1. PURPOSE:
To standardize and describe the process for safely transporting human research participant specimens within, to or from University Hospitals (UH) facilities.

2. SCOPE:
This SOP applies to all personnel who are responsible for transporting human research participant specimens for research purposes within or to UH facilities.

This SOP covers transport of Biological Substances Category B only. Category A Infectious Substances should not be transported using this SOP. Individuals planning to transport Category A Infectious Substances should contact: Department of Hospital Safety: Safety@UHHospitals.org.

3. RESPONSIBLE INDIVIDUALS:
Principal investigator (PI) and when delegated by the PI, individuals also involved with the research including but not limited to sub-investigators, Research Nurse, Study Coordinator, and/or other pertinent research staff.

4. DEFINITIONS:

**Patient Specimens** – Human or animal materials, 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, and disease treatment and prevention. Anything that is a therapeutic product is not considered a specimen, e.g., stem cells collected for treatment purposes.

- **Clinical Research Specimens** – (A subcategory of the definition of patient specimens developed for purposes of this SOP.) Specimens collected directly from humans including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for the purposes of research and investigational activities.

**Department of Transportation (DOT)** – The US federal agency working under the authority of Congress to regulate the safe transportation of hazardous materials in intrastate, interstate, and foreign commerce.

**International Air Transport Association (IATA)** – Publishes the Dangerous Goods Regulations, which are instructions for transporting dangerous goods by air and are based on the International Civil Aviation Organization’s (ICAO) Technical Instructions.
Infectious Substances (class 6.2) – Substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites and fungi) and other agents such as prions, which can cause disease in humans and animals. Infectious substances are further categorized into:

- **Infectious Substance Category A** – An infectious substance is one that is in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal diseases to humans or animals. These are subject to the strictest shipping requirements (special paperwork, labels, containers), whether in cultures or in human or animal specimens. Examples include, but aren’t limited to, Ebola virus, Hepatitis B virus (cultures only) and West Nile virus (cultures only).

- **Biological Substance Category B** – All other infectious substances are classified as Category B infectious substances. These are still subject to the shipping regulations but with lesser requirements in terms of shipping papers and quality of containers.

**Exempt Human Specimen** – According to DOT and IATA regulations, Patient Specimens from a non-infectious human or animal are exempt from Infectious Substance regulations. These materials must be deemed non-infectious before they are classified as an exempt specimen. If there is suspicion that the material being transported contains a pathogen, it must be classified as an infectious material (either Category A or Category B). While patient specimens are exempt from shipping requirements, packaging requirements must still be met (triple packing). See below for packaging requirements.

Please refer to the Glossary for definitions of other terms in this SOP.

### 5. POLICY STATEMENT:

All research personnel responsible for transporting participant specimens for a UHCMC IRB approved protocol are required to adhere to this SOP. This may include, but is not limited to, transporting specimens between other University Hospitals sites and University Hospitals Cleveland Medical Center (UHCMC), Case Western Reserve University, or any location where the specimens are originally collected and subsequently delivered. Participant specimens must be taken directly from the place of collection to the receiving facility and should not be taken to any other location (such as employee’s home).

Individuals responsible for transporting human research participant specimens must take Hazardous Materials Training every two years and maintain a current certificate of DOT/IATA training on file.
6. PROCEDURES:

6.1. Training

6.1.1. DOT/IATA Hazardous Materials/Dangerous Goods Training applies to any individual who:

- Prepares hazardous materials for transportation
- Selects packaging or packages for hazardous materials
- Completes a shipper’s declaration or other paperwork associated with the transport of hazardous materials
- Loads, unloads, or handles hazardous materials
- Is responsible for safety during the transportation of hazardous materials
- Operates a vehicle used to transport hazardous materials
- Ships or transports materials on dry ice

6.1.2. Training must take place within 90 days of initial employment or change in job function. Affected employees shall receive this training every two years. There is a three month “window” that allows recurrent training conducted within the final three months of the two year period to be considered to have been completed on the expiration date of the two year period.

6.2. Classification of Specimens

6.2.1. To determine appropriate packaging for transport, classify specimens using the guide in Appendix B.

6.3. Triple Packing

6.3.1. All infectious material (category A or B) and exempt human specimens packaging must meet the following conditions to comply with DOT and IATA regulation (Triple Packing):

6.3.1.1. Leak proof primary receptacle
6.3.1.2. Leak proof secondary receptacle
6.3.1.3. Outer packaging that is appropriate for the material being transported (capacity, strength, etc.) and at least one surface having minimum external dimensions of 100 mm x 100 mm.

