

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Research Technical Operations
POLICY NUMBER: RTO-103
REPLACES: New Policy
EFFECTIVE DATE: 1/9/09
REVISION DATE: _____
POSTED FROM: August 25, 2008 to September 23, 2008

TITLE: Biological Materials Transport

SUMMARY:

Seattle Children's Research Institute has established a compliant, cost-effective, expedient, and standardized method for the transport of biological materials between sites. Additionally, adherence to this policy and procedure will mitigate risk and increase safety to samples, staff, and the general public, while ensuring compliance with all applicable laws. This Biological Materials Transport policy details the requirements for all transportation of biological materials to and from the Research Institute.

POLICY/PROCEDURE:

All biological materials transported from the Hospital to the Seattle Children's Hospital Research Institute shall conform to the policy procedures outlined below. This policy addresses and complies with all applicable international, federal, state, and local laws regarding transportation of biological materials, including but not limited to the International Air Transportation Authority, Department of Transportation, Environmental Protection Agency, and Occupational Safety and Health Act. Deviations to this policy may result in disciplinary action and loss of privilege.

- 1) This policy outlines packaging, preparation for shipment, transport, receipt, and delivery of Exempt or Biological Substances, Category B at Children's Research.
- 2) Transport of Biological Substances, Category B and/or Exempt (as defined below) on the Children's Research shuttle or by approved courier is allowed when packaged according to the terms and conditions contained within this policy.
- 3) Transport of any hazardous materials other than Exempt or Category B biological specimens is strictly prohibited on Children's shuttles or by courier. This includes Category A, Infectious Substances (typically Biosafety Level 2, 3 or 4 agents), Select Agents, hazardous chemicals, and radioactive materials. These materials are subject to specific transportation laws and regulations. For further explanation,

instructions and assistance in the transport of these materials, contact Research Technical Operations. Some of these materials require specific licensing approval, release statements, or import/export permitting, so allow for this in planning these shipments.

- 4) Employees packaging and/or transporting specimens must review this Policy (RTO-103) and complete the following CHEX training: *Diagnostic Specimen (Biological Substances Category B) Transport and Shipping v1.0*. This policy needs to be reviewed annually and refresher training completed every two years, or as regulations dictate and notification is given by Director, Research Technical Operations.
- 5) *Biological Substances, Category B* are defined as human or animal material being transported for diagnostic or investigational purposes including excreta, secreta, blood and its components, tissue and tissue fluids. Category B excludes live infected humans or animals, however, specimens known to originate from a patient with an infectious disease should still be transported as a Biological Substance, Category B.
- 6) *Exempt Human/Animal Specimens* are defined as clinical specimens (blood, secreta, excreta, tissue fluid) not known to contain or suspected to contain a pathogen; or a Biological Substance, Category B, specimen in which the pathogen has been neutralized or inactivated so it cannot cause a disease when exposure to it occurs.
- 7) There are three authorized methods of transport for biological materials at Children's. These include researcher prearranged shipments, accompanied shuttle shipments and preauthorized courier service shipments.
- 8) All specimen transported by shuttle must be secure within the vehicle. All Green Line Shuttles are equipped with a luggage strap to accommodate this. All shipments must either be accompanied by the shipper or prior arrangements for collection at the destination must be made by the shipper. Specimens are not allowed left on the shuttle beyond a point-to- point.
- 9) Research Support Services and Transportation accept no responsibility for lost, damaged, or otherwise compromised specimen during transport.
- 10) Other methods for specimen transport include approved courier services or an authorized shipper (e.g. – World Courier, FedEx). These packages (including after-hours deliveries) will be held in a designated, locked cabinet on the Building 1 loading dock. They can be obtained through Security.
- 11) For liability and safety, taxi cabs and personal vehicles are discouraged for Exempt specimen and Category B specimen transport.

PROCEDURE:

- 103.1 Specimen Processing/Sending Researcher Responsibility
 - 103.1.1 Shippers must ensure that shipments are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to persons or animals during shipment.
 - 103.1.2 In the instance Consignee/Receiving Researcher is not reachable, the specimen may not be sent. For RSPL shipments, RSPL team will make two attempts at contact, and if unsuccessful, will leave a message requesting an immediate return phone call.
 - 103.1.3 Contact the Research Specimen Processing Lab for approved packaging materials. It is the responsibility of the shipper to purchase packaging materials. These can either be purchased through the RSPL as part of their service or through Research Purchasing. If undamaged, packages can be reused. For questions regarding appropriate packaging, contact Research Technical Operations.
 - 103.1.4 The following packing instructions apply to all Category B and Exempt Biological Specimens:
 - 103.1.4.1 Water Tight Primary Receptacle: This refers to the receptacle directly containing the material for transport. All primary containers must be water tight, or sift proof if transporting a solid.
 - 103.1.4.1.1 The Maximum Quantity Allowed per primary receptacle is 500mL or 500g. Total per outer container must not exceed 4kg or 4L.
 - 103.1.4.1.2 Substances shipped at ambient temperatures or higher must be shipped inside primary receptacles made of glass, metal, or plastic.
 - 103.1.4.1.3 Lyophilized substances must be shipped in primary receptacles that are either flame-sealed glass ampoules or rubber-stoppered glass vials with metal seals.
 - 103.1.4.2 Water Tight Secondary Receptacle: This refers to a plastic, metal or cardboard like container with a screw top lid or other water tight seal. The primary container goes inside this container. Screw caps must be reinforced with adhesive tape if shipped at ambient temperatures or higher.
 - 103.1.4.2.1 Absorbent Material must be placed inside the watertight secondary container and must surround the entire primary container. The absorbing material must be capable of absorbing the entire liquid contents of the primary container.
 - 103.1.4.2.1.1 Exceptions requiring no absorbent: large body parts or whole organs; solid substances containing no liquids.
 - 103.1.4.2.2 Prevent contact of multiple primary containers by wrapping each individual container. Each tube must be

- wrapped in absorbent materials, bubble wrap or placed in a specially designed Styrofoam container.
- 103.1.4.2.3 Shock absorbent material must be placed between the secondary container and the outer shipping container when shipping volumes greater than 50 ml. The material must be of at least equal volume to the absorbent material surrounding the primary container and it must completely surround the secondary container. This is a US Public Health Service requirement.
 - 103.1.4.3 An itemized list of the contents must be enclosed in the package between the secondary container and the outer box (e.g. - 4 x 10mL vials).
 - 103.1.4.4 Rigid Outer Container: This container must be a rigid box and the outside of the box must contain the appropriate *UN3373, Biological Substance, Category B* shipping label. This label must be affixed on two opposite sides of the outer container.
 - 103.1.4.4.1 Packages must be at least 4 inches (100 mm) in the smallest overall dimension.
 - 103.1.4.5 Appendix B contains images demonstrating examples of appropriate packaging for Exempt or Category B Substances shipping.
 - 103.1.4.6 The shipper is required to make advance arrangements with the consignee. This is to ensure that there will be someone to receive the package.
 - 103.1.4.7 Due to Department of Transportation, Hazardous Materials Regulations, shipping liquid nitrogen (hazardous material) is not allowed on Children's shuttles.

103.2 Transport

- 103.2.1 All packages containing biological materials that are placed in Children's shuttles must be secure within the vehicle.
- 103.2.2 Each Green Line Shuttle is equipped with a process for securing packages within the vehicle. Packages must be placed upright in the designated area prior to transport.
- 103.2.3 Damage to the designated area for securing specimen should be reported to Transportation immediately.

103.3 Researcher Accompanied Shipments

- 103.3.1 Researchers may accompany shipments on the shuttle.
- 103.3.2 All packaging requirements, as outlined above, apply.
- 103.3.3 The package must be secure in the designated area of the vehicle.
- 103.3.4 No additional paperwork or notification is necessary, assuming the sending researcher is also the consignee.
- 103.3.5 It is the responsibility of the researcher to ensure that the package is securely placed in the vehicle prior to transport and removed from the vehicle at destination.

- 103.3.6 This is approved for transportation of biological materials to and from any of the Children's Green Line Shuttle stops, assuming all applicable procedures, as outlined in this policy, are met.
- 103.4 Researcher Unaccompanied Shipments
- 103.4.1 These shipments must be placed on the shuttle by the sender and arrangements must be made for collection at the destination.
- 103.4.2 Transportation accepts no responsibility for specimen left on the shuttle.
- 103.5 Courier Shipments
- 103.5.1 Shipments that are especially time or temperature sensitive, and/or after-hours shipments may use a pre-approved courier service. This use requires coordination through Technical Operations and approval prior to use.
- 103.5.2 Technical Operations maintains a list of approved courier services. These are available through Technical Operations and/or on the Intranet at:
http://child/research/research_support_services/research_technical_operations/default.asp
- 103.5.3 It is the responsibility of the Researcher or shipper to offer the package to the courier service delivery driver.
- 103.5.4 During regular business hours, defined as 8am – 4:30pm, Monday – Friday, courier deliveries to Research will be placed in the specimen cabinet on the loading dock. These can be retrieved through the Security guard on-site.
- 103.5.5 After-hours, consignee must be available at the Building 1 lobby to receive courier shipments. As these shipments are specific to temperature or time sensitive specimens, it is the responsibility of the sender to ensure that there is someone available for receipt. If there is no one available to receive the package, it will be returned to the sender.
- 103.5.6 Emergency courier shipments have a timeframe of one hour, which includes notification, scheduling, pick-up and delivery to Research. The request for emergency shipments needs to be indicated to the courier company.
- 103.6 Security Responsibility (Research)
- 103.6.1 Security is responsible for assisting the courier service staff with access to the loading dock and the specimen cabinet.
- 103.6.2 Security will enter the receipt time on the Receivers Transmittal Log.
- 103.6.3 Security will make two attempts to contact the consignee.
- 103.6.4 Security assumes no liability for packages that are not retrieved in a timely manner.
- 103.6.5 If the package is broken, damaged, leaking, packed inappropriately or the label is incomplete, Security is NOT to accept the package. The following steps must be taken:

- 103.6.5.1 Immediately notify the consignee of an inappropriate package. If this information is missing, activate the Emergency Contact List for Research.
- 103.6.5.2 If available, give as much information as possible, including any available contact information.

