

Title: Policy on Shipment or Transport of Items and Goods	Policy Category: Risk Management & Security
Issuing Authority: Enterprise Risk Management	Responsibility: Enterprise Risk Management
	Office for Research & Innovation
Publication Date: 11/20/2025	Next Review Date: 11/20/2028

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Policy Statement/Background:

Stony Brook University recognizes that shipping items and goods is a necessary function. This policy includes specific rules and expectations that a Shipper must follow when shipping items and goods as part of an individual's role and/or responsibilities. Furthermore, this policy exists to help the University meet compliance obligations while mitigating risks.

Scope

This policy applies to all outgoing University shipments, whether domestic or international, and includes all tangible items regardless of originating location and/or where shipped from. Intangible items are not part of this policy.

Transporting items or goods personally ("hand-carrying") involves similar risks for the University as shipping via commercial carriers. A hand-carry is a shipment for the purposes of this policy (unless stated otherwise).

Policy:

All University shipments must comply with all applicable regulations and standards outlined in this policy, as well as any other relevant policies and procedures that may apply. This includes shipments of any Regulated Items regardless of where the shipment originates from, method of payment (e.g. P-Card) and funding source.

All Shippers are expected to utilize University resources in order to comply with this policy and related rules and procedures that govern Regulated Items. Such

resources are detailed below and include, but are not limited to: University websites, staff, training materials, or manuals that pertain to the specific kind of Regulated Item they intend to ship (e.g., the Export Controls Compliance Manual for international shipping, the Environmental Health & Safety (EH&S) website for shipping hazardous materials, etc.). Lastly, the University's Central Services Department offers comprehensive central mail services and can assist with general shipping inquiries.

A. Shipping of Dangerous Goods/Hazardous Materials:

All individuals who package, ship or transport hazardous materials or dangerous goods (HM/DG Shippers) must comply with this policy and all of the rules and regulations of the US Department of Transportation (US DOT), the International Air Transportation Association (IATA), other approved carriers and regulatory agencies. Only properly trained and documented University/Hospital HM/DG Shippers are allowed to ship or transport hazardous materials.

<u>The Shipping of Hazardous Materials (Dangerous Goods) Policy</u> can be found at the <u>EH&S Shipping of Dangerous Goods website</u>. For questions or training, contact the Department of Environmental Health and Safety at 631-632-6410 or <u>ehsafety@stonybrook.edu</u>.

Any University employee who has direct oversight of HM/DG Shippers shall do the following on behalf of their Department:

- 1. Notify the Department of Environmental Health and Safety at 631-632-6410 or ehsafety@stonybrook.edu if contacted by any outside regulatory agency.
- 2. Ensure that all employees who work with hazardous materials obtain and maintain the appropriate level of training for their job responsibilities.
- The Department shipping the dangerous goods will be responsible for any expense incurred in safe and compliant shipping of hazardous materials.
- 4. Designate an individual within the lab/facility to ensure compliance with this policy.
- 5. Ensure that all hazardous materials are identified, classified, packaged, marked, and labeled in accordance with the appropriate shipping regulations prior to offering for transport.
- The Department shipping the dangerous goods will be responsible for paying any associated fines and penalties for any compliance deficiencies.
- 7. Comply with and assist EH&S in implementing this policy.

- 8. Support EH&S and/or regulatory agencies during audits and investigations.
- 9. Assure this policy is being implemented within their area of responsibility.

B. International Shipments/Export Controls

All international shipments of Regulated Items from the University are exports and must therefore be assessed for compliance with any applicable export controls restrictions as per the <u>University Export Controls Policy</u>. In certain cases, international shipments may require a government-issued export license prior to the item being shipped out of the country.

Export licenses are typically only required when there is a national security risk or foreign policy concern related to the shipment. Examples of licensable international shipments/exports include:

- Shipments of items found on the <u>Commerce Control List</u> (e.g., Dual Use items such as semiconductors, lasers, viruses, etc.) or on the <u>United States Munitions List</u> (e.g., military grade equipment such as night vision devices, infrared cameras, etc.).
- Shipments being sent to recipients, inclusive of universities and individuals, who are on a Restricted Parties List.
- Shipments being sent to recipients, primarily commercial entities, who are owned 50% or more, directly or indirectly, by a parent entity on the Entity List, Military End-User List, or Specially Designated Nationals List.
- Shipments to <u>sanctioned countries</u> (Cuba, Iran, North Korea, Ukraine (Crimea, Luhansk, and Donetsk only), Russia, Belarus, Venezuela)
- Shipments being sent for a purpose or end use of concern (e.g., development or production of weapons of mass destruction (WMD), assistance or support to a foreign military, etc.)

Shippers are to review the instructions on this webpage prior to initiating any international shipments. If after review of these instructions it appears an export license may be required, or if such determination cannot be made, Shippers must contact the Office of Research Security (ORS) at ovpr researchsecurity admin@stonybrook.edu before proceeding to ship. Only ORS is authorized to submit export license applications and/or determine if a license exception is available.

