines:

- International Civil Aviation Organization (ICAO) is the United Nations (UN) body that regulates all international civil aviation involving UN member states. ICAO promulgates the Technical Instructions for the Safe Transport of Dangerous Goods by Air. The Technical Instructions include requirements applicable to the shipping of dangerous goods by air.
- The International Air Transport Association (IATA) is a trade association of the world's major airlines that publishes the Dangerous Goods Regulations (DGR), which comply with the ICAO Technical Instructions. The annually updated DGR provides practical assistance to shippers involved in all aspects of dangerous goods transport by air.
- The United States Department of Transportation (DOT) has incorporated the DGR regulations into the Code of Federal Regulations (CFR) Title 49 Sections 171-180.
- The Federal Aviation Administration (FAA) is the regulatory body within DOT which enforces CFR 49. The FAA investigates incidents regarding potential violations of CFR 49 and may levy substantial fines to individuals and/or institutions failing to comply with requirements. U.S. Public Health Service 42 CFR Part 72.
- Centers for Disease Control and Prevention (CDC) NIH Guidelines *on Biosafety in Microbiological and Biomedical Laboratories* (BMBL 5th edition). This document describes standard and special microbiological practices, safety equipment, and facilities for Biosafety Levels (BSL) 1-4 containment required for working with biohazardous materials. **Note:** Risk Group (RG) 4 agents will not be handled at TRSI.
- National Institutes of Health (NIH): [Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#). This NIH document addresses the safe conduct of research involving handling of recombinant or synthetic nucleic acid molecules and organisms containing them. Florida has established an Institutional Biosafety Committee (IBC) with authority to evaluate and approve or deny proposed recombinant or synthetic nucleic acid molecule research using the mandatory *NIH Guidelines* as minimum standard.
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188; June 12, 2002 regulates possession, use and transfer of Select Agents and Toxins under the jurisdiction of the U.S. Department of Health & Human Services (HHS) 42 CFR part 73) and by the U.S. Department of Agriculture (USDA) (9 CFR part 121 and 7 CFR part 331).
- U.S. Postal Service 39 CFR Part 111.
- U.S. Department of Labor, OSHA CFR 1910.1030 Occupational Safety and Health Administration: [Bloodborne Pathogens Standard](#) (BBP) address the occupational health risk caused by exposure to human blood and Other Potentially Infectious Materials (OPIM). The BBP includes engineering and work-practice controls, personal protective equipment (PPE), training, vaccination, and medical follow-up of exposure incidents.

Penalties

- Individual civil penalty of not less than \$250 or more than \$25,000 per violation.
- Willful violations may result in fines up to \$250,000 and/or up to 5 years in prison.
- Business entities or institutions may be fined up to \$500,000 per violation.

Inspections

- Regulatory agencies such as the Missouri Department of Transportation (MODOT), FAA, IATA, have the right to inspect the facilities at the University of Missouri.
- EH&S will serve as the primary point of contact for all shipping related regulatory agencies.

7.4.3 Laboratory Shipper

The Laboratory Shipper is the individual responsible for packaging the biological material(s) for shipment. The Laboratory Shipper employees can be from any of the following University of Missouri:

- University of Missouri Research Laboratory Employees and Students
- Office of Animal Resources (OAR)
- Environmental Health and Safety (EH&S)

The Laboratory Shipper will ensure the proper packaging for the biological materials to be shipped. In general, an infectious substance is any material known to contain or can reasonably be expected to contain pathogens (e.g., bacteria, viruses, prions, parasites, fungi, etc). DOT Hazardous Material Regulations (HMR) found in 49 CFR Parts 171-180 define infectious substances as: Infectious substances known or are reasonably expected to contain pathogens.

Laboratory Shippers receive DOT/IATA Shipping Training on proper shipping methods during the 1 hour Biological Materials Shipping Training. Information on training is located at the EHS website at ehs.missouri.edu.

To determine which packaging standard to use, contact EHS and/or FedEx or to make the appropriate hazard class determination:

- Class 6.2 Infectious Substance, Category A
 - Specimens transported in a form capable of causing permanent disability, life threatening condition or fatal disease to humans or animals. (For a complete list, refer to IATA Dangerous Goods Regulations, 51st Edition, 2010).
- Class 6.2 Infectious Substance, Category B
 - Infectious Substance which does not meet the criteria for inclusion in Category A
- Patient Specimens: means human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimens include excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g. transwabs, culture media, and blood culture bottles). **NOTE:** Cultures are not included in this definition, only inoculated media.
- Biological Products (FDA regulated finished unfinished products, e.g., vaccines)
- Genetically modified microorganisms and organisms
- Infected animals

