

Shipping and Receiving Biological Materials: A Guide for Vanderbilt Researchers

Every day, many different types of biological materials are sent from and received at Vanderbilt University. This guide was prepared to provide guidance to research labs on:

- 1. best practices when receiving biological materials,
- 2. processes for shipping biological materials from campus (and requesting assistance for shipping), and
- 3. permits required by state, federal, or international authorities for the transportation of biological materials.

If you have questions about any of these topics, please contact <u>VUBiosafety@vanderbilt.edu</u> for assistance prior to initiating shipment or receipt of biological materials!

NOTE: Some materials may be subject to export controls and/or material transfer agreements (MTAs). Seek additional guidance from <u>Vanderbilt Export Compliance</u> and <u>Center for Technology Transfer and Commercialization</u>.

Safely Receiving Biological Materials in the Lab

When receiving biological materials to your lab, there are many things to consider to safely obtain, open, and secure your new materials.

- 1. Reach out to VU Biosafety if these materials are not previously captured on your lab's biomaterials registration. Engaging with the Biosafety Team before receiving new materials will allow time for amendment of your registration and approval by the IBC of these new materials/activities, providing for fewer delays in the initiation of work once the materials arrive on campus. Remember: Materials and samples originating from a BSL-3 or select agent lab must be registered with and approved by the IBC prior to receipt to ensure that biocontainment requirements have been met.
- 2. Whenever possible, have biological materials shipped directly to your laboratory space. This practice decreases the risk of biological materials being present in administrative areas that are not equipped to manage a leaking package.
- 3. If materials are coming from outside the United States, permits may be required for their transport. The CDC and USDA regulate and permit the import of agents deemed to have a possible impact on human, animal, and/or plant health. See the <u>permitting section</u> of this guide for more information.
- 4. If feasible, open packages containing biological materials inside a biosafety cabinet. Packages and their contents can easily be damaged during transport. Opening a package within a biosafety cabinet provides containment if the primary or secondary transport containers were compromised.
- 5. Secure all biological materials from the general public. Any risk group 2 (RG2) or higher materials must be secured in a unit that is not accessible to others outside the approved research group. At a minimum, the unit must be labeled with the biohazard symbol and locked if in a publicly accessible area.



Import Permit Program

How to Ship Biological Materials - How to Request Shipping Assistance

What types of materials are regulated for shipment?

Many biological materials are classified as Hazardous Materials or Dangerous Goods and are regulated by the US Department of Transportation (DOT).

Regulated materials include:

- agents infectious to humans or animals,
- human or animal clinical specimens,
- human cells (including immortalized cell lines),
- · genetically modified organisms (GMOs), and
- acutely hazardous biological toxins.

Note: Nucleic acids (DNA or RNA) and purified proteins are not considered dangerous goods and subject to these regulations.

Additionally, non-viable / inactivated samples are not regulated as "live" samples.

To ship any of these regulated materials above by air, the shipper must be currently trained and certified in accordance with DOT requirements for shipping these materials. Because most labs ship regulated biomaterials infrequently, it is not beneficial for lab members to get trained and certified for shipping such materials. Instead, research teams can request assistance from the VU Biosafety team to prepare shipments.

What if you are shipping non-hazardous unregulated materials on dry ice?

Dry ice is regulated as a Dangerous Good when shipped by air. If you are shipping unregulated materials on dry ice, you must:

- 1. Be currently trained and certified for shipping on dry ice. Complete the Dry Ice Shipping Training in Oracle Learn to receive a certificate from VU Biosafety and meet this requirement. (Note: This training is only valid for two years from your completion date.), and
- 2. Use the triple pack system for packaging your non-hazardous unregulated shipments. (More information on this packing configuration can be found in Attachment 1 of this guidance document.)

What is the process for scheduling assistance from VU Biosafety for regulated shipments?

Two weeks prior to shipment, contact VU Biosafety with the following information:

- 1. what biological materials will be shipped,
- 2. the quantity and configuration of materials (e.g., identify the primary container and the number of samples).
- 3. the destination location, and
- 4. the timeline for shipment.

