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 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 case report forms.

3.2 Designated project staff responsibilities include:

3.2.1 Responsible for completing, signing, correcting and managing CRFs, as required by the specific task and project needs.

3.2.2 Responsible for verifying that the data entered into the CRFs are complete and accurate, with oversight from the PI.

3.2.3 Responsible for identifying inaccurate data entry and notifying the Project Manager (PM), or data entry verification staff.

3.2.4 Responsible for ensuring all data corrections are captured accurately.

3.2.5 Responsible for 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 ACRONYMS AND DEFINITIONS

4.1 **Authorization form** – Document 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

4.3 **CAPA** – Corrective and preventive action

4.4 **Case ID** – Case identification. Unique alphanumeric parent identification and assigned to a complete kit's components (e.g., GTEX-123456).

4.5 **CDR** – Comprehensive Data Resource

4.6 **Corrective action** – An action to eliminate the cause of a detected nonconformity.

4.7 **CRF** – Case report form. CRFs are printed or electronic data collection tools used to capture all protocol/project related information and serve as the project's official documentation.

4.8 **EDC** – Electronic data capture performed in the comprehensive data repository.

4.9 **GCP** – Good Clinical Practice

4.10 **ICD** – Informed consent document

4.11 **Major nonconformance** – A nonconformance or a series of minor nonconformances that have a significant effect on product, processes, or outcome of processes.

4.12 **Minor nonconformance** – A nonconformance characterized by minor discrepancies with little or no effect on product, processes, or outcome of processes.

4.13 **NC** – Nonconformance

4.14 **NCR** – Nonconformance report

4.15 **NOK** – Next of kin

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

4.17 **PDF** – Portable document format

4.18 **PHI** – Protected Health Information

4.19 **PI** – Principal Investigator

4.20 **PM** – Project Manager

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

4.22 **SOP** – Standard operating procedure

4.23 **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.

4.24 **Specimen ID** – 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.

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 informed consent documents (ICD) and next of kin (NOK) authorization form, 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:

7.2.5.3.1 On the paper form: Please provide as much information as is possible , such as “12/2001” if a test was performed on an unknown day in December 2001.

7.2.5.3.2 In CDR: The date must be estimated in order to be entered in the CDR. Note "Date Estimated" on the paper CRF and indicate the estimated date as a complete date, e.g. "12/15/2001".

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 any 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 noted to be 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 JPG 01/06/2012

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 Form (PM-0003-F2): To be completed upon consent as soon as possible but no later than 2 days.*** (see Attachment 7)

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 form (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 case report form (PM-0003-F6). To be completed upon medical record review - as soon as possible but no later than 10 days.***

7.4.5 GTEx Data Correction Form (PM-0004-F1). 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
Informed Consent Verification Form (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 Form (PM-0003-F5)	Immediately upon completion of procurement	Within 2 business days of collection event
GTEx Clinical Collection Case Report Form (PM-0003-F6)	Immediately upon completion of medical history review	Within 10 business days of collection event
GTEx Data Correction Form (PM-0004-F1)	Immediately upon identification of data discrepancy	N/A

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

7.6.1 See ***caHUB CDR Data Services User's Guide*** for more specific procedures.

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 within 24 hours of issue notification.

7.7.3.1.1 Email Project Manager 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 7 calendar days of issue notification.

7.7.3.2.1 Email Project Manager 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 be forwarded via e-mail.

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.

8.0 ATTACHMENTS

8.1 Informed Consent Verification Form, PM-0003-F2

8.2 GTEx Donor Eligibility Criteria Form, PM-0003-F4

8.3 GTEx Tissue Recovery Form, PM-0003-F5

8.4 GTEx Clinical Collection Case Report Form, PM-0003-F6

APPROVALS	
NAME / TITLE	

EFFECTIVE/REVISION HISTORY			
REV #	DESCRIPTION OF CHANGE	AUTHOR	EFFECTIVE/REVISION DATE