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1.0 PURPOSE

The purpose of this document is to provide instructions to correct data entry errors in the program.

2.0 SCOPE



This procedure covers the entry of candidate and biospecimen data into multiple systems: the Comprehensive Data Resource Data Services (CDR DS) and all data capture systems used by participants.

3.0 RESPONSIBILITY

- 3.1 When possible, the BSS is responsible for correcting its own data entry errors in the system in a timely manner.
- 3.2 The CDR DS Informatics team is responsible for maintaining and updating the systems and associated documentation. Other participants are responsible for maintaining and updating their site based data capture systems and associated documentation.

4.0 DEFINITIONS & ACRONYMS

- 4.1 **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 (SOPs) and protocols.
- 4.2 **Business Day** – Monday through Friday, excluding the holidays of the organization using this SOP and associated work instructions.
- 4.3 **CBR** - Comprehensive Biospecimen Resource. Centralized entity responsible for creating and managing the kit components shipped to the source sites. Also responsible for informatics support with the CDR, storage and processing of all designated biospecimens (and associated inventory data) collected for use, creation of slides and digital images, and maintenance of the image management system, as well as quality checks on collected and processed specimens. The CBR serves as the re-distribution biorepository.
- 4.4 **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.).
- 4.5 **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.

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- 4.6 **DCF** – Data Correction Form. Documents the identification and resolution of data entry errors.
- 4.7 **DM** – Data Manager. Study Management Group that controls the quality of data gathered during the tissue procurement process by verifying the accuracy of data in the system and ensuring the data correction process is followed.
- 4.8 **Processing facility** – Any facility that receives GTEr biospecimens whose shipments are tracked in the CBR system.
- 4.9 **SOP** – Standard Operating Procedure. An established procedure to be followed in carrying out a given operation or in a given situation.
- 4.10 **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



NA

6.0 MATERIALS AND EQUIPMENT

- 6.1 Computer with internet access
- 6.2 Adobe Reader v.9.0 and later

7.0 PROCEDURE

- 7.1 Any member of the participating project initiative or BSS can identify data entry errors.
 - 7.1.1 The issue identifier determines if the error can be corrected at the BSS in the CDR or in any participants' data capture systems.
 - 7.1.1.1 A data entry error can be corrected at the site level if the data field where the error occurred is not static (hard coded in case).
 - 7.1.1.2 CRFs made available for data entry to site personnel when a case enters "**Data Entry Underway**" Status can be modified and corrected at the site level. The data contained in these CRFs are dynamic.
 - 7.1.2 If yes, the BSS is instructed to take corrective action.
 - 7.1.2.1 The BSS updates paper forms and appropriate participants' data capture systems and saves changes.
 - 7.1.2.2 The BSS determines the "case status" in the CDR.
 - 7.1.2.3 If the CDR case status is "Data Entry Underway" or "Data Entry Complete" the BSS updates the CDR and saves changes.
 - 7.1.2.4 If the CDR case status is "BSS QA Review Complete" the BSS contacts the Study Management Group DM team and requests access to the locked case and the DM places the case in Remediation.
 - 7.1.2.5 BSS updates CDR and saves changes.
 - 7.1.3 If no, issue identifier should initiate a DCF.
- 7.2 The issue identifier documents the issue source site, the project case ID and project systems affected, and the error identified on the editable DCF PDF. The issue identifier sends the DCF to the Study Management Group DM. This initiates the DCF process.
- 7.3 The DM receives the DCF and logs the issue appropriately. The DCF is assigned a unique identifier which references the case ID and date of notification. I.e., DCF-PROJ123-04132013.
- 7.4 The DM forwards the DCF to the project manager (PM) at the site where the error occurred (BSS, Study Management Group, etc.).
- 7.5 The PM at the site verifies the error and completes section 1 (questions 1a-1d) of the DCF, which is a detailed description of the error with corrective actions and sign off.
- 7.6 If the error affects data on a paper form, the BSS PM hand corrects the paper form and uploads it to the appropriate participants' data capture system using the procedure documented in the **specified User Guide**.
- 7.7 The PM returns the DCF with a completed section 1 to the DM.
- 7.8 The DM receives the DCF and determines the proper corrective action.
- 7.9 If the error requires modification to a data capture system, the DM sends the DCF to the participating PM.
- 7.10 The CDR alerts the participating PM via email to correct the error, complete and sign section 2 (questions 2a-2c) of the DCF, and return it to the Study Management Group DM.
- 7.11 If the error requires a modification to a CDR component, the DM assigns it to the appropriate informatics team staff.
- 7.12 The assigned staff corrects the CDR, completes and signs section 3 (questions 2d-2f) of the DCF, and returns it to the DM.

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- 7.13 The site where the error occurred verifies the correction, completes and signs section 4 (questions 3a-3d) of the DCF, and returns it to the DM.
- 7.14 The DM verifies the correction and completes and signs section 5 (questions 3e-3h) of the DCF.
- 7.15 The DM completes the DCF documentation and any associated documentation linked to an identified issue.
- 7.16 If the error noted in the DCF is deemed significant by the Study Management Group or BSS, a Nonconformance Report (NCR), including a Root Cause Analysis and Corrective/Preventive Actions (CAPA) plan will be required from the originating entity.