

 <b>NATIONAL CANCER INSTITUTE</b>  Biorepositories and Biospecimen Research Branch		<b>GTEx Kit Receipt, Supplies, and Shipping Procedure</b>	
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## 1.0 PURPOSE

This procedure describes the process that biospecimen source sites (BSSs) follow to receive collection kits from the Comprehensive Biospecimen Resource (CBR), and the process the BSSs use to package biospecimens for shipment to the CBR, the Brain Bank (BB) or the Laboratory Data Analysis Coordinating Center (LDACC).

## 2.0 SCOPE

This procedure applies to all of the organizations involved in the collection and migration of biospecimens, specifically: the CBR, Brain Bank, LDACC, and the participating BSSs.

## 3.0 RESPONSIBILITY

- 3.1 **Biospecimen Source Site (BSS):** To collect and ship biospecimens to the appropriate processing/analysis facility.
- 3.2 **Comprehensive Biospecimen Resource (CBR):** To manage the preparation and distribution of the Aqua, Yellow, Green, and Pink shipping kits and skin biopsy media; and receipt of the Aqua kit and Pink kit specimen collections. They will also serve as the re-distribution center for biospecimens.
- 3.3 **Study Management Group:** They will train the BSSs on the type of biospecimens to be collected and their transportation requirements, e.g., shipping temperature and International Air and Transportation Association (IATA) regulation.
- 3.4 **Brain Bank (BB):** They will receive all brain and hair specimens from the BSSs.
- 3.5 **Laboratory Data Analysis and Coordinating Center (LDACC):** They will receive the blood, skin samples and half of the collected PAXgene® tissue aliquots from the BSSs.

## 4.0 DEFINITIONS & ACRONYMS

- 4.1 **BB – Brain Bank.** Enlisted as the receiving and processing facility for the brain, brain stem, and hair biospecimens collected for the GTEx project.
- 4.2 **BRIMS-** Biorepository Information Management System at the CBR used for tracking shipments to and from the CBR and BSS, as well as inventory.
- 4.3 **BSS – Biospecimen Source Site.** Hospitals and/or research facilities tasked to collect, process, store, and ship clinically-annotated biospecimens and associated data in accordance with program-developed standard operating procedures and protocols.
- 4.4 **CBR – Comprehensive Biospecimen Resource.** Centralized entity responsible for creating and managing the kit components shipped to the source sites. Also responsible for

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informatics support with the CDR, storage and processing all designated biospecimens (and associated inventory data) collected, creation of slides and digital images, maintenance of the image management system, and quality checks on collected and processed specimens.

- 4.5 **CDR** – Comprehensive Data Resource. Centralized custom-made informatics system that stores and reports all collection, handling, and processing data for biospecimens and annotations collected for use by this program. The system provides secure, role-based access for BSSs to input data related to each case collected that is associated with a Limited Data Set related to the donor. Interfaces are provided to other systems that contain related case data (e.g., inventory data at the CBR, molecular data at the molecular analysis facility, research data in dbGaP, etc.)
- 4.6 **CRF** – Case report form. A paper or electronic form used to collect donor or case-related data. Most data for each patient participating is captured and/or documented on one or more CRFs. Each form captures all protocol-/project-related information and serves as the project’s official data collection device.
- 4.7 **GTEx** – Genotype-Tissue Expression. An NIH Common Fund program initiated to determine how genetic variation controls gene expression and its relationship to disease. GTEx aims to study human gene expression and regulation in multiple tissues, providing valuable insights into the mechanisms of gene regulation and, in the future, its disease-related perturbations. Genetic variation between individuals will be examined for correlation with differences in gene expression level to identify regions of the genome that influence whether and how much a gene is expressed. GTEx provides a base set of biospecimens and data whose quality is verified by the Pathology Resource Center prior to being analyzed by the LDACC.
- 4.8 **IATA** – International Air Transport Association. The governing body that creates regulation for international air transport, including regulations controlling the transport of Dangerous Goods By Air. Persons handling transportation of biospecimens must be trained and certified to ship the appropriate hazard class according to International Air Transport Association (IATA)/International Civil Aviation Organization (ICAO) regulations. Packaging and shipping should conform to all governing regulations. Air shipments should conform to IATA standards. Ground shipments should conform to applicable federal standards. All personnel involved in shipping biological materials should be trained properly for both air and ground shipments.
- 4.9 **LDACC** – Laboratory, Data Analysis, and Coordinating Center. Research institute responsible for the overall coordination of GTEx activities and molecular and statistical analysis laboratory.

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- 4.10 **Study Management Group**– Group providing integrated program management, operational, developmental, and analysis support for major programs requiring integration of biomedical science and informatics capabilities.
- 4.11 **PDF** – Portable document format. A file format used to represent documents in a manner independent of application software, hardware, and operating systems. Each PDF file encapsulates a complete description of a fixed-layout flat document, including the text, fonts, graphics, and other information needed to display it. Can contain clickable links and buttons, form fields, video, and audio, as well as logic.
- 4.12 **SOP** – Standard operating procedure. An established procedure to be followed in carrying out a given operation or in a given situation.
- 4.13 **TCDF** – Tissue collection data form. A paper form used in the tissue recovery room to record specimen collection data. Informally called Manifest.