6.3.2. Primary receptacles must be leak proof and must have positive closures (screw-on, snap-on, or push-on) that are taped. Primary receptacles can be glass, plastic or metal.

Examples of acceptable Primary receptacles are plastic canisters, glass or plastic jars, glass or plastic vials.
6.3.3. Secondary packaging must be leak proof for liquids and shift proof for solids. There **must be a biohazard label** on the secondary packaging. Note: It is an OSHA regulation, not IATA, that a **biohazard label** must be placed on the outside of the secondary container. This is done for hazard communication reasons.

Examples of acceptable Secondary receptacles are sealed Styrofoam containers, sealed plastic bags, plastic canisters and screw-cap cans. All must have biohazard labels on them.

6.3.4. If the material being transported is a liquid, there must be absorbent material placed between the primary receptacle and the secondary receptacle. Make sure enough absorbent material is used to absorb all of the liquid if an accident occurs. If several fragile primary packages are used (e.g., glass vials), they must be secured or wrapped in a manner that prevents contact with each other.

Examples of acceptable Absorbent Materials are paper towels, cotton balls, cellulose wadding, Kimwipes®, and super-absorbent packets.

6.3.5. The material is then placed in an Outer Packaging container. Outer Packaging must be sturdy, rigid and the appropriate size.

Examples of acceptable Outer Packaging are rigid plastic containers, wood boxes, rigid coolers, corrugated fiberboard or cardboard boxes.

Examples of **unacceptable** outer packaging are FedEx® packaging, Styrofoam boxes, plastic bags, paper envelopes.

6.3.6. An external label is placed on the Outer Packaging container as determined by the classification of enclosed specimens and whether dry ice is being utilized. (See Section 6.4, Labeling)

6.3.7. Quantity limitations apply:

6.3.7.1. Primary receptacle(s) must not contain more than 1 liter of liquid.

6.3.7.2. For specimens that are packaged with dangerous goods that are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances: (e.g. preservatives and fixatives)

6.3.7.2.1. Each primary container must not contain more than 30 milliliters of liquid dangerous goods that are DOT Class 3 (Flammable), Class 8 (Corrosive) or Class 9 (Miscellaneous).
6.3.7.2.2. Each primary container must not contain more than 30 grams of solid dangerous goods that are DOT Class 4 (Flammable), Class 8 (Corrosive) or Class 9 (Miscellaneous).

6.3.7.3. Outer packaging: (the overall package)
6.3.7.3.1. For liquids, the outer packaging must not contain more than 4 liters. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

6.3.7.3.2. For solids, except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kilograms. Again, this quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

6.4. Labeling
6.4.1. Follow the protocol regarding the labeling of participant specimens and the primary receptacle.

6.4.2. Specimens are then placed in a puncture resistant secondary container. This container is labeled with the international biohazard symbol and closed prior to transport. The biohazard label must be placed on the outside of the secondary container.

6.4.3. The sturdy Outer Packaging should include the appropriate labeling as required per the contents.
6.4.3.1. Proper labeling of Biological Substance, Category B specimens includes:
   - UN Identification Number UN3373
   - Proper shipping name as follows: UN3373 Biological Substance, Category B.

6.4.3.2. Mark packages containing exempt specimens, “Exempt Human Specimens”.
6.4.3.3. Proper labeling of packages containing dry ice includes:
- UN Identification Number for dry ice: **UN 1845**
- Proper shipping name: **Dry Ice or Carbon dioxide (solid)**
- Hazard class 9 (miscellaneous) **label**.

6.5. **Transporting and/or packing samples with dry ice (solid Carbon Dioxide or CO₂)**

6.5.1. Dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack.

6.5.2. Venting: Dry ice must never be packaged in an airtight container. This may lead to a build-up of pressure inside the container, thus causing an explosion. Allow for proper venting of dry ice; do not tape Styrofoam containers containing dry ice closed, tape the outer box only.

6.5.3. Compatibility: Due to the low temperature of dry ice, many materials such as plastics may be rendered brittle and permeable. Make sure packaging materials are not susceptible to damage from exposure to dry ice.

6.5.4. Package Quality: The shipper is responsible for choosing a package which will withstand normal transport activity intact. Packages must be able to withstand multiple handlings and vibrations that occur during normal transportation. Outer and inner packages must be constructed and closed in a manner so that the contents remain within the package.

