

Ragon Institute of MGH, MIT and Harvard Standard Operating Procedure Transportation and Shipment of Research Samples

I. Purpose

This Standard Operating Procedure (SOP) governs the safe and compliant transport and shipment of all research samples coming in and going out of the Ragon Institute at 400 Technology Square, Cambridge.

II. Scope

This SOP applies to **all** Ragon Institute Colleagues and External Collaborators that transport or ship **any** research samples in and out of the Ragon Institute. It includes walking while carrying samples in the vicinity of the Ragon Institute as well as traditional methods of shipping such as using the Partners Shuttle or a third-party vendor.

III. Responsibilities

A. Shipper (Ragon Institute Colleagues and External Collaborators)

1. Must read and understand this SOP, and abide by all regulatory requirements for the shipment of research samples.
2. Must be IATA/DOT trained every 2 years if shipping Category A or B materials, Exempt Patient Specimens or materials on dry ice.
 - i. Ragon Institute colleagues must maintain a copy and provide their training certificate to the Ragon Institute Biosafety Officer. Training is provided online through the MGH Clinical Research Program and can be found at <http://hub.partners.org/hazmat/>
 - ii. External collaborators must provide their training certificate to their Ragon Institute colleague upon request.

B. Ragon Institute Biosafety Officer

1. Will maintain the file of IATA/DOT training certificates and interface with regulatory agencies as needed.
2. Will coordinate access to IATA/DOT training for those Ragon Institute Colleagues who require training.
3. Will assist with the import/export permit process, and file permit applications on behalf of Ragon Institute principal investigators.
4. Will refer colleagues to the Ragon Institute Regulatory staff for assistance with other internal/external requirements such as but not limited to Institutional Review Board (IRB) and Material Transfer Agreement (MTA) processes.
5. Will provide technical resources on matters related to safety, compliance and training for IATA/DOT requirements.

IV. Definitions

Infectious Substance, Category A: An infectious substance which is transported in a form that when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. For example, cultures of *Mycobacterium tuberculosis* and Human Immunodeficiency Virus.

Biological Substance, Category B: An infectious substance NOT in a form generally capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals. For example, most blood, tissue, and urine samples containing common microorganisms that are considered Diagnostic Specimens are considered Biological Substances, Category B. Blood that is positive for Human Immunodeficiency Virus (HIV) is an example of a Category B material.

Exempt Patient Specimen: Samples not suspected to be infected with a microorganism, such as blood or urine sent for testing to monitor cholesterol or glucose levels.

Research Samples: Biological materials such as but not limited to blood samples, cell lines and microorganisms that may or may not be infectious and may or may not be transported on dry ice.

BWH: Brigham and Women's Hospital.

MGH: Massachusetts General Hospital.

DOT: United States Department of Transportation.

IATA: International Air Transport Association.

Shipper: A trained person who packages research samples for transport out of the Ragon Institute or for transport to the Ragon Institute.

External Collaborators: Anyone who is not a Ragon Institute Colleague and is not physically located at the time of shipment at the 400 Technology Square location.

Ragon Institute Colleagues: Members of the Ragon Institute who are physically located at the 400 Technology Square location or go offsite to obtain research samples that will be transported to the 400 Technology Square location.

Ragon Institute Service Elevator: The elevator designated for freight and construction in the 400 Technology Square building. It is also the largest of the four elevators.

Packing Instruction 620: IATA specifications for packaging an Infectious Substance, Category A.

Packing Instruction 650: IATA specifications for packaging a Biological Substance, Category B.

V. Procedure

A. Transport of Research Samples To The Ragon Institute by External Collaborators

1. Prior to receipt of research samples, the Ragon Institute Colleague will work with the External Collaborator to obtain the following information. The Ragon Institute Colleague will provide the information to the Ragon Institute Biosafety Officer, who can determine if registration is required with the Partners Institutional Biosafety Committee (PIBC) and if import/export permits are required.
 - a) A full description of the research samples. Indicate whether research samples are fixed or unfixed. For microorganisms, include strain information including antibiotic resistance and susceptibility as appropriate.
 - b) If an import/export permit is required, this must be stated and all permits must be received prior to shipping. Please note that the Ragon Institute cannot receive any microorganisms or toxins that are regulated as "Select Agents" by the United States government. The information must also state whether the research materials to be shipped include any of the following:
 - 1) Exempt patient (human or animal) specimen