103.7 Consignee/Researcher Responsibility

- 103.7.1 The researcher responsible for ultimate receipt of the package must be available for receipt of the package. A notification from the shipper will alert that there is a package en route.
- 103.7.2 When the package is retrieved, the consignee must sign and date the Receivers Transmittal Log to close the chain of custody for the package. This is conspicuously located adjacent to the designated package drop spot on the loading dock.

Submitting Office: Research Technical Operations

Approved by:

\s\ David Moore 1/09/09
Director, Research Technical Operations / EH&S

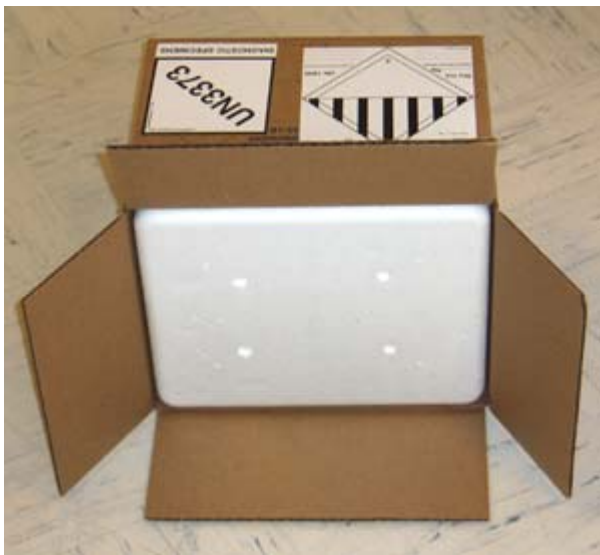
\s\ James B. Hendricks, PhD 1/09/09
President, Seattle Children's Research Institute

APPENDIX A - Packaging

Biological Substances, Category B and Exempt Specimen Outer Packaging Requirements:

- Contain enough cushioning material to immobilize the secondary container.
- Be strong, tightly closed, and rigid enough to withstand repeated drop testing from up to 4 ft.
- Not have total contents that exceed 4 Liters or 4 kilograms and primary containers not to exceed 500g or 500mL
- Be at least 4 inches in overall external dimensions to provide enough space for labeling.

**Figure 1. Outer Packaging
Example: Cardboard box**



**Figure 2. Primary receptacle,
secondary container, and outer
packaging**



APPENDIX B – Emergency Response

Seattle Children's Hospital Research Institute has established guidelines to help ensure the safety of staff during an emergency. The following outlines specific procedures in the event of an emergency involving the Green Line Shuttle.

In the event of an emergency, employees will take the following immediate actions:

- Account for the whereabouts and condition of all passengers. If there are injured passengers, call 911 and notify Occupational Health Services.
- In the event of an exposure, immediately report to Occupational Health Services.
- In the event of a disabled shuttle and when there is a specimen on the shuttle, call Yellow/Greytop Cab and arrange for safe and expedient specimen transport to the Research Institute. All appropriate paperwork should accompany any specimen transport. Cab vouchers are available on the shuttle. *This is the only instance when cab transport of specimens is preferable.*
- Call Transportation Supervisor to report damaged or stranded vehicle. Request activation of a back-up shuttle.
- Remain with the vehicle, if this does not present increased danger.
- In the event that remaining with the vehicle presents an increase in threat to personal safety, remove all personal and valuable items. Close and lock all doors. Notify Shuttle Supervisor and Research Security.

In the event of a spill or release, the driver is to decontaminate the spill with Lysol IC, which will be located on the shuttle.

- Use Lysol IC liberally and wipe down all potentially contaminated areas.
- Nitrile gloves must be worn and all spill clean-up materials must be contained in the clear plastic bags located in the first-aid kits. If the spill materials are large enough, use the black plastic bags.
- Packaged spill clean-up materials are to be bagged, sealed with tape and delivered to Shipping and Receiving at the Research Institute.
- Contact Research Security.

Contacts:

Research Security – 206.941.0461
Research Reception – 206.884.7300
Occupational Health Services – 206.987.2633
Research Technical Operations – 206.484.4718
Shuttle Supervisor – 206.599.9389
Taxi – 206.622.6500