C. Material Transfer Considerations

If the material or article that you would like to have shipped meets the definition of a Material or Article Requiring a University-Approved MTA, please reach out to Intellectual Property Partners at sbu_mta@stonybrook.edu to request a Material Transfer Agreement (MTA) or guidance on shipping such materials. For more information regarding MTA requirements, please see:

https://www.stonybrook.edu/commcms/ipp/inventors/Transfer materials/.

D. <u>Controlled Substances</u>

All controlled substances, regardless of schedule, that are designated for disposal must be packaged and shipped to an outside reverse distributor in accordance with the instructions on form 41 (Drug Enforcement Administration), form 2340 (Bureau of Narcotic Enforcement) and form 166 (inventory form). This includes out of date (expired), damaged or otherwise unusable or unwanted controlled substances. If the bottle is empty, it can be thrown away with regular waste. Information about reverse distributors can be found here. Information about the Bureau of Narcotic Enforcement (BNE) forms can be found here. The Drug Enforcement Administration form 41 can be found here.

E. Human Subjects Material

Human samples with or without associated protected health information (PHI) require the Institutional Review Board's (IRB) review and prior written approval of the shipment. Contact the Office of Research Compliance at <a href="https://orc.ncbi.nlm.nih.gov/orc.

Shipping human subject material (including biological samples and specimens) with or without associated PHI also requires adherence to all other subsections of this Policy (e.g., Dangerous Goods, Export Controls, Material Transfer Agreements, etc.).

The University must implement reasonable safeguards to protect PHI during shipping. Reasonable safeguards include: 1) using reputable shipping companies and shipping and handling methods like certified mail that offer tracking and delivery confirmation, require recipient signature and verification of identity; 2) minimizing the risk of PHI exposure by ensuring packages are sealed properly and no PHI is visible from the outside; 3) shipping only minimum necessary PHI; 4) verifying that all PHI being shipped

relates to the correct individual(s) and; 5) that the recipient address has been verified.

If associated PHI is being shipped without the patient's authorization, contact the University Privacy Office at
HIPAA@stonybrookmedicine.edu">https://example.com/html/>
HIPAA@stonybrookmedicine.edu or see SBUH Policy #RC0034.

If it is discovered that any PHI is lost or received by an unintended recipient, the matter must be reported to the University Privacy Office by calling 631-444-5796 or emailing <u>HIPAA@stonybrookmedicine.edu</u>.

F. Shipment of Animals

All inquiries pertaining to importing or exporting of animals for research purposes must be directed to DLAR department via <u>this website</u>. Animals cannot be received, shipped or ordered without the supervision of DLAR department coordination.

G. Retention of Records

Records and documents pertaining to the shipment of Regulated Items shall be maintained by the Shipper in accordance with relevant statute, regulation, or University policy/procedure/practice, including whatever requirements are found in this Policy. Whenever possible, such records and documents shall be saved in a readily-accessible centralized location rather than in individual drives, emails, or folders. Shippers should be mindful of the following:

- Export Control: For international shipments/exports, all documents associated with the shipment must be saved for five years from date of export.
- 2. **Hazardous Materials**: Documentation (manifests) related to shipping of hazardous materials are to be retained for at least 24 months after the date of shipment.
- Material Transfer Agreements (MTAs): Shipments that are maintained by the University's technology transfer office in accordance with the Research Foundation for SUNY's <u>document retention policy</u>. A fully-executed copy of any such MTA is provided to the researchers for their records.

Definitions:

Hazardous Material (HM): Substance or material that pose an unreasonable risk to health, safety, property or the environment when transported in commerce. Also known as materials "Regulated for Transportation." For the purposes of this policy, DG and HM can be used interchangeably.

Material or Article Requiring a University-Approved MTA: This shall include tangible materials that are created or collected at the University and are subject to the <u>SUNY Patents and Inventions policy</u> (outgoing) and/or are subject to an MTA or other agreement when originally received by the University (outgoing/incoming). Illustrative examples of such tangible materials include, but are not limited to, mouse lines, antibodies, cell lines, human materials, prototypes, chemical compounds & materials.

Regulated Item: Any material or article being shipped (or hand-carried) that is legally controlled by a U.S. federal law, regulation, or regulatory standard (e.g., ITAR/EAR, IATA, etc.) and/or requires a University-approved Material Transfer Agreement.

Shipper: Any individual who initiates the shipment (or hand-carry) of a Regulated Item.

Contact:

Additional information about this policy is available here:

Enterprise Risk Management

411 Administration Building Stony Brook, NY 11794 (631) 632-9500 www.stonybrook.edu/risk

Office for Research & Innovation

S5424, Frank Melville Jr. Memorial Library Stony Brook, NY 11794 (631) 632-7932 https://research.stonybrook.edu/offices

Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- Export Control Policy
- EH&S Shipping of Dangerous Goods Website
- SUNY Patents and Inventions Policy 8 CRR-NY 335.28
- <u>Use of Controlled Substances in Research and Instructional Activities</u> Policy
- Stony Brook University: Mail Services Information Website
- NIH Policy on Enhancing Security Measures for Human Biospecimens