- 2) Biological substance, category B, UN 3373
 - 3) Infectious substance, category A, UN 2814 or 2900
 - 4) Dry Ice
- c) For Category A and B materials, a copy of the IATA/DOT shipping training certificate for the person who will be shipping the samples to the Ragon Institute. There is no further need to provide a certificate during the period that the certificate is valid. A new certificate will be required when training is renewed and/or if another individual will be packaging and shipping or transporting samples to be delivered to the Ragon Institute. The Ragon Institute Colleague will verify that a valid certificate is on file for each shipper identified on incoming packages.
 - d) Review and approval by the Ragon Institute Biosafety Officer. In some cases this may require additional review and approval from the Partners Institutional Biosafety Committee (PIBC) that oversees work with biohazardous materials at the Ragon Institute. The Ragon Institute cannot guarantee that this approval can be obtained quickly as the PIBC meets monthly. Therefore plan accordingly.
 - e) In some cases regulatory permits will be required for the import/export of the material to be shipped. The External Collaborator is required to obtain any required export permits. The Ragon Institute Colleague is responsible for working with the Ragon Institute Biosafety Officer to obtain any required import permits. The process to obtain import and export permits may require substantial time and thus it is prudent to plan well in advance of any shipment. In addition, the Ragon Institute Colleague is responsible for coordinating with the Ragon Institute Regulatory Staff for all other regulatory requirements such as but not limited to Material Transfer Agreements and Institutional Review Board (IRB) approvals.
2. Once the above have been successfully completed, the Ragon Institute Colleague will notify the External Collaborator that shipment of samples can be scheduled. The Ragon Institute Colleague will notify the Ragon Institute Receptionist that a shipment is expected with the expected date and time of arrival. The External Collaborator must:
 - a) Ensure that the person at their respective institution that classifies, packs and ships the samples has current (within 2 years) IATA/DOT shipping training certification. Review Appendix A (Shipping Classification Guide) and Appendix B (Packaging Material Selection Guide) for further information.
 - b) Agree to abide by all IATA and DOT requirements, and **agree to not use public transportation or personal vehicles (including rideshare services such as but not limited to Uber, Lyft and ZipCar)** for the transport of samples to the Ragon Institute. **Category A materials must be shipped via FedEx, World Courier, or similar carrier to the Ragon Institute.**
 - c) **Confirm that dry ice is placed in a non-airtight container to prevent explosion.**
 - d) Ship or transport samples to the Ragon Institute:
 1. Using FedEx or courier service (e.g. World Courier) for external collaborators not within walking distance to the Ragon or on a Partners shuttle service route. Check with the Ragon Institute Colleague to determine the best date for shipping with consideration to holidays and adverse weather conditions. Shipments must be scheduled to arrive at the Ragon Institute Reception Desk between 8:30am and 5:00pm EST. Couriers often take upwards of 2 hours to complete a delivery so

- plan accordingly. The samples must be delivered to the 1st floor reception desk at the Ragon Institute at 400 Technology Square, and placed in the package tray as directed by the Ragon Institute Receptionist. The Receptionist will contact the Ragon Institute Colleague who will come to the 1st floor to pick up the package and take the samples to the appropriate location using the service elevator.
2. Using the Partners shuttle service with a completed bill of lading (for MGH and BWH affiliated collaborators not within walking distance to the Ragon Institute). The External Collaborator must accompany the shipment on the shuttle at all times. The samples must be packed and transported in accordance with DOT requirements, as they will be in a vehicle on public roadways. The samples must be delivered to the 1st floor reception desk at the Ragon Institute at 400 Technology Square, and placed in the package tray as directed by the Ragon Institute Receptionist. The Receptionist will contact the Ragon Institute Colleague who will come to the 1st floor to meet the External Collaborator and take the samples to the appropriate location using the service elevator.
 3. Using a taxi or courier service if the service provider agrees to transport research samples. Use the informational card (Appendix C) to inform the driver about the materials you are requesting to be transported. The samples must be packed and transported in accordance with DOT requirements, as they will be moved on public roadways. It is strongly suggested that the package be placed in a shopping bag so as not to draw unwanted attention. The samples must be delivered to the 1st floor reception desk at the Ragon Institute at 400 Technology Square, and placed in the package tray as directed by the Ragon Institute Receptionist. The Receptionist will contact the Ragon Institute Colleague who will come to the 1st floor to pick up the package and take the samples to the appropriate location using the service elevator.
 4. Via walking to the Ragon Institute (for collaborators within the Kendall Square and MGH area) and with prior arrangement with the Ragon Institute Colleague. **The samples must be packed and transported in accordance with DOT requirements, as they will be moved on public roadways.** It is strongly suggested that the package be placed in a shopping bag so as not to draw unwanted attention. The samples must be delivered to the 1st floor reception desk at the Ragon Institute at 400 Technology Square, and placed in the package tray as directed by the Ragon Institute Receptionist. The Receptionist will contact the Ragon Institute Colleague who will come to the 1st floor to meet the External Collaborator and take the samples to the appropriate location using the service elevator.
- e) If the samples are to be returned to the collaborating institution, the trained Ragon Institute Colleague will pack and ship the materials to the institution using IATA/DOT compliant packaging. The institution may be charged a fee for any shipping materials as well as the FedEx or other courier costs associated with dangerous goods shipping. The requirements in section V.B will be adhered to.

