**Public Release of caHUB Standard Operating Procedures (SOPs) for the Genotype-Tissue Expression Project (GTEx)**

*The National Cancer Institute's (NCI) cancer Human Biobank (caHUB) program is pleased to release to the public a compendium of Standard Operating Procedures (SOPs) that are currently guiding the successful collection of normal human biospecimens for the NIH Genotype-Tissue Expression (GTEx) project. caHUB is releasing these SOPs to the public to provide transparency about the biospecimen collections that caHUB is conducting for the GTEx program and to enable high quality biospecimen collection by others in the research community.*

The cancer Human Biobank (caHUB) initiative was established by the National Cancer Institute's (NCI) Office of Biorepositories and Biospecimen Research (OBBR) to provide a national biobanking infrastructure governed by standardized methods for biospecimen collection, annotation, storage and distribution. Biospecimens are tissues and fluids taken from the human body and used for diagnosis, analysis and research.

In a successful pilot project, caHUB has collected high quality biospecimens and associated data to enable genomic research in the Genotype-Tissue Expression (GTEx) project, a National Institutes of Health (NIH) Common Fund initiative. The goal of the GTEx project (http:// commonfund.nih.gov/GTEx) is to increase our understanding of how changes in our genes contribute to common human diseases, in order to improve health care for future generations. The biospecimens for the project are obtained from deceased donors identified through autopsy or organ and tissue transplant programs. Every donor's generous gift of tissues and medical information to the GTEx project makes possible research that will help improve our understanding of common diseases, giving hope that we will find better ways to prevent, diagnose, treat, and eventually cure these diseases in the future. A groundbreaking research initiative, the GTEx project will generate a unique set of high-quality genomic data for the broad community of medical researchers.

The success of GTEx depends on the ability to successfully procure and store high quality biospecimens for analysis. caHUB acquires the biospecimens and associated data for GTEx through a complex operational infrastructure with several components as follows:

- **Biospecimen Source Sites (BSSs)** are rapid autopsy and organ procurement organizations that obtain patient consent, acquire specimens, and ship them to one of a number of program sites.
- The **Comprehensive Biospecimen Resource (CBR)** is a centralized site that assembles collection and shipping kits, receives most biospecimens from the BSSs for processing and storage, and ships biospecimens from the BSSs to the processing and analysis facilities.
- The **Brain Bank (BB)** receives brain and hair samples directly from BSSs.

- **The Laboratory Data Analysis and Coordinating Center (LDACC)** receives blood and skin samples shipped directly from the BSSs. Eventually, all samples are sent to the LDACC for genomic analysis.
- The **Comprehensive Data Resource (CDR)** is a centralized data storage facility that obtains patient and specimen data from BSSs and other program sites that handle and analyze samples.

Successful collection of normal human biospecimens from rapid autopsies and organ donors requires complex operations and a stringent QA/QC process. For this reason, caHUB has created a large number of SOPs to govern operations in the following areas:

- Ethical and regulatory procedures
- Biospecimen collecting and tracking
- Data collection
- Production of collection and shipping kits and checklists
- Pathology review

caHUB is releasing these SOPs to the public to provide transparency about the biospecimen collections that caHUB is conducting for the GTEx program, and to enable high quality biospecimen collection by others in the research community. These SOPs delineate exactly the procedures that govern biospecimen collection, processing, storage, and distribution as they are currently being practiced for GTEx. These SOPs will serve as an important reference as data from GTEx analysis of the biospecimens are published. While these SOPs reflect the specific logistics required by caHUB to collect tissue for this particular project, it is hoped that these documents can serve as a model for other scientists wishing to collect biospecimens for experimental purposes from rapid autopsies and organ donors.

Some important notes on these SOPs:

1. The names of specific institutions, vendors, people, email addresses, phone numbers, and geographic locations have been removed in these documents. Internal revision information relevant during the SOP development process has also been removed, as this information does not govern the biobanking operation.
2. Brand names of supplies and reagents were retained.
3. PAXgene® Tissue is the tissue preservation method utilized in these SOPs. Other tissue preservation methods are not described in these SOPs but users may want to substitute their own tissue preservation method(s) of choice.
4. The Informed Consent templates provided herein were developed as initial resources that were then adapted by the Biospecimen Source Sites to accommodate their own existing processes and procedures. These templates are not the exact consent forms being used at the Biospecimen Source Sites.

5. Since the Informed Consent Verification Forms were site-specific, one representative form was made generic (removing site name throughout the form, including the title).

For more information about tissue donation for the GTEx Project, please visit http://www.genome.gov/gtex.

For questions or comments on these SOPS, please contact: nciobbr@mail.nih.gov.