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1.0 PURPOSE

- 1.1 This work instruction provides the specific steps necessary to pack and ship the Comprehensive Biospecimen Resource (CBR)-issued GTEx dry ice kit (the Pink kit).
- 1.2 The procedure section is divided into four subsections: the kit receipt at the biospecimen source site (BSS); packing instructions; shipping instructions; and alert of shipment.

2.0 ENVIRONMENTAL HEALTH & SAFETY

- 2.1 Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association (IATA)/International Civil Aviation Organization (ICAO) regulations.
- 2.2 Persons packaging the shipment must be trained in the use, handling, and shipping of dry ice (UN1845) and the proper personal protective equipment (PPE) is to be worn when working with dry ice.

3.0 PROCEDURE

Kit Receipt at the BSS

- 3.1 Contents correspond to supplies shown in Figure 1.
 - 3.1.1 One fiberboard outer shipping box (95 kPa).
 - 3.1.2 Styrofoam™ insulation box and lid inside clear bag.
 - 3.1.3 Three 10.25" x 14" Biohazard Bags (95 kPa).
 - 3.1.4 One 24" tape strip to seal the fiberboard box.
 - 3.1.5 Pre-printed FedEx return label.
- 3.2 Upon kit receipt, verify contents of kit using the list above (3.1.1 3.1.5) and receive kit in BRIMS.
- 3.3 If the kit is incomplete or broken:
 - 3.3.1 Receive in Biorepository Information Management System (BRIMS) the kit contents that are present.
 - 3.3.2 Email kit content issues to the CBR.
 - 3.3.3 CBR will follow-up with an action for resolution.



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Figure 1: Pink kit (Dry Ice)

Packing Instructions

- 3.4 On the day the kit is to be shipped, complete the following steps:
- 3.5 Pink kit cryosettes will be numbered GTEx-XXXXXX-5001 to 5030.

NOTE: The BSSs will be directed to ship no less than three cases at a time, to reduce shipping costs.

Cases will be held at -80°C until three cases are ready to ship. The Pink kit will hold six 2" freezer boxes holding no more than 21 cryosettes/box. The BSS Technical Project Manager (TPM) or CBR manager may request shipment sooner than accumulation of the 3 cases.

*See Section 4.1 of the work instruction for an approved alternate storage and shipping procedure

- 3.5.1 Remove a Pink kit from the storage area.
- 3.5.2 Locate dry Ice and have adequate quantity available to fill the kit. Layer dry ice on the bottom of the Styrofoam™ box just to cover the bottom.
- 3.5.3 Remove 3 complete cases (six 2" freezer boxes) from -80°C storage, and place two boxes into each of the provided biohazard bags. Place them in the biohazard bags two boxes wide (side by side), and stack the bags three bags in the bottom of the Pink kit.
- 3.5.4 Use of the data logger:
 - 3.5.4.1 For all BSSs, the first two dry ice shipments from any current or new site should contain dry ice data loggers. If the 1st two shipments are without incident, and review of the data logger by the CBR team indicates the



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shipments were within the targeted temperature range throughout transit, the BSS will be authorized to discontinue use of the dry ice data loggers. The CBR coordinator and CBR manager will inform the BSS once approved to discontinue data logger use. If a shipment records a temperature outside of the accepted range, additional shipments will be logged until a minimum of 2 shipments that maintained the targeted range have been received.

- 3.5.4.2 Activate the data logger according to the Dry Ice Data Logger Usage SOP, PBS-01.092.
- 3.5.4.3 Place the activated logger into the kit between the second and third biohazard bag. See Figure 2.



Figure 2: Pink kit (dry ice) data logger placement

- 3.5.5 Fill the shipping box with dry ice, covering the sample boxes. Dry ice must be loaded such that it fills the entire insulated shipper to the top.
- 3.5.6 Place the Styrofoam™ lid on the insulated shipper.
- 3.5.7 Fill out all the Pink kit information in **BRIMS**. Print the **Chain of Custody (CoC) Form** and **Manifest** from **BRIMS** and place on top of the Styrofoam™ lid (ensure you keep a copy of each of these forms for your records).
- 3.5.8 Fold the plastic bag over the lid, close the outer shipping box, and tape it closed.
- 3.5.9 Remove the yellow colored "PEEL OFF LABEL BEFORE SAMPLES ARE SHIPPED" label on the outside of the shipping package so that the UN3373 stamp underneath is visible.