## 5.0 ENVIRONMENTAL HEALTH & SAFETY

- 5.1 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.
- 5.2 Certification must take place **every 2 years**, however, regulations may change annually so it is the responsibility of the IATA-certified person to review the regulations annually.
  - 5.2.1 Training may be conducted through the BSS, or offered through the Study Management Group.
  - 5.2.2 Verification of training materials, testing and certification must be provided to the Study Management Group to certify all staff involved with shipping procedures.
- 5.3 Persons handling the blood collection tubes or PAXgene® tissue containers should be aware of the hazards associated with the chemicals, and how to handle an accidental spill or exposure by reviewing the Material Safety Data Sheets. Latex or nitrile rubber gloves are required for persons directly handling the PAXgene® tissue containers.
- 5.4 Persons handling dry ice should have appropriate UN1845 training, and wear freezer gloves when handling dry ice and frozen samples.
- 5.5 Appropriate personal protective equipment should be worn at all times to include but not limited to:
  - Gown or lab coat;
  - Hair bonnet, mask, and shoe covers, per institutional requirements;
  - Latex or nitrile rubber gloves.

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## 6.0 PROCEDURE

### Kit Supplies to the BSS's

- 6.1 The CBR will provide the following color-coded kits to each BSS: the GTEEx Blood & Skin Biopsies Collection Kit to be shipped to the LDACC (Yellow kit); the GTEEx Whole Brain, Brain Stem and Hair Collection Kit to be shipped to the BB (Green kit); the GTEEx PAXgene Tissue Fixative/Stabilizer Collection Kit (Aqua kit) and GTEEx Dry Ice Preserved Tissue Collection Kit (Pink kit) to be shipped to the CBR. The overpacks, one for routine collections and another for collections with frozen tissue are also supplied by the CBR.
- 6.2 The BSSs should contact the CBR for their kit needs. Please email the CBR the type and number of kits needed. This allows ample time to ship the kits within the week. Requests received later in the week may not be able to be shipped until the following week.
- 6.3 The BSS verifies the contents of all kit shipments for any discrepancies. If a discrepancy or other issue precluding use is found, the BSS should email or call the CBR. The BSS should receive the partial kit in BRIMS. A resolution will be provided by the CBR.
- 6.4 If freezer bricks are a component of the kit, place in a -20°C freezer for at least 6 hours. Freezer bricks should be frozen **SOLID** when used.
- 6.5 **NOTE: The YELLOW kit freezer bricks remain stored at room temperature! DO NOT FREEZE!**

### Collection Event & Packing

- 6.6 Once a donor has been identified, retrieve the appropriate specimen collection kit(s) from the storage location.
  - 6.6.1 There are two types of overpacks, one for routine Post Mortem collections and the other for Post Mortem collections with frozen tissue.
- 6.7 If the brain is being collected, follow the SOP for shipping and notifications as listed in the instructions within the **Alert of Pending Collection** subsection of the **GTEEx Work Instruction for Whole Brain, Brain Stem, and Hair Collection Receipt and Shipping (Green Kit), OP-0001-W2**. A phone call must be placed by the procurement team to alert the Brain Bank hotline of an impending shipment, which in turn alerts the on-call staff.

- 6.8 Collect the specimen(s) using the **GTEEx Tissue Processing Procedure, PR-0004, and its associated work instructions**. Print and use the **Manifest and Chain of Custody (CoC)** form from BRIMS.
- 6.9 Prepare the collected specimen(s) for shipment using the appropriate color-coded work instruction(s): use the **GTEEx Work Instruction for Blood and Skin Biopsy Receipt and Shipping (Yellow Kit), OP-0001-W1** for the Yellow kit; the **GTEEx Work Instruction for Whole Brain, Brain Stem, and Hair Collection Receipt and Shipping (Green Kit), OP-0001-W2** for the Green kit; the **GTEEx Work Instruction for PAXgene Tissue Fixative/Stabilizer Collection Receipt and Shipping (Aqua Kit), OP-0001-W3** for the Aqua kit; or the **GTEEx Work Instruction for Dry Ice Preserved Tissue Collection Receipt and Shipping (Pink Kit), OP-0001-W6** for the Pink kit.
- 6.10 Follow the courier instructions to ship the aqua, green, and yellow kits. The pink kit should be shipped by FedEx.

### **Kit Shipping**

- 6.11 An automatic alert or manual email alert will be sent to the LDACC and CBR indicating pending shipment of a collection using the appropriate color-coded work instruction: for the Aqua kit, refer to the Alert of Collection subsection in the **GTEEx Work Instruction for PAXgene Tissue Fixative/Stabilizer Collection Receipt and Shipping (Aqua Kit), OP-0001-W3**; for the Pink kit, refer to the Alert of Shipment subsection in the **GTEEx Work Instruction for Dry Ice Preserved Tissue Collection Receipt and Shipping (Pink Kit), OP-0001-W6**; for the Yellow kit, refer to the Alert of Pending Collection subsection in the **GTEEx Work Instruction for Blood and Skin Biopsy Receipt and Shipping (Yellow Kit), OP-0001-W1**; and for the Green kit, alert the Brain Bank hotline of a shipment, and refer to the Alert of Pending collection subsection in the **GTEEx Work Instruction for Whole Brain, Brain Stem, and Hair Collection Receipt and Shipping (Green Kit), OP-0001-W2**. If automated alerts are not available, then a manual email alert is to be sent.