A member of the Biosafety Team will respond with any follow-up questions and to schedule an appointment to package and ship your materials.

NOTE: Ensure that someone will be available to receive the package at its destination on the proposed arrival dates.

What packaging is suitable for shipments of biological materials?

If your lab is providing the packaging, both a styrofoam container (i.e., insert) and outer cardboard shell must be used and the styrofoam must fit snugly inside the cardboard box. VU Biosafety can provide 95 kPa-rated pouches for secondary containment of your samples.

Are there any differences if shipping internationally?

Generally, genetically modified organisms (GMOs) are not regulated for domestic transport within the United States. If your materials are being sent internationally, dangerous goods regulations may apply.

NOTE: Any modified organism (including bacteria), cells from modified organisms (e.g., transgenic research animals), and cells from any species used in tissue culture that have been modified are all similarly controlled under these regulations.

Where can packages be placed for pickup?

Ideally, you will schedule a pickup with your courier of choice from your lab. If this is not possible, the Biosafety Team will work with you to identify an alternative pickup location. If neither of these options are feasible you may be able to take the package to a courier storefront for drop-off.

NOTE: Most couriers do not allow for the drop-off of any dangerous goods (including dry ice) at all stores. For example, FedEx drop-offs of dangerous goods are only accepted at FedEx Ship Centers (not FedEx Office stores).

Any other questions?

Contact <u>VUBiosafety@vanderbilt.edu</u> with any other questions pertaining to the shipment of biological materials.

Shipping/Receiving Biological Materials: Import and Export Permits

The transport, import, and export of many biological materials may be subject to various state, federal, and international regulations. These regulations may depend on the nature of the materials, the origin and destination of the shipment, and the intended use(s) of the materials. This document provides information regarding common agencies and permitting requirements that may apply to various biological materials used in research at Vanderbilt.

Biomaterials subject to these regulations and permits are typically materials, agents, and specimens that:

- 1. can impact human, animal, or plant health,
- 2. may lead to disruptions in the food, animal, or crop supply, and/or
- 3. may cause widespread disease.

Permits for these types of materials typically come with specific requirements pertaining to specific biosafety/biocontainment practices, inactivation or destruction following work with the materials, restrictions on transfer and transport of the materials to other PIs or locations, and on-site laboratory inspections.

If you are planning to obtain materials subject to permits or have questions regarding the applicability of specific permits and regulations to your research, contact VUBiosafety@vanderbilt.edu for assistance. The Biosafety team can assist you in completing your application and with preparing for regulatory inspections.

The table on the following page outlines agencies that may require you to apply for a permit before receiving or transporting biological materials. (Click on each agency for more information.) The permit process involves completion of an application including information detailing the safe and secure handling of the materials and may include an inspection of your laboratory facilities. Materials shipped without the proper permit may be held up in transit.

Biomaterials Permits Table

Agency	Types of materials regulated	Examples
CDC IPP ¹ USDA APHIS* VS ²	 Agents infectious to humans Vectors of human disease Materials expected to contain infectious agents Animals and animal products Animal source materials Agricultural pathogens 	 Rabies virus, Acinetobacter baumannii Bats, non-human primates Bacteria- or virus-infected cells Live animals, embryos, gametes Animal tissues, cell lines from livestock or poultry Microbes infectious to animals
USDA APHIS PPQ ³ USDA APHIS BRS ⁴	 Plant pests Plant pathogens Certain plants and plant products Organisms developed using 	 Mites and insects Microbes infectious to plants Noxious weeds and parasitic plants Soil, seeds, fruit, vegetables Genetically engineered plants
OUTFOR	genetic engineering, including gene drive-modified organisms	Gene drive-modified insects Genetically modified microbes infectious to plants
CITES ⁵	Wild plants and animals, especially endangered species	 Live or dead endangered species Endangered animal products (e.g., ivory)
<u>USFWS</u> ⁶	Wildlife, wildlife products, and plantsInvasive species	Species/products governed by CITESMigratory birdsInjurious wildlife
TWRA ⁷	 Terrestrial and aquatic animals in Tennessee Research in Wildlife Management Areas (WMA) 	 Animals collected or tagged on public or private land in Tennessee Field research on state land

