1.0 PURPOSE

This procedure provides instructions for completing, signing, correcting and filling out the project related case report forms (CRFs) in paper and electronic formats.

2.0 SCOPE

CRFs can be printed or electronic data collection tools can be used to capture all protocol related information and are considered the project's official documentation.

3.0 RESPONSIBILITY

3.1 Only project staff that are designated by the principal investigator (PI) or biospecimen source site (BSS) may complete CRFs.

3.2 Designated project staff responsibilities include:

3.2.1 Completing, signing, correcting and managing CRFs, as required by the specific task and project needs

3.2.2 Verifying that the data entered into the CRFs are complete and accurate, with oversight from the PI

3.2.3 Identifying inaccurate data entry and notifying the project manager (PM) or data entry verification staff

3.2.4 Ensuring all data corrections are captured accurately

3.2.5 Forwarding copies of CRFs and other associated documents to all relevant parties and working with other parties per project specific standard operating procedures (SOPs)

3.3 Project staff, with oversight from the PI and PM, are responsible for securing the CRFs and complying with project data retention policies, as applicable.

4.0 DEFINITIONS & ACRONYMS

4.1 **Authorization form** – Used to obtain the documented decision to make an anatomical gift of body or body parts and associated data by an agent of the decedent. Document provides information about donation uses, rights, risks and alternatives.

4.2 **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 SOPs and protocols.

4.3 **CAPA** – Corrective Action/Preventive Action

4.4 **Case ID** – Unique alpha-numeric identification of a case. This coded ID is assigned by the BSS to all of the components of a collection kit at the time that a consented donor is identified. This ID subsequently identifies the genealogy of all specimens collected and/or aliquots derived from that case.

4.5 **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.

4.6 **CDR** – Comprehensive Data Resource. Centralized custom-made informatics system for 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 LDACC, etc.).

4.7 **Corrective action** – An action or activity instituted to eliminate the cause of a detected nonconformity or other undesirable situation.

4.8 **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.

4.9 **EDC** – Electronic data capture. Performed in the CDR.

4.10 **GCP** – Good Clinical Practice. An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

4.11 **ICF** – Informed Consent Form. A legally-binding data collection form used to capture each donor stipulation that their tissues may be used for medical research.

4.12 **NOK** – Next of Kin. Nearest relative to the donor with the responsibility of providing consent for use of donor tissues on behalf of the donor.

4.13 **Nonconformance** – Lack of compliance with a specified process or procedure or failure to fulfill a requirement.

4.14 **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.

4.15 **PHI** – Protected Health Information. Individually identifiable health information as defined in the HIPAA regulations (45 CFR § 160.103) that is or has been collected or maintained by the covered entity in the course of providing healthcare that can be linked back to the individual participant.

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

4.17 **PM** – Project Manager. Each PM is responsible for the planning and implementation of all activities that will deliver the systems, documents, and resources to meet the requirements of their project using all appropriate processes and procedures.

4.18 **Project staff** – Local BSS staff identified as qualified, per PM and PI, to participate in the project.

4.19 **SOP** – Standard Operating Procedure. An established procedure to be followed in carrying out a given operation or in a given situation.

4.20 **Source document** – Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory results, memoranda, participant diaries, recorded data from automated instruments, x-rays, etc.) that are used in a clinical trial or research studies.

4.21 **Specimen ID** – Identifies each biospecimen collected from a study subject and is used on all biospecimen containers (i.e., cryosettes, tissue cassettes, cryovials) and glass slides. Specimen identification consisting of a case ID (e.g., GTEX-123456) and a sequence number (e.g., 7890) that together form the final alpha-numeric ID; e.g., GTEX-123456-7890.

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

5.0 ENVIRONMENTAL HEALTH & SAFETY

Not Applicable

6.0 MATERIALS/EQUIPMENT

Not Applicable

7.0 PROCEDURE

7.1 Authority to Complete CRFs: The following must be verified prior to capturing data on project CRFs:

7.1.1 PI must ensure designated authority and necessary training to BSS project staff to complete CRFs.

7.1.2 BSS project staff must ensure that the correct version of the CRF, per project SOP, is being used to capture project data.

7.1.3 BSS project staff must ensure the necessary approvals or authorizations have been documented by the participant/donor, including completed and verified ICF and NOK authorization forms, PRIOR to collecting data on CRFs.

7.2 Techniques for Data Collection: The following techniques should be followed when capturing data on project CRFs:

7.2.1 Always use a blue or black ballpoint pen for entering data into paper forms. Never use pencil or other writing instruments.

7.2.2 Data entered must be accurate, clear and legible.

7.2.3 Abbreviations and acronyms must be avoided unless previously agreed upon and documented by the PM.

7.2.4 Patient identifying information should not be included in the CRF.

7.2.4.1 **Only the Case ID and Specimen ID numbers should be recorded on the form.** The Case ID will only be available if a donor has consented and has passed the eligibility criteria and a donor collection kit has been identified. The Case ID will be associated with the collection kit appropriate for the type of biospecimens being collected.

7.2.4.2 Other identifiers such as medical record number, social security number, or other direct or indirect identifiers should not be included.

7.2.4.3 CRF may contain dates (mm/dd/yyyy) such as date of birth and other related dates associated with the donor and donor biospecimen collections.