B. Transport of Research Samples Out Of The Ragon Institute by Ragon Colleagues

1. Review the need for any regulatory permits required for the import/export of the material to be shipped. The External Collaborator is required to obtain any required import permits. In some cases the Ragon Institute may need to file for a new import permit to name the collaborator as a recipient. The Ragon Institute Colleague is responsible for working with the Ragon Institute Biosafety Officer to obtain any required export permits. The process to obtain import and export permits may require substantial time and thus it is prudent to plan well in advance of any shipment. In addition, the Ragon Institute Colleague is responsible for coordinating with the Ragon Institute Regulatory Staff for all other regulatory requirements such as but not limited to Material Transfer Agreements and Institutional Review Board (IRB) approvals.
2. For non-local shipments, determine with the External Collaborator via email the appropriate date for shipping so that the package does not sit on the Collaborator's loading dock potentially compromising the integrity of the research samples. Typically this means shipping domestic shipments on Mondays/Tuesdays/Wednesdays and international shipments on Mondays.
3. Classify the research samples. If you need assistance, contact Ragon Institute Environmental Health & Safety. Review Appendix A (Shipping Classification Guide) for further information.
 - i. UN3373: Biological Substance, Category B
 - ii. UN2814: Infectious Substance, affecting humans
 - iii. UN2900: Infectious Substance, affecting animals
 - iv. Exempt Patient Specimens
4. Package the research samples. Review Appendix B (Packaging Material Selection Guide) for further information. Consider the volume of samples that need to be transported when selecting the appropriate packaging and mode of transportation.
Confirm that dry ice is placed in a non-airtight container to prevent explosion.
 - i. For UN3373, use Packing Instruction 650 and appropriate containers from SafTPak.
 - ii. For UN2814, use Packing Instruction 602 and appropriate shipping containers and packaging materials from SafTPak.
 - iii. For UN2900, use Packing Instruction 602 and appropriate shipping containers and packaging materials from SafTPak.
 - iv. For Exempt Patient Specimens, use the following directions:
 - a) Package is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate. (this would be in lieu of a UN3373 label).
 - b) The packaging must consist of three components:
 1. a leak-proof primary receptacle(s);
 2. a leak-proof secondary packaging; and
 3. an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm;
 - c) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.

- d) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.
5. Transport or ship the research samples via one of the following methods. Note that the use of personal or rental vehicles and public transportation is not allowed. **This includes rideshare services such as but not limited to Uber, Lyft and ZipCar.**
- i. Using FedEx or courier service (e.g. World Courier).
 - ii. Using the Partners shuttle service with a completed bill of lading. You must accompany your shipment on the shuttle at all times.
 - iii. Using a taxi or courier service if the service provider agrees to transport research samples. Use the informational card (Appendix C) to inform the driver about the materials you are requesting to be transported.
 - iv. Via walking for locations within the Kendall Square and MGH area only. It is strongly suggested that the package be placed in a shopping bag so as not to draw unwanted attention.

C. Transport of Research Samples To The Ragon Institute by Ragon Colleagues

1. Transport of research samples to the Ragon Institute by Ragon Colleagues is primarily for transporting such materials within the greater Boston/Cambridge area when the Ragon Colleague goes to the collaborating institution to pick up samples to transport back to the Ragon Institute. Transport from a location outside of the greater Boston/Cambridge area will require following the procedures outlined in Section V.A. of this procedure. Prior to transporting research samples to the Ragon Institute, you must:
 - a. Confirm that your Principal Investigator has approval from the Partners Institutional Biosafety Committee (PIBC). Contact the Ragon Institute Biosafety Officer for assistance. The PIBC cannot guarantee that this approval can be obtained quickly as the committee meets monthly. Therefore plan accordingly.
 - b. Confirm with the Ragon Institute Regulatory Staff that your Principal Investigator has Institutional Review Board (IRB) approval if necessary and that all necessary Material Transfer Agreements are in place.
 - c. Agree to abide by all IATA and DOT requirements, and agree to not use public transportation or personal vehicles (including rideshare services such as Uber, Lyft, and ZipCar) for the transport of samples.
 - d. Follow the instructions in Section V.B (Transport of Research Samples Out Of The Ragon Institute) of this SOP related to classification and packaging. If the collaborating institution supplying the research samples is responsible for classification and packaging before turning the package over to you, you must ensure that it has been done correctly before you transport the samples.
 - e. Note that while it may not be illegal to transport non-hazardous research materials and equipment in personal carry-on or checked luggage for domestic and international air transportation, you may be subject to questioning by regulatory authorities and potentially have your materials/equipment confiscated. Always check with the Biosafety Officer before you attempt to transport such materials. In some cases a letter can be prepared for you to document the non-hazardous nature of the materials.