¹Centers for Disease Control and Prevention Import Permit Program; *United States Department of Agriculture Animal and Plant Health Inspection Service; ²USDA APHIS Veterinary Services Division; ³USDA APHIS Plant Protection and Quarantine Division; ⁴USDA APHIS Biotechnology Regulatory Services Division; ⁵Convention on International Trade in Endangered Species of Wild Fauna and Flora; ⁶United States Fish and Wildlife Service; ⁷Tennessee Wildlife Resources Agency

Attachment 1

PACKAGING BIOLOGIAL MATERIALS <u>NOT</u> CLASSIFIED AS HAZARDOUS MATERIALS OR DANGEROUS GOODS* FOR SHIPMENT BY AIR

Using the "Triple-Package System"

*This guide reflects the minimum standard to be used for packaging materials <u>that are not</u> regulated as: "exempt human specimens", "exempt animal specimens", "Biological substances, Category B", "Infectious substance, affecting humans", "Infectious substance, affecting animals", or "Genetically modified microorganisms". Additional packaging requirements (including personnel training) apply to these regulated categories.

Examples of biological materials that are not regulated as any of the above include: microbiological agents that are not infectious to humans or animals, mammalian cells <u>other than</u> human or non-human primate origin, biologically inactivated tissues and body fluids, and purified proteins.

Whether biological materials are regulated for shipment or not, it is prudent for you to package these materials in a manner that will assure they arrive at their destination undamaged and without any potential for environmental release. This can be accomplished by using a triple-package system. The components of this system are outlined below:

- 1. Primary Container: This container is your "sample" container. It should be designed for leak-proof or sift-proof containment of the material within. Do not use "makeshift" containers such as food containers, disposable gloves or syringes. When shipping liquids, a secondary seal of the lid is advised (i.e., parafilm). If shipping several primary containers, a means of cushioning or separation (i.e., bubble wrap, etc.) should be used to reduce the possibility of the containers damaging each other. Assure that liquids are oriented in an upright position to further minimize the potential for leakage.
- 2. **Secondary Container:** Your primary container(s) will be placed inside this container. The purpose of this container is to capture any leakage from the primary containers. Therefore, this container should be properly sealed for transport. Additionally, adequate absorbent materials should be placed inside this container to absorb any leaking of liquids from primary containers.
- 3. Outer Package: The purpose of this package is to provide protection against physical damage to the inner contents that may occur during the transport process. Mailing envelopes, styrofoam boxes, and lightweight cardboard containers are not likely to withstand the mechanical hazards of manual handling and package processing equipment. Therefore, it is strongly advised that the outer package be a sturdy fiberboard box. Cushioning or spacer material (such as bubble wrap) should be placed in the box to fill up the remaining space and keep the contents from shifting in the box. A list of contents between the secondary container and the outer packaging is also advised. Orientation arrows should also be placed on the outer package if it contains liquids.

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Note about the outside of your package: Biological materials that are not regulated should not have any marking on the outer package that could be confused for a biohazard indicator. Don't put descriptive content terms or biohazard symbols on the box. Such terms may result in your materials being returned or trigger unnecessary investigative actions by couriers.

<u>Got Dry Ice or flammable solvents?</u> These are sometimes found in bio-related shipments, and these materials ARE regulated for air shipment. If you ship non-regulated materials on Dry Ice, you must be currently trained for Dry Ice shipping. This training is available and self-assignable through Oracle Learn. If shipping in solvents, contact <u>VU Biosafety</u> for assistance.

Shipping abroad? Consult with your recipient regarding specific restrictions or permits that may apply. These may vary by state or country.