The Laboratory Shipper will ensure the following the proper packaging for the biological materials to be shipped for the following types of unregulated packages for assurance:

- Substances which do not contain infectious substances or unlikely to cause disease
- Substances containing non-pathogenic microorganisms
- Substances in which pathogens have been neutralized or inactivated and no longer pose a health risk
- Environmental samples (e.g. food, water) which do not pose a significant risk of infection
- Dried blood spots (fecal occult blood)
- Blood products to be used for transfusion or tissues and organs for transplantation

7.4.4 Biosafety Office Shipping Responsibilities

The Biosafety Office is responsible for:

- Overseeing and approving the packaging of biological and infectious substances from the University of Missouri campus
- Advising laboratory staff on the proper shipping and packaging for biological substances off-site
- Serving as a back-up emergency contact for off-site shipments 24/7
- Reviewing and updating this policy as needed
- Providing training to laboratory shippers on biological materials
- Serving as the primary 24/365 Security contact for the University
- Primary contact for any regulatory inspections in the biological shipping processes
- Copies and record-keeping for Category A declarations and maintains copies for FAA/DOT Inspections

7.4.5 Shipper and Receiver Responsibilities

Staff shipping or receiving are responsible for:

- Shipping biological and infectious materials off the University of Missouri campus;
- Maintaining current 49 CFR IATA/DOT Training completed every 2 years;
- Reviewing and updating this policy as needed; and
- Providing support for regulatory inspections.

Shipping and Receiving personnel who ship infectious substances including patient (clinical) specimens, human-derived research materials, infectious microorganisms, certain genetically-modified organisms, etc. must complete a training program prior to shipping Infectious or biological substances. Personnel will be trained every two years on IATA/DOT Shipping Infectious Substances.

7.4.5.1 Shipping by Ground and Air

Transporting Infectious Substances by Ground

When these materials are transported, Department of Transportation (DOT) Hazardous Materials Regulations may apply and are extremely complex in nature. Laboratory personnel must properly package, transport, and handle any Infectious substances which are used in their research. Labeling using the universal biohazard symbol is also required for any infectious biological materials in order to prevent accidental exposure to unsuspecting personnel who may be exposed to the biological material (e.g., couriers, administrative staff, and janitors).

Packaging Requirements

For specification packaging for HAZMAT or Dangerous Goods (DG), contact Shipping and Receiving to obtain specialty packaging types several days in advance. The following packaging requirements apply to all ground transport of infectious substances prepared for transport:

- **Category A:** must never be transported by ground in a motor vehicle. Materials may only be shipped by air or hand carried from building to building. Contact EH&S before planning to ship any Category A Infectious substance (Class 6.2, UN2814 affecting humans and UN2900 affecting animals).
 - Shipments must be consigned by air with a commercial carrier (e.g., FedEx).
- **Category B:** follow the IATA/DOT requirements for Packaging Instruction, PI 650, Class 6.2, UN3373.

- **Exempt Patient/Animal Specimens¹**: will be triple-packaged (i.e., as in Category B with leak proof primary and secondary containers², absorbent material for liquids, and a rigid outer container). A biohazard symbol must be placed on either the primary or secondary container.
- **Genetically Modified Organisms**: will be triple-packaged (i.e., as in Category B with leak proof primary and secondary containers², absorbent material for liquids, and a rigid outer container). Class 9, UN3245.

Means of Transport

The following are means by which Infectious Substances may be legally transported within and around the University of Missouri campus. The DOT Hazardous Material Regulations (49 CFR Parts 171-180) regulates the movement of Division 6.2 Infectious Substances and are regulated when carriage is considered to be "in commerce". Note: 6.2 Infectious substances cannot be FedEx ground, only air in accordance with IATA regulations.

Transport by Contracted Carrier

Commercial or private carriers (i.e., commercial transport companies) are subject to the HMR. These include companies such as FedEx, DHL as well as medical couriers LabCorp, Quest, etc. Transport of infectious substances to **other institutions or entities** such as another university, a waste disposal facility, or a return to the manufacturer will only be done by DOT licensed hazardous materials carriers to another location via a public roadway. When PI's leave an institution, the research gets transferred to the new institution, which then becomes the owner; however, the original institution is legally responsible for the shipment to the new institution. Contact EH&S for consultation.

As of October 1, 2006 the DOT regulations state that Materials of Trade or (MOTS, see 49 CFR §173.6) exceptions only apply to patient specimens or those samples that would be otherwise considered Category B that are contained in a human (patient) or animal sample (no cultures). Therefore personal or dedicated vehicle transport in addition to carrier transport can only use a MOTS, exception for Patient Specimens.