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- 3.5.10 Remove the yellow colored "PEEL OFF LABEL BEFORE SAMPLES ARE SHIPPED" labels on the outside of the shipping package so that the CLASS 9 MISCELLANEOUS SHIPPING LABEL (Dry Ice label) is visible.
 - 3.5.10.1 Be sure to write the weight of the dry ice on the Class 9 Dry Ice label prior to shipping. With all three biohazard bags containing six 2" boxes inside, there should be approximately 15lbs of dry ice.

NOTE: Courier will refuse shipment if the dry ice weight is not labeled.

Shipping Instructions

3.6 Contact the CBR to alert them that a dry ice shipment is pending. An automated alert will suffice as well. Verify all steps are complete and ship to the CBR via FedEx overnight using the included pre-printed FedEx return label.

Alert of Shipment

- 3.7 Timeline of alert to CBR
 - 3.7.4 Alert should be sent upon shipment of specimens and requested to include 3 cases per shipment, or as directed by the BSS TPM or CBR manager.
- 3.8 Method of alert to CBR may be automated or by email. If by email, please follow guidelines below:
 - 3.8.4 Please include GTEx Case IDs for all applicable donors within the shipment (# of cases) in the subject line of e-mail
 - 3.8.5 Indicate notice of pending shipment
 - 3.8.6 Indicate the date of anticipated shipment
 - 3.8.7 Indicate the date of anticipated arrival at the CBR
 - 3.8.8 Indicate the tracking number/company used to ship
 - 3.8.9 E-mail notification of pending shipments to the CBR



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- 3.9 Use the following instructions for the e-mail template for correspondence to the CBR:
 - 3.9.4 Subject line: Name of BSS, Donor Case IDs (# of cases) Pink Kit
 - 3.9.5 Body of e-mail: (Please note: Do not state date of collection/procurement in the body of the email or subject line).

Hello CBR,

Please consider this e-mail notification that "#" GTEx donor collections have been completed and are being shipped.

The shipment will be shipped to you on <INSERT DATE> and is expected to arrive by <INSERT DATE>. The tracking number of the shipment to the CBR is <INSERT TRACKING NUMBER>.

Thank You, <Insert Site Name>

4. Alternate storage of dry ice frozen biospecimens

- 4.1 In the event of a freezer failure, absence of freezer, or due to any other emergencies (e.g. weather related), please follow the instructions below:
 - 4.1.1 If alternate storage (short-term or long-term) is needed at any site for GTEx dry ice frozen biospecimens, the biospecimens should be stored in a PINK kit Styrofoam™ insulated shipper with a data logger. Pre-identified lab personnel will be informed of case collection time and kit location, and given direction for maintenance of the biospecimens in dry ice until shipment.
 - 4.1.2 The biospecimens should be stored inside the freezer boxes within the PINK kit cooler filled with sufficient dry ice. Sufficient dry ice is established by ensuring dry ice is present under, surrounding, and above the biospecimen boxes. The dry ice should be packed, but still allow for the lid to fit snugly.
 - 4.1.3 An activated dry ice data logger should remain with the biospecimens at all times and this same logger should be included within the shipping kit to continue to record the temperature. It is highly preferable that the dry ice biospecimens are shipped as soon as possible. However, due to shipping constraints, cases occurring from late Thursday through Sunday are to be maintained on dry ice for shipment on Monday. Therefore, pre-identified on-call lab personnel shall be trained on dry ice and data logger use, and should be aware they are responsible for verifying the temperature as indicated on the dry ice data logger and the level of dry ice every 24 hours until shipment.
 - 4.1.4 The BSS shall maintain a log of all temperature checks until shipment. The dry ice should be topped off at each check as listed in (4.1.3) to ensure it surrounds the box of biospecimens (above, under, around).



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- 4.1.5 These checks should be recorded on the manual temperature log. The log should be filed both with the case file locally, as well as forwarded by email to the GTEx TPM and CBR manager.. The BSS may use their own log.
 - 4.1.5.1 While this alternate method allows for dry ice specimens to be shipped immediately overnight (one case/shipment), if a shipment would arrive at the CBR after 5PM Friday, please alert the CBR and CBR manager of an impending, late shipment.
- 4.1.6 Data logger data will be forwarded to the CBR coordinator for review of these cases from these sites. Data will be provided by the CBR, upon request, following data logger download and shipment receipt.