1.0 PURPOSE

This procedure provides a stepwise process for the development of the Material Transfer Agreement/Data Use Agreement (MTA/DUA) based on project and program needs and for ensuring the effective implementation of the agreement's terms and conditions for GTEx partnering sites. The MTA/DUA specifies the rights, obligations and restrictions of both the provider and the recipient regarding the materials, to include data, being transferred.

2.0 SCOPE

This procedure applies to all individuals who may collect, transfer and/or receive biospecimens and/or data as part of GTEx operations to include: BSS; CBR; collaborators' facilities; end users of biospecimens and associated data, etc. The requirements of individual projects will determine which parties will be involved in the development and implementation of the MTA/DUA.

3.0 RESPONSIBILITY

3.1.1 **ELR lead and Project Team** is responsible for working with the project sponsor to refine the requirements for implementation of the MTA/DUA. Additional parties that are involved in development and execution of this SOP will include Project Team, Biospecimen Source Site staff, Comprehensive Biospecimen Resource, Comprehensive Data Resource, and other collaborating staff.

4.0 DEFINITIONS & ACRONYMS

4.1 **BSS** – Biospecimen Source Site. Hospitals and/or research facilities who collect, process, store, and ship clinically-annotated biospecimens and associated data for the GTEx program in accordance with program-developed SOPs and protocols.

4.2 **CBR** – Comprehensive Biospecimen Resource. Centralized facility to provide collection kits to the BSS, receive and process specimens from the BSS, and distribute specimens to qualified research entities.

4.3 **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 at the Broad Institute, etc.).

4.4 **Ethical, Legal and Regulatory (ELR) Manager** – Responsible for reviewing the ethical, legal, and/or regulatory impact of each withdrawal/recall request, approving the Withdrawal/Recall Request, investigating questions or issues, consulting with lead to

resolve problems, and notifying the Requester when the process is complete. Member of the Withdrawal Approval Group.

4.5 **Material Transfer and Data Use Agreement** – An agreement that governs the transfer of tangible research materials and data between two organizations, when the recipient intends to use it for his or her own research purposes. It defines the rights and obligations of the provider and the recipient with respect to the use of the materials.

4.6 **PI** – Principal Investigator. The lead scientist at the BSS, CBR, research facility, or other institution in charge of the experiment or research project.

4.7 **Study Management Group** – A group providing integrated program management and operational, developmental, and analysis support requiring integration of biomedical science and informatics capabilities.

4.8 **TPM** – The individual responsible for direct communications with those involved with submitted SOPs, forms or other documents, as well as ensuring that relevant procedures and forms are assessed and controlled.

4.9

BBRB	Biorepositories and Biospecimen Research Branch
DCO	Document Control Order
PMT	Program Management Team
PT	Project Team
QM	Quality Management

5.0 ENVIRONMENTAL HEALTH & SAFETY

N/A

6.0 MATERIALS/EQUIPMENT

N/A

7.0 PROCEDURE

7.1 Development of Materials Transfer Agreements (MTA) and Data Use Agreements (DUA)

7.1.1 GTEx PT contacts ELR for MTA/DUA development and provide information regarding the project's requirements and operational design in order to develop

the MTA/DUA. Project requirements are defined by the project sponsor and may be further clarified and refined by consultation with ELR and the PT.

7.1.2 ELR reviews project requirements and operational design with the PT and identifies any deficiencies and provides solutions for consideration by the PT and the sponsor. PM is responsible for ensuring that the sponsor/BBRB is in concurrence with any solutions prior to implementation.

7.1.3 ELR identifies materials and/or data exchange and develops a Material and Data Flow Chart (if appropriate) to represent the Project's requirements. ELR forwards draft MTA/DUA to GTEx PT.

7.1.4 PM reviews draft requirements with appropriate project leads and sponsor/BBRB, as applicable. If approved the GTEx PT sends final requirements to ELR to finalize. If rejected, requirements are returned to ELR to address the identified deficiencies.

7.1.5 ELR forwards the approved draft MTA/DUA to the Study Management Group's Legal Department (cc PT).

7.1.6 The Study Management Group's Medical Legal Team reviews and revises the draft MTA/DUA document, as needed. The team then forwards the document to ELR and the PT for review.

7.1.7 ELR and the PT review the MTA/DUA to ensure all requirements are met. The Study Management Group's ELR is responsible for making final edits and addressing all comments to include cleanup of the document.

7.1.8 ELR lead forwards the final and approved version of the MTA/DUA to the legal representative and/or other appropriate parties defined in the project requirements for review and execution.

7.1.9 The legal representative or other appropriate party entity reviews and responds with approval, revisions required or with clarifications needed.

7.1.10 ELR, PT and the Study Management Group's legal team work to resolve any outstanding issues with the site through communications via meetings, email, phone or teleconference.

7.1.11 Once the site/collaborator has approved the document for execution, ELR will instruct the site to execute the agreement, in which the institution's signatory authority will sign and date the form. Instructions should include a due by date for return of the document and the format for which the signed agreement must be returned. The signatures from all Authorized Officials and Recipient Scientists (PI, CBR, and CDR Representatives, as applicable) listed on the agreement must be provided.

7.1.12 Once returned, ELR will provide a final review of the signed agreement for completeness. ELR will collate all signature pages from all sites/collaborators to create a single packet. ELR will create copies for storage and documentation. The packet will be forwarded to the Study Management Group's legal and Research Office, the PT and all sites/collaborators as the final executed agreement. The last signature date on the agreement is considered the executed date.

7.1.13 The TPM will forward the finalized document to QM for the DCO process which ensures proper electronic documentation in a shared format.

7.1.14 QM will assign a DCO number and completes the DCO process.

7.1.15 The document will be archived electronically by QM in a document system.