2. Transport samples to the Ragon Institute via one of the following methods.
 - a. Using FedEx (for locations not within walking distance to the Ragon Institute or on a Partners shuttle service route) or courier service (e.g. World Courier). Remember to determine the best date for shipping with consideration to holidays and adverse weather conditions. Shipments must be scheduled to arrive at the Ragon Institute Reception Desk between 8:30am and 5:00pm EST. Couriers often take upwards of 2 hours to complete a delivery so plan accordingly. Notify the Ragon Institute Receptionist of the shipment with the expected date and time of arrival.
 - b. Using the Partners shuttle service with a completed bill of lading (for MGH and BWH affiliated collaborators not within walking distance to the Ragon Institute). You must accompany your shipment on the shuttle at all times. You must use the service elevator when transporting your samples to your laboratory location on the 7th, 8th, or 9th floors of 400 Technology Square.
 - c. Using a taxi or courier service if the service provider agrees to transport research samples. Use the informational card (Appendix C) to inform the driver about the materials you are requesting to be transported. The samples must be delivered to the 1st floor reception desk at the Ragon Institute at 400 Technology Square, and placed in the package tray as directed by the Ragon Institute Receptionist. The Receptionist will contact the Ragon Institute Colleague who will come to the 1st floor to pick up the package and take the samples to the appropriate location using the service elevator.
 - d. Via walking for locations within the Kendall Square and MGH area only. Your samples must be packed and transported in accordance with DOT requirements, as you will be moving on public roadways. It is strongly suggested that the package be placed in a shopping bag so as not to draw unwanted attention. You must use the service elevator when transporting your samples to your laboratory location on the 7th, 8th or 9th floors of 400 Technology Square.

D. Regulatory Inspections

1. If a regulator from an agency that oversees shipping such as but not limited to the United States Federal Aviation Agency (FAA) or Department of Transportation (DOT) visits the Ragon Institute for inspectional purposes, Ragon Institute Colleagues are required to escort the visitor to the 1st floor reception area where the visitor must verify credentials and register as a visitor according to Ragon Institute established visitor policy.
2. The Ragon Institute Receptionist will contact a member of the Ragon Institute Regulatory Staff, the Ragon Institute Biosafety Officer, as well as the Ragon Institute Administrative Director to inform them of the regulatory visit. If a member of the Ragon Institute Regulatory Staff and/or the Biosafety Officer is unavailable, the Ragon Institute Receptionist will call the Ragon Institute Facilities Manager.
3. A member of the Ragon Institute Regulatory Staff, the Biosafety Officer or the Facilities Manager will come to the reception area, greet the visitor, determine the nature of the visit, and determine if any additional Ragon Institute staff should be present during the visit.
4. A member of the Ragon Institute Regulatory Staff, the Biosafety Officer or the Facilities Manager will accompany the visitor at all times, provide requested documentation, and

take notes during the visit. The notes will summarize the name of the visitor and agency, the visit purpose, any documentation that was requested, findings and/or recommendations that are provided during the visit, estimated date of receipt of a regulatory report, and any other action items that are required.

5. After the visitor exits the premises, the Ragon Institute Biosafety Officer will coordinate a de-brief meeting with the necessary Ragon Institute Colleagues.
6. The Ragon Institute Biosafety Officer will coordinate communications between the Ragon Institute and the regulatory agency, as well as communicate to the Ragon Institute Colleagues any findings that may require changes in procedures to satisfy regulatory agency requirements. If warranted, the Biosafety Officer will contact the Partners Institutional Biosafety Committee (PIBC) if the regulatory inquiry involves biological material approved for use by the PIBC.

Appendix A: Shipping Classification Guide

Is the material a patient specimen?

NOTE: Patient specimens are material collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention (excluding fixed slides).

NO

YES

Does the substance contain, or may be reasonably expected to contain, infectious agents which may cause disease in humans or animals?