7.4.6 Import, Export Permits and Licenses

International Shipments

Shipping and receiving animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms may require the approval of federal agencies, both domestic and foreign. Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture. An import/export permit may be required when shipping biological materials internationally. Whether you are exporting or importing, every shipment needs an invoice so customs will be able to assess what you are shipping and the value. Contact EHS, as soon as possible, if you plan to ship materials internationally, shipments of biological materials to certain countries require additional approval through the Office of Research.

Importing Research Materials

In addition to the IATA Dangerous Goods Regulations, many import and/or customs regulations may apply to materials your lab is importing. Principal Investigators are required to apply for and maintain valid permits when importing regulated materials. Contact EH&S for assistance in acquiring any necessary permits. It is advised to allow at least 4-6 weeks to obtain either a USDA or CDC permits before making arrangements to receive shipments.

CDC Permit to Import or Transport Agents or Vectors of Human Disease

CDC permits are required when shipping any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids, unfixed tissues), or biological vectors of infectious animals, bats, insects, arthropods and snails. Go to <http://www.cdc.gov/od/eaipp> for information regarding the CDC Etiologic Agent Import Program.

USDA/APHIS Veterinary Permits (16-3, 16-6, 16-7)

USDA/ APHIS permits are required for imports/ exports and inter-state transport of:

- animal or plant pathogens including challenge material from the USDA
- specimens reasonably believed to contain animal or plant pathogens*
- vectors of animal or plant disease*
- potentially hazardous animal or plant products

A USDA/APHIS Permit 16-3 may be needed for the importation of controlled material or for the transport of organisms or vectors or animal products or by-products.

*USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease." http://www.access.gpo.gov/nara/cfr/waisidx_03/9cfrv1_03.html.

An Import/Transport permit:

- must be obtained by the intended receiver of the material before shipment is made
- is good for one year and is amendable/renewable
- application (VS Form 16-3) can be downloaded at: http://www.aphis.usda.gov/import_export/animals/downloads/vs16_3.pdf
- form is for either foreign import or interstate transfer
- requires 6 to 8 weeks for processing

To determine if the material you wish to transport requires a permit, visit the APHIS: National Center for Import and Export (NCIE) Website at http://www.aphis.usda.gov/import_export/index.shtml

NOTE: According to the USDA, "Generally, a USDA veterinary permit (VS-16-6) 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, antisera, bulk shipments of test kit reagents, and microorganisms including bacteria, viruses, protozoa, and fungi. Exceptions to this requirement are human and non-human primate tissues, serum, and blood ."

USDA/APHIS Veterinary Permit (16-6)

A USDA/APHIS Permit 16-6 may be needed for the importation of materials derived from animals or exposed to animal-source materials. APHIS permits are required to import or domestically transfer animal pathogens, a plant pest, plant biological agent, or other material listed below. Note: An import permit may be required for interstate transfer of a USDA regulated materials. Information on USDA/APHIS Guidelines on exempt

materials are provided and may include biological materials such as proteins, enzymes and genetic materials at the following link: http://www.aphis.usda.gov/plant_health/permits/index.shtml.

USDA/APHIS Veterinary Permit (16-7)

A USDA/APHIS Permit 16-7 may be needed for to import cell cultures and their products.

Materials that do not require a USDA Import Permit

SPECIAL NOTE: To facilitate entry at a U.S. port, the exporter usually, but not always, provides a letter containing specific information (see Guidelines 1100-1122 below) about the material. This letter should be included with the shipping documents and be available for review by U.S. port officials at the port of arrival. (This means the document will NOT be placed inside the package--or port officials will not have access to it.).

- [1100](#) Human Pharmaceuticals and Human Vaccines Containing Animal Components
- [1101](#) Human and Non-Human Primate Material (excluding cell cultures)
- [1102](#) Feline and Canine Material
- [1103](#) Live Laboratory Mammals and Their Material (for research purposes)
- [1104](#) Amphibians, Fish, Reptiles, Shellfish and Aquatic Species(includes venom)
- [1105](#) Chemically Synthesized Materials
- [1110](#) Microbial Produced Materials
- [1114](#) Recombinant Microbes and Their Products
- [1116](#) Non-pathogenic Microorganisms
- [1120](#) Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
- [1121](#) Test Kits
- [1122](#) Animal Feeds, Feed Supplements, and Pre-Mixes

FDA Import Permit

Drugs, biologics, cosmetics, medical devices, all food (except most meat and poultry), and electronic products that emit radiation require a permit or registration before importation into the United States. Please see the following link for more information <http://www.fda.gov/ora/import>.

