

<b>Institutional Handbook of Operating Procedures</b> <b>Policy 02.10.01</b>	
Section: General Administration	Responsible Vice President: VP Business Operations and Facilities
Subject: Health and Safety	Responsible Entity: Environmental Health and Safety

**I. Title**

*Shipping and Receiving Policies: Research Materials and Clinical Samples*

**II. Policy**

UTMB is committed to supporting national and international efforts that encourage the sharing and dissemination of important research resources. UTMB is also cognizant of local, state, federal and international shipping regulations that may apply to certain outgoing and incoming shipments. Environmental Health and Safety (EHS) is responsible for the oversight of all shipments of certain research materials and clinical samples leaving UTMB campuses. EHS will work with UTMB employees to ensure that all outgoing shipments are correctly classified, packaged, labeled, and contains the appropriate documentation as required by the applicable agencies. In addition, EHS is responsible for the oversight of all shipments of certain incoming research materials and clinical samples.

Shipping and Receiving Materials/Samples that are subject to this policy include:

- Biological materials- includes but is not limited to infectious agents, proteins, nucleic material, recombinant biological material, tissues, body fluids of human or animal origin, and antigens/antibodies.
- Radioactive materials.
- Chemicals.
- Clinical research samples.

**III. Definitions**

**Research materials (RM):** materials (biological, chemical, radioactive, research pharmaceuticals) that are used in basic research activities.

**Clinical samples (CS):** samples collected from humans for diagnosis or confirmation that are sent for further analysis.

**Animal clinical samples (ACS):** samples collected from animals for diagnosis or confirmation that are sent for further analysis.

**Clinical research samples (CRS):** research samples that are generated during a human clinical trial that are sent for further analysis.

**UTMB shipper:** any UTMB employee who has completed the required shipping training approved by EHS to ship hazardous material as defined by the IATA/DOT regulations.

**EHS shipper:** EHS employee who is authorized to ship hazardous material as defined by the IATA/DOT regulations.

**Requestor:** UTMB employee who wishes to send or receive RM, CS, ACS, and CRS.

**IV. Shipping - Outgoing****A. International Shipping (shipping to non-U.S. destinations): Research Materials, Clinical Samples, Animal Clinical Samples and Clinical Research Samples**

1. Requestors, who wish to ship RM, CS, ACS, and CRS, to a foreign destination should first contact UTMB's Office of Technology Transfer (OTT) to determine if (i) a Material Transfer Agreement is needed between UTMB and the receiving entity and (ii) an U.S. export control license is required prior to shipment. (See UTMB Policy 6.0.4: Export Control Compliance for more information on the export control procedures).
2. The Requestor must submit the request for shipping to EHS, along with all necessary documentation, such as MTA, U.S. export control license, foreign recipient's import permit if needed.
3. An EHS Shipper will contact the Requestor to schedule the shipment.

**B. Domestic Shipping (shipping within the U.S.): Research Materials, Clinical Samples, Animal Clinical Samples and Clinical Research Samples**

- All CS, CRS must be shipped by an UTMB Shipper or EHS Shipper.
- Radioactive RM, CS, ACS, and CRS must be shipped and documented by EHS Shipper or UTMB Shipper in Nuclear Medicine.
- Determination as to whether RM, CS, ACS and CRS stored in chemicals is considered a hazardous materials shipment subject to regulation must be performed by an EHS Shipper or a UTMB Shipper. Shipments determined to be subject to regulation must be shipped by an EHS Shipper or UTMB Shipper in accordance with DOT requirements.
- IATA Exempt human/animal specimens, Cat B and Cat A samples must be shipped by an UTMB Shipper or EHS Shipper.
- UTMB Shippers and Requestors must notify the Galveston County Health Department per the Texas Health & Safety Code § 81.089, of ALL sample shipments containing infectious material prior to leaving the state of Texas.
- Federally regulated select agents and toxins material shipment must be coordinated through EHS prior to shipment.

**V. Receiving-Incoming****A. General requirements for receiving Research Materials**

- All RM containing federally regulated select agents and toxins must be coordinated by the Requestor with EHS prior to arrival on UTMB campus.
- All shipments of RM containing radioactive material must be coordinated by the Requestor with EHS prior to arrival on UTMB campus. All research radioactive material shipments must be approved by and delivered to the EHS Radiation Safety Office.
- The Requestor must notify EHS of shipments containing risk group 3 and 4 agents prior to its arrival on UTMB campus.
- UTMB Shippers/Requestor must notify the Galveston County Health Department of ALL sample shipments containing infectious material prior to their arrival on campus.

**VI. Overview of Responsibilities:**

The Requestor is responsible for:

- Ensuring that the samples shipped are properly labeled and prepared for transportation.
- Obtaining and maintaining Domestic/Imports permits.
- Ensuring that OTT was contacted for all international shipments
- Notifying the Galveston County Health Department of ALL sample shipments containing infectious material prior to them leaving or arriving on campus.

UTMB shipper is responsible for:

- Ensuring that their required training is current and appropriate for the material to be shipped. Note: all training courses must be approved by EHS.
- Ensuring that all shipping documents are correctly completed.
- Ensuring that the samples are packaged according to regulations.
- Notifying the Galveston County Health Department of ALL sample shipments containing infectious material prior to their departure from campus.
- Maintaining all shipping documents per the appropriate retention period, including related permits.

EHS shipper is responsible for:

- Ensuring that their required training is current and appropriate for the material to be shipped.
- Ensuring that all shipping documents and related shipping forms are completed.
- Ensuring that the samples are packaged according to regulations.
- Notifying the Galveston County Health Department of ALL sample shipments containing infectious material prior to their departure from campus.
- Ensuring that (1) all international shipping documents and records, including but not limited to Automated Export Shipping (AES) forms, waybills, invoices, permits are completed, and (2) all samples or materials are packaged and maintained in accordance with the applicable policies and regulations.
- Maintaining all shipping documents per the appropriate retention period, including related permits and license.

EHS is responsible for:

- For oversight of training for shipping of RM, CS, ACS, and CRS material.
- Providing DOT/IATA Shipping Training Courses or approving recommendations for third-party shipping training that can meet DOT/IATA shipping.

## **VII. Enforcement and Compliance**

Any UTMB faculty member, employee, contractor, or student who fails to comply with this policy is subject to discipline, up to and including termination of employment for employees or suspension or expulsion in the case of students. In the case of a violation of federal or state criminal or civil law, violators may be subject to civil or criminal penalties.

## **VIII. Relevant Federal and State Statutes**

Department of Transportation (DOT), [Code of Federal Regulations 49 CFR 105](#)  
[International Air Trade Association \(IATA\)](#)  
[Department of Commerce \(Export Controls\)](#)  
[CDC Import Permit, Title 42 Part 71 Subpart F](#)  
[USDA Import Permit](#)  
[Federal Select Agent Program, 7 CFR 331, 9 CFR 121, and 42 CFR 73](#)  
[Texas Health & Safety Code §81.089](#)

## **IX. Additional References**

Details regarding UTMB shipping program, shipping requests and its process are available on the [Environmental Health and Safety \(EHS\) website](#).

**X. Dates Approved or Amended**

<i>Originated: 06/13/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>

**XI. Contact Information**

[Environmental Health and Safety](#)  
(409) 772-1781, [ehsshipp@utmb.edu](mailto:ehsshipp@utmb.edu)