NOTE: The following substances are exempt from Infectious Substance Shipping Regulations; environmental samples (including food and water samples) which are not considered to pose a significant risk of infection, material collected for transplant or transfusion, material that has been neutralized or inactivated to no longer pose a health risk, organisms that are non-pathogenic to humans or animals, dried blood spots, and fecal occult screening tests.

NO

YES

Is this a substance being transported in a form (for some organisms cultures only, for other organisms both specimens and cultures) capable of causing permanent disability, life threatening or fatal disease?

NO

YES

Material is Not Regulated

If using dry ice, shipping training for dry ice is required.

Biological Substance, Category B
UN3373

IATA Packing Instruction 650

Examples: HIV positive blood.

Infectious Substance shipping training required. If using dry ice, shipping training for dry ice is required.

Category A: Infectious Substance

Human UN2814

Animal UN2900

IATA Packing Instruction 620

Examples: M. Tb and HIV cultures.

Infectious Substance shipping training required. If using dry ice, shipping training for dry ice

Is there minimal likelihood that pathogens are present?

NOTE: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

NOTE: If there is reason to suspect that the specimen contains a pathogen, it must not be shipped as exempt from Class 6.2

Pathogens are expected to be present.
(sample from HIV-positive donor, for example)

Pathogens are not reasonably expected to be present.

Note: For shipping purposes, patient samples are not assumed to be pathogenic unless there is a specific reason to believe they are (HIV-positive donor, for example)

Material is an **Exempt Patient Specimen** and not considered Division 6.2 Infectious Substance but requires packing that has:

- 1) A leak-proof primary receptacle
- 2) A leak-proof secondary packing
- 3) For liquid specimens place absorbent material between primary and secondary package
- 4) An outer package with adequate strength of its capacity, mass, and intended use, and with at least one surface having dimensions of 100mmX 100mm
- 5) Mark package "Exempt Human Specimen"

Specimen "January" or "Exempt 16, 2017 Animal Specimen"

If using dry ice, shipping training for dry ice is required.

Appendix B: Packaging Material Selection Guide

Once you have properly classified your shipment, select the appropriate SafTPak product from the list below.

Product information may be found at <http://www.saftpak.com/StpPack/stpackaging.aspx>

I. Infectious Substance, Category A

- a. STP-100, reusable shipping system, ambient
- b. STP-110, ambient
- c. STP-130, ambient
- d. STP-310, insulated

II. Biological Substance, Category B

- a. STP-200, reusable shipping system, ambient
- b. STP-210, ambient, small
- c. STP-210xs, ambient, extra small
- d. STP-250, ambient, medium
- e. STP-250MD, ambient, large
- f. STP-270, ambient
- g. STP-302, insulated
- h. STP-308SYS, insulated
- i. STP-309DI, insulated, dry ice
- j. STP-309SYS, insulated
- k. STP-320, insulated
- l. STP-320R, insulated, with reusable secondary pressure vessel
- m. STP-340, insulated, with disposable secondary pressure vessel
- n. STP-340R, insulated, with reusable secondary pressure vessel

III. Exempt Patient Specimens

- a. STP-200, reusable shipping system, ambient
- b. STP-210, ambient, small
- c. STP-210EXMT, ambient, small
- d. STP-210xs, ambient, extra small
- e. STP-250, ambient, medium
- f. STP-250MD, ambient, large
- g. STP-270, ambient
- h. STP-270EXMT, ambient, large
- i. STP-308SYS, insulated
- j. STP-309DI, insulated, dry ice
- k. STP-309SYS, insulated
- l. STP-320, insulated
- m. STP-320R, insulated, with reusable secondary pressure vessel
- n. STP-340, insulated, with disposable secondary pressure vessel
- o. STP-340R, insulated, with reusable secondary pressure vessel

NOTE: "Make Your Own" packaging is not allowed! Packaging must be tested as a whole for IATA/DOT regulations. The above kits are tested and meet IATA/DOT requirements.

**Appendix C
Informational Card**

Dear Taxi or Courier Driver,

I am requesting that you transport the following research materials on my behalf to the destination listed below. I have packaged the materials according to relevant shipping regulations. If you have any questions, please contact me at the number listed below. I will answer the phone at this number at any time during the transport period.

Thank you.

Print Name:

Date:

Contact Number:

Please deliver the materials to:

Name:

Location:

Contact Number:

Special Instructions (if any):

The research materials I am requesting transport for have been packaged according to Department of Transportation (DOT) requirements by a trained person. They include:

Non-infectious research samples (exempt patient samples).

Biological substances (Category B).

Packaged on dry ice.