

## SOP for Export and Import

NAME	INTERNATIONAL SHIPPING
VERSION	1.0
PREPARED BY	Export Control Office
APPROVED BY	AVP, Research Compliance and Regulatory Affairs
DATE APPROVED	3/21/2023
LAST REVISED	

1.0 *Purpose*: The purpose of this SOP is to outline the procedures that must be followed when shipping items (including commodities, materials, software) outside the United States.

2.0 *Key Operational Units*: Depending on the shipment, there are several units that must review, approve, provide guidance and/or be notified before the shipment is done. They include:

- Export Control Office (ECO).
- The Office of Sponsored Programs (OSP).
- Office of Technology Transfer (OTT).
- Environmental Health and Safety Office (EHSO).

3.0 *Information required for review, approval, and/or guidance*: The following information is necessary for evaluating shipments. Operational units may request additional information as necessary.

- A description of items to be shipped.
- Quantity to be shipped.
- Frequency of shipment
- If the items to be shipped will be used in research, information on research project including:
  - A brief description of research.
  - Location where items will be shipped to and where research will be conducted.
  - Research Sponsor, where applicable.
  - Collaborating institution(s), if applicable.
  - Collaborating investigators
- Whether items will be brought back to the United States and after how long.
- End user, i.e., recipient entity (if different from collaborating institution).
- End use i.e., what the item will be used for.

Requestors may use the International Shipping Form available in REDCap via this link

<https://redcap.emory.edu/surveys/?s=AR389NFWTTWHK3MF>. Form is also available as [PDF here](#).

4.0 *Export License*: Certain shipments require an Export License from the US federal government to be shipped to foreign destinations. Whether a license is required depends on

- what is being shipped,
- the country of destination,
- the ultimate end user,
- and the ultimate end use.

ECO is responsible for evaluating shipments to determine (a) the Export Control Classification Number (ECCN) of the item (b) if an Export License is required and, (c) for applying for the license on behalf of the person or department making the shipment. Please contact the ECO [exportcontrol@emory.edu](mailto:exportcontrol@emory.edu) for assistance in determining if your shipment requires a license. An application for Export License can take anywhere between one to three months before it is granted, so shippers are advised to factor in time delays when planning.

5.0 *Electronic Export Information (EEI) Filing*: ECO assists shippers by filing EEI and/or by providing trade-specific information as may be required by custom brokers. This includes:

- Hand-carried items.
- Items shipped via courier services such as FedEx. Contact ECO to help coordinate with the courier services. ECO will generate an Internal Transaction Number (ITN) which will be necessary to include on the shipping label.
- If a custom broker will file EEI on behalf of the shipper, the shipper must ensure that Emory's Employer Identification number (EIN) is used on the filing.

6.0 *Infectious Agents, Biological Materials and Dry Ice*: All shipments of chemical or biological materials must be reviewed by EHSO. Under U.S. Department of Transportation (DOT) regulations and International Air Transport Association (IATA) regulations, these types of material require special shipping documentation and packaging. Training is required for persons undertaking any of the following:

- Determining the hazard class
- Selecting packaging
- Securing the closure of a package
- Marking and labeling packages
- Preparing and reviewing shipping documentation

7.0 *Export Controlled Biological Agents and Toxins*: Many bacteria, viruses, toxins, and fungi are export controlled and require a license to be transferred outside the U.S. Small quantities or attenuated strains that are otherwise excluded from select agents or toxins by Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA) or Center for Disease Control (CDC) remain controlled under export control regulations. Likewise, genetically modified materials and genetic elements that code for certain gene(s) that are specific to the biological agents or that code for a controlled toxin are regulated, and require license to be exported outside the U.S.

8.0 *Import and Export Permits*: Many biological materials require a researcher to obtain permits from U.S. Centers for Disease Control and Prevention (CDC), and/or U.S. Department of Agriculture (USDA) Animal and Plant Health Inspectorate Services (USDA/APHIS). CDC and/or USDA/APHIS permits prior to shipping these materials.

- The CDC and USDA/APHIS regulates the import and export of biological materials (e.g., infectious materials, plants, agricultural products, animals, animal products, veterinary biologics, genetically engineered organisms, etc.) These programs ensure that the importation/exportation of these agents is monitored and that facilities receiving permits have the appropriate biosafety measures in place to work with the agents.
- Use the CDC "Do I Need An Import Permit?" e-Tool <https://www.cdc.gov/cpr/ipp/etool.htm> to determine if a CDC Import Permit is required for your shipment.

- Use the USDA/APHIS eFile “Guide Me” tool <https://efile.aphis.usda.gov/s/guide-me> to determine if an USDA/APHIS Permit is required for your shipment.
- Additionally, other countries may have import/export requirements that must be met prior to shipments entering or leaving their borders. The collaborating institution/entity must apply for any permits required from their own country and a copy of the permit must accompany the shipment.

9.0 *Material Transfer Agreement (MTA) and other agreements:* an agreement may be required when sending or receiving items as follows:

- For transfer of any research materials that will not be used in/on/with human subjects. contact Office of Technology Transfer (OTT) at [OTT-MTA@emory.edu](mailto:OTT-MTA@emory.edu)
- Transfer of certain equipment without payment and not for use in/on human subjects. Please contact Office of Technology Transfer (OTT) at [OTT-MTA@emory.edu](mailto:OTT-MTA@emory.edu)

10.0 *Shipment of items that are subject to Sponsored Research:* If you are shipping material that is subject to a sponsored research project or a research subcontract, please notify Office of Sponsored Research (OSP) [osp@emory.edu](mailto:osp@emory.edu). For transfer of any drugs, devices, etc. to be used in/on/with human subjects, contact the Office of Sponsored Research (OSP) [osp-contracts@listserv.cc.emory.edu](mailto:osp-contracts@listserv.cc.emory.edu).

#### 11.0 Definitions

*Comprehensively Embargoed Countries:* The Office of Foreign Assets Controls (OFAC), Department of Treasury administers economic and trade sanctions imposed by the U.S. against certain countries and groups of individuals. The sanctions programs vary in scope. Some target specific exports while others are more comprehensive, encompassing broad prohibitions at the country level. Comprehensive sanctions generally prohibit all transactions including imports and exports without government authorization. Countries that are considered comprehensively embargoed currently include Cuba, Iran, North Korea, Syria and Ukraine (Crimea, Donetsk and Luhansk regions). For purposes of this SOP, Emory is also including Russia owing to the evolving sanctions against the country.

*Export License:* A written permission from the federal government authorizing export that is otherwise prohibited under the export regulations.

*Import Permit:* written permission from US regulatory entities (e.g., CDC, USDA/APHIS, CITES, etc.) or the governments of other countries authorizing the import of biological materials to ensure facilities receiving the material have the appropriate biosafety measures in place to work with the agents.

*Export Permit:* written permission from US regulatory entities (e.g., USDA/APHIS, CITES, etc.) authorizing export of biological materials.

*Electronic Export Information:* Information that is required to be filled electronically when the value of the commodity is over \$2,500 or if a validated export license is required to export the commodity. EEI filing is also required for commodities on the commerce control list destined for Russia, China and Venezuela, **irrespective of the dollar value.**