6.6. **Methods of Transportation**

6.6.1. If possible, it is recommended that established shipping services are used to transport specimens. This includes courier services between facilities.
6.6.2. Personal modes of transportation can be used to transport materials.
  6.6.2.1. Avoid exposing specimens to direct sunlight or leaving them in a vehicle during warm weather conditions.
  6.6.2.2. The specimens should be kept in a cool place and taken to the appropriate lab as soon as possible.
  6.6.2.3. Specimens are not to be taken back to an individual’s home and stored overnight.

6.7. Spill Kits and Sharps Containers
  6.7.1. All individuals transporting specimens must have a Spill Kit. (See Appendix C)
  6.7.2. If a spill occurs, the UH Safety Office must be notified immediately at 216.844.7745 (select option 2).
  6.7.3. If the study personnel are responsible for the collection of samples, any sharps used are to be disposed of in an appropriate location in an appropriate container.
  6.7.4. University Hospitals Laboratory Services recommends that the Spill Kit contains the items indicated in Appendix C.

7. REFERENCES
The regulations for hazardous material transportation are found in the Code of Federal Regulations under 49 CFR parts 100-185.

8. FORMS OR ATTACHMENTS
   Appendix A: Additional Glossary Terms
   Appendix B: Classification Guide for Transport of Clinical Research Specimens
   Appendix C: Spill Kit and Instructions
   UH Policy SA-6 Spill Response
   UH Policy IC-2 Standard Precautions/PPE

APPROVALS
Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– January 24, 2018

Developed by the UH Clinical Research Center SOP Committee
Appendix A: Additional Glossary Terms

**Hazardous Materials (HM)** – Materials capable of posing an unreasonable risk to health and safety and property when transported in commerce.

**Pipeline and Hazardous Materials Safety Administration (PHMSA)** – Division within DOT responsible with coordinating a national safety program for the transportation of hazardous materials by air, rail, highway and water.

**Dangerous Goods (DG)** – Articles or substances capable of posing a significant risk to health, safety or to property when transported by air.

**Occupational Safety and Health Administration (OSHA)** – The main US federal agency charged with the enforcement of safety and health legislation.
Appendix C: Spill Kit and Instructions

All individuals transporting specimens must have a Spill Kit. If a spill occurs, the UH Safety Office must be notified immediately at 216.844.7745 (select option 2)

A. Kit Contents
   1. 2 Pairs of Nitrile Gloves
   2. Safety glasses/goggles
   3. Absorbent Pads
   4. Neutralizing agent or solidifier (various ones depending on samples)
   5. Scoop/Scraper
   6. Hard Surface Disinfectant Wipes
   7. Disposal Bags - 2
   8. Instructions

   Body fluid spill kits can be purchased through I Procurement under oracle # 051780.
   Chemical neutralizer must be purchased separately if needed.
   Chemical Spill kits can be purchased under oracle # 017256.

B. Instructions
   1. Contact the UH Safety Office immediately at 216.844.7745 (option 2)
   2. Put on gloves and eye protection. Always wear protective gear and exercise caution during clean up.
   3. Lay the absorbent pads on top of the spilled material. If applicable, sprinkle neutralizer or solidifier over spill evenly instead of using the absorbent pads. The fluid will quickly set; add more as necessary to insure any liquid is completely contacted.
   4. Once absorbent pads are saturated, place them into the disposal bag.
   5. Where a neutralizer or solidifier is used, remove solidified material using scoop and scraper and place into the disposal bags.
   6. Clean area with a hard surface wipe or disinfectant, if available.
   7. After cleanup is completed, remove all personal protection equipment (PPE) and place into disposal bag. Seal disposal bag using the single goose-neck knock to prevent leakage.
   8. Dispose of all waste in accordance with local, state and federal regulations. Contact the UH Safety Office for any disposal questions.
### Appendix B

#### CLASSIFICATION GUIDE FOR TRANSPORT OF CLINICAL RESEARCH SPECIMENS

**Clinical Research Specimens:** Specimens collected directly from humans including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluid swabs and body parts being transported for the purposes of research and investigational activities.

Does the specimen contain an infectious substance?

*Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are micro-organisms including bacteria, viruses, rickettsiae, parasites, fungi and other agents such as prions, which can cause disease in humans or animals.*

- YES
- NO

Is the specimen in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals?

- YES
- NO

**Infectious Substance Category A**
(SOP SC-402 does not apply)
Contact: Hospital Safety

**Biologic Substance Category B**

**Exempt Human Specimen**
Not subject to DOT/IATA regulations
- Must be triple packed for transport
- Dry ice regulations apply