7.2.5 All sections must be completed. No spaces or boxes may be left blank.

7.2.5.1 Avoid using unclear/ambiguous statements such as “unavailable”.

7.2.5.2 If information is missing, the following abbreviations must be used:

NA: not applicable

ND: not done (a comment may be required as an explanation)

UU: unknown/not able to identify in medical record review

7.2.5.3 For missing or unknown dates, mark "Unknown".

7.2.6 All recorded data must be entered in the unit(s) specified on the CRF.

7.2.7 Open text comment fields should be used to capture information specific to CRF content; i.e., procurement comments on the tissue recovery CRF should pertain specifically to procurement or processing information. Informed consent CRF comments should pertain specifically to issues related to the consenting process or documentation, etc.

7.2.7.1 **Reminder:** PHI ***must not*** be entered into open text comment fields.

7.2.8 The information entered into the CRF must be the same information on the source document/medical record.

7.2.9 PDF copies of paper completed CRFs should be uploaded to the CDR within 10 business days of data collection completion. If possible, all CRFs should be converted into a single PDF before uploading.

7.2.9.1 This can be done by going into the CDR system and clicking on the button titled “new file upload”.

7.3 Making Corrections on CRFs: The following techniques should be followed when a CRF entry is incorrect and a correction is needed:

7.3.1 To make a correction, **DO NOT** use correction fluid or white out at any time.

7.3.2 Draw a single line through the incorrect item and write the correct information next to the error.

7.3.3 Corrections should not obscure the original entry.

7.3.4 For each correction, draw a single line through the incorrect entry and write the correct entry next to it. Then initial and write the date near the correction. Example:

7	~~5~~ 4 JPR mm/dd/yyyy

If the correction is not made prior to CDR data entry post-procurement, the BSS project team should update the relevant page(s) with the change(s), initial and date the form, and re-upload the revised CRF.

7.3.5 PDF copies for the corrected CRFs should be uploaded to the CDR within 10 business days of data collection.

7.3.5.1 This can be done by going into the CDR system and clicking on the button titled “new file upload”.

7.4 CRF Completion:

ALL CRFs are required to be completed electronically. When a paper CRF is used, it should be completed according to the CRF-specific guidance.

The data recorded on the TRF is required to have a source record, whether on the provided TRF or on a local form version. The medical collection CRF is required to have source records, whether on the provided medical collection form or other medical records, etc.

7.4.1 Informed consent verification CRF (***PM-0003-F1/F2***): ***To be completed upon consent as soon as possible but no later than two days after consent.***

7.4.2 ***GTEx Donor Eligibility Criteria form (PM-0003-F4). To be completed as soon as possible but no later than two days .***

7.4.3 ***GTEx Tissue Recovery CRF (PM-0003-F5). To be completed, upon completion of procurement, as soon as possible but no later than two days .***

7.4.4 ***GTEx Clinical Collection CRF (PM-0003-F6). To be completed, upon medical record review, as soon as possible but no later than 10 days after review .***

7.4.5 GTEx Data Correction Form (DCF) (OP-0016-F2). To be completed, upon initiation of DCF, as soon as possible.

7.5 CRF Completion and Data Entry Timelines:

7.5.1 Timetable for paper CRF completion and EDC completion:

CRF Name	Time to Complete Paper CRF	Time to Complete EDC
[Organization] Informed Consent Verification Form (PM-0003-F1, PM-0003-F2)	Immediately upon completion of screening and consenting process	Within 2 business days of collection event
GTEx Donor Eligibility Criteria Form (PM-0003-F4)	Immediately upon verification of eligibility	Within 2 business days of collection event
GTEx Tissue Recovery CRF (PM-0003-F5)	Immediately upon completion of procurement	Within 2 business days of collection event

GTEx Clinical Collection CRF (PM-0003-F6)	Immediately upon completion of medical history review	Within 10 business days of collection event
GTEx Data Correction Form (OP-0016-F2)	Immediately upon identification of data discrepancy	N/A

7.6 CRF Data Verification: The Study Management Group staff will review CDR data entry and communicate any discrepancies to the site staff.

7.7 Filing and Storage of CRFs:

7.7.1 A legible copy of the CRF must be securely retained at the site or at a designated storage facility that is secure for the project retention period after the close out of the project.

7.7.2 PM or designated staff may contact the originating site for data clarifications as part of data management verification procedures.

7.7.3 The BSS PI or designated project staff is required to process the data queries and clarifications in a timely manner.

7.7.3.1 If query relates to tissue type identification or labeling- resolution is expected as soon as possible upon issuance of a DCF.

7.7.3.1.1 Email PM or Issue Manager, if necessary, a CAPA will be issued.

7.7.3.2 If query is NOT related to tissue identification (e.g. clinically related), a response/resolution is requested within 3 business days of issue notification.

7.7.3.2.1 Email PM or Issue Manager, if necessary, a CAPA will be issued.

7.7.3.3 A BSS identified error should be corrected immediately upon identification of error.

7.7.3.3.1 If the EDC is locked, a notification for data entry error resolution should emailed to the appropriate individuals.

7.7.3.3.2 Identify Case ID and case report form/field for correction. The CDR will place the file in remediation which will allow the site to correct the data in the CDR.