U.S. Fish and Wildlife Permit

A permit may be required for transporting fish, wildlife, endangered species, or materials. http://www.fws.gov/international/DMA_DSA/permits/permits_home.html

Export License

Several Government Agencies restrict the export of certain research materials and technologies, including biological, chemical and military-related research (e.g., those with direct military applications or commercial or "dual use" application that may also have military application) The regulations may require in such circumstances that the University of Missouri apply for a license with the appropriate agency, or find and record an exception to the regulations. Licenses are not easily obtained and require careful preparation and a considerable amount of lead-time. Penalties are severe for non-compliance, including monetary and criminal punishment.

The definition of an "export" is quite broad. In addition to the shipment or transmission of physical items or software either out of the United States or to a foreign national within the United States, a "deemed export" is

considered to be the verbal, written, electronic, and/or visual disclosures of controlled scientific and/or technical information related to export controlled items to foreign nationals in the United States.

An Export License may be required from the Commerce Department's Bureau of Industry and Security (BIS) under the Export Administration Regulations (EAR), the State Department's Directorate of Defense Trade Controls (DDTC) under the International Traffic in Arms Regulations (ITAR), or the Treasury Department's Office of Foreign Assets Control (OFAC) Regulations.

Export of Biological Materials

When exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents, an Export License may be required. Contact EH&S at biosafety@missouri.edu. If you are planning on exporting infectious substances (Category A or B only) a license(s) may be required if:

- Item on the EAR Commerce Control List (CCL), or technology concerning a listed item, is to be exported
- Information or equipment is subject to EAR and:
 - Destination is a country with restricted entities on the EAR Entity List
 - End user is on the Denied Persons or Specially Designated Nationals Lists
 - Destination is an OFAC-embargoed country
 - Destination is another U.S.-embargoed country
 - Export will support a nuclear, missile, chemical or biological weapons program

Here is a link to the Excluded Parties List System: <https://www.epls.gov>. This is not an all-inclusive list, but is a starting resource. Any questions or concerns regarding export exclusions, contact the MU Office of Research Compliance at (573) 882-9500.

Exemptions for Technology

Most research results at the University of Missouri are exempt from control under the EAR and ITAR under one of three key exemptions:

1. Involves "fundamental research" (so long as there are no restrictions on publication of the research or other restrictions on the dissemination of the information);
2. Involves information that is "publicly available" (EAR) or that is in the "public domain" (ITAR); or
3. Involves "educational information" (i.e., information released by instruction in catalog courses and associated teaching laboratories at academic institutions in the United States, other than for certain encrypted software).

However, these exemptions are unavailable for international physical shipments. If the Laboratory Shipper are shipping or exporting equipment, infectious substances, clinical specimens, or other hazardous materials, EHS can provide guidance and assistance concerning the permitting, licensing, packaging and shipping of these materials. Researchers must be cognizant of relevant import, export, or other transfer requirements (e.g., requirements under an MTA) that involve their research materials.

For more information BEFORE you transport or ship research materials contact the University of Missouri Biosafety staff at biosafety@missouri.edu or call 882-7018.

7.4.7 Material Transfer Agreements

A Material Transfer Agreement (MTA) is required when transferring or receiving biological materials, such as reagents, cell lines, plasmids, and vectors, from outside MU. The agreement defines the rights of the provider and the recipient with respect to the materials and any derivatives.

The MU Office of Technology Management and Industry Relations (OTMIR) is responsible for the negotiation and completion of these documents. Only authorized university administrators can execute these agreements. Principals Investigators may submit an [MTA Request Form](#), contact the OTMIR directly at 882-5016, or by email at tmir@missouri.edu.

7.4.8 CDC/USDA Select Agent Requirements

The CDC and USDA regulate the possession, use, and transfer of Select Agents and Toxins (SA) that have the potential to pose a severe threat to public health and safety of American agriculture. The CDC and USDA Select Agent Program oversee these activities and register all laboratories and other entities in the U.S. that possess, use, or transfer a Select Agent or Toxin. The U.S. Departments of Health and Human Services (HHS) and USDA published detailed rules for the possession, use, and transfer of SAs (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) in the Federal Register on March 18, 2005. The most current list can be found at www.cdc.gov. The University of Missouri will not possess, use, or transfer Select Agents, unless the Select Agents or Toxins are registered (See the University of Missouri Select Agent Biosafety Plan).

The transfer or shipment of Select Agents and Toxins is also regulated by the CDC and the USDA. Importation requires either a CDC/PHS Import Permit or an APHIS VS Permit, depending on the agent. Agents are categorized as either a CDC, USDA, or overlap (both agencies) agent and each agency's rules apply. Intrastate transfer (e.g., Florida to any other state) requires a VA Permit for all USDA/APHIS regulated agents. A list of the current Select Agents and their respective agency can be found at <http://www.selectagents.gov>.