

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 research samples in and out of the Ragon Institute.

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 provide their training certificate to the Ragon Institute Regulatory Staff. 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 Regulatory Staff
 - 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 as needed.
 - 4. Will assist with other internal/external requirements such as but not limited to Institutional Review Board (IRB) and Material Transfer Agreement (MTA) processes.
- C. Ragon Institute Environmental Health & Safety (EH&S)
 - 1. Will provide technical resources to the Ragon Institute Colleagues and Regulatory Staff on matters related to safety, compliance and training for IATA/DOT requirements. A member of the EH&S team serves as the Ragon Institute Biosafety Officer.

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

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

microorganisms that are considered Diagnostic Specimens are considered Biological Substances, Category B.

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 4 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 collected information is to be provided to the Ragon Institute Regulatory Staff for document retention purposes.
 - 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) A letter or email from the Collaborator's Biosafety Officer or Institutional Biosafety Committee indicating that the research samples have been previously reviewed and approved by the institution. 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

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

- c) 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 (IBC) that oversees work with biohazardous materials at the Ragon Institute. The Ragon Institute cannot guarantee that this approval can be obtained quickly as the Partners IBC meets monthly. Therefore plan accordingly.
 - e) Review and approval by the Ragon Institute Regulatory Staff. 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 Regulatory Staff 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 for the transport of samples to the Ragon Institute. Transport via bicycles and mopeds is not encouraged but is not prohibited. It is suggested that Category A materials be shipped via FedEx, World Courier, US Ground or similar carrier to the Ragon Institute.
 - c) Ship or transport samples to the Ragon Institute:
 1. Using FedEx or courier service (e.g. US Ground, 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

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

- 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 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 or riding a bicycle or moped to the Ragon Institute (for collaborators within the Kendall Square and MGH area) and with prior arrangement with the Ragon Institute Colleague. Transport via bicycles and mopeds is not encouraged but is not prohibited. 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.
- d) 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.

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

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

- required import permits. The Ragon Institute Colleague is responsible for working with the Ragon Institute Regulatory Staff 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 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.
 - 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.

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

- i. Using FedEx or courier service (e.g. US Ground, 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 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 or riding a bicycle or moped for locations within the Kendall Square and MGH area only. Transport via bicycles and mopeds is not encouraged but is not prohibited. 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 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.
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. US Ground, 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.

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

- c. Using a taxi 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 or riding a bicycle or moped for locations within the Kendall Square and MGH area only. Transport via bicycles and mopeds is not encouraged but is not prohibited. 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

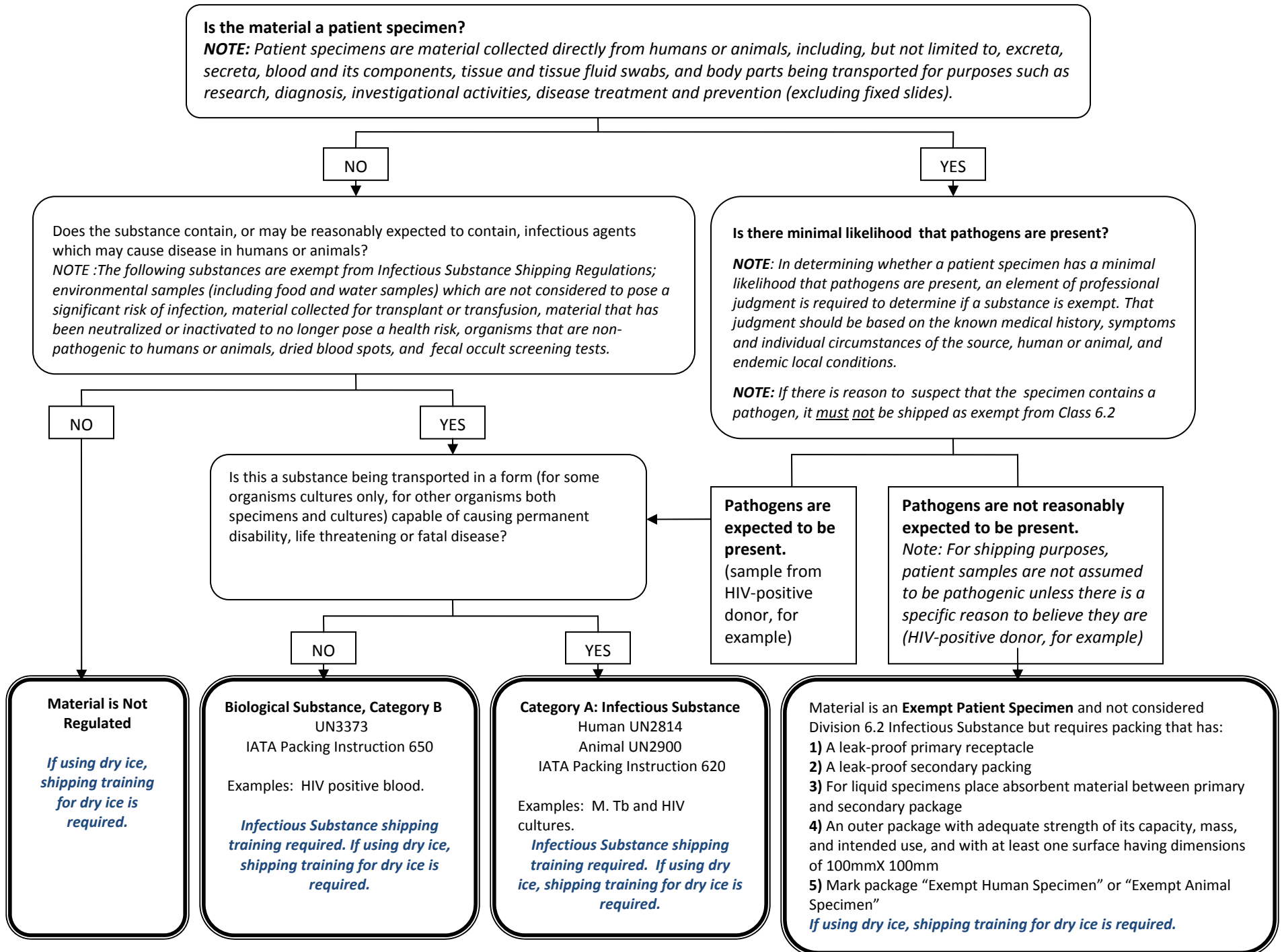
1. If a regulator from an agency that oversees shipping such as but not limited to the United States Federal Aviation Agency (FAA) or Department of Transportation (DOT) visits the Ragon Institute for inspectional purposes, Ragon Institute Colleagues are required to escort the visitor to the 1st floor 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 as well as the Ragon Institute Administrative Director to inform them of the regulatory visit. If a member of the Ragon Institute Regulatory Staff is unavailable, the Ragon Institute Receptionist will call the Ragon Institute Laboratory Manager.
3. A member of the Ragon Institute Regulatory Staff or the Laboratory 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 or the Laboratory 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 Regulatory Staff will coordinate a de-brief meeting with the necessary Ragon Institute Colleagues including the Administrative Director or her designee, and the Ragon Institute Biosafety Officer and Laboratory Manager.
6. The Ragon Institute Regulatory Staff 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.

RAGON INSTITUTE

SOP #01-12 [JUNE2013]

E.

Appendix A: Shipping Classification Guide



Appendix A: Shipping Classification Guide

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 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).**

____ **Infectious substance (Category A).**

____ **Packaged on dry ice.**