



1.0 PURPOSE

The purpose of this procedure is to provide instructions to the participating Biospecimen Source Sites (BSS's) for entering biospecimen and candidate data into the systems that support the caHUB (cancer Human Biobank) program.

2.0 SCOPE

This procedure covers the entry of candidate and biospecimen data into two caHUB systems: the Comprehensive Data Resource Data Services (CDR-DS) and the Bio4D system used by the Comprehensive Biospecimen Resource (CBR).

3.0 RESPONSIBILITY

- 3.1 The BSS is responsible for entering data into caHUB systems in a timely manner.
- 3.2 The caHUB Informatics is responsible for maintaining and updating the caHUB systems and associated documentation.

4.0 ACRONYMS & DEFINITIONS

- 4.1 **Bio4D** – This is the biospecimen inventory management system provided and administered by the Comprehensive Biospecimen Resource (CBR).
- 4.2 **Biorepository** – The institution contracted to participate in this project.
- 4.3 **Biospecimen** – Tissues and fluids taken from the human body and used for research.
- 4.4 **Biospecimen Source Site (BSS)** – Institutional staff at each contracted BSS will perform the following in the caHUB systems: creation of candidate records, acknowledgement of candidate consent, linking of de-identified candidate to collected biospecimens, data entry, and data verification.
- 4.5 **Business Day** – The days Monday through Friday, excluding holidays of the organization using this SOP and associated work instructions.
- 4.6 **cancer Human Biobank (caHUB)** – The caHUB is a project-driven NCI initiative designed to provide high-quality, well-annotated biospecimens and structured logistical operational procedures and processes to NCI and NIH-sponsored projects.
- 4.7 **Case Report Form (CRF)** – Paper form used to collect project data. All data on each patient participating in the caHUB are held and/or documented on one or more CRFs.
- 4.8 **Collection Protocol** – A Standard Operating Procedure (SOP) that implements the experimental design, and defines what will be done at a level of detail sufficiently specific to provide unambiguous instructions to operational staff to carry out the study, perform the necessary procedures, collect the requisite data, and provide specimens and data to the study sponsor.
- 4.9 **Comprehensive Data Resource Data Services (CDR DS)** – A computerized system designed for the collection of clinical data in electronic format, providing the de-identified linkage between consented candidates and biospecimen collections (cases).



- 4.10 **Genotype-Tissue Expression Project (GTEx)** – This initiative will determine how genetic variation controls gene expression and its relationship to disease. The National Cancer Institute's (NCI) cancer Human Biobank (caHUB) will lead the GTEx biospecimen acquisition sub-initiative comprised of three biospecimen source sites and a laboratory data analysis and coordinating center.
- 4.11 **Principal Investigator (PI)** – The local scientist at the BSS in charge of the experiment or research project.
- 4.12 **Processing facility** – Any facility that receives caHUB biospecimens whose shipments are tracked in the Bio4D system.
- 4.13 **Specimen ID** – Specimen identification, consisting of a Case ID (e.g., GTEX-123456) and a sequence number (e.g., GTEX-123456-0125)
- 4.14 **Standard Operating Procedure (SOP)** – A document written to establish the tools and processes needed for a given task to ensure consistency.
- 4.15 **Tissue Reporting Form (TRF)** – A paper form used in the collection room to record specimen collection data.
- 4.16 **User ID** – Assigned by the administrator for each individual given access to the CDR. This is a unique ID based on each individual's personal email address and is password protected.

5.0 WORKFLOW

Before work begins in CDR Data Services by caHUB personnel, data entry occurs at the BSS and processing centers to which the biospecimens are shipped. For details of these entry operations refer to the **Work Instruction for Data Entry at BSS (IT-0001-W1)** and the associated Bio4D users guides.

A more detailed overall system workflow can be found in attachment caHUB Candidate and Specimen Data Entry Process Flow (IT-0001-P1)

6.0 SUPPORT

If you have questions or technical problems while using the application, contact the CDR help desk.

7.0 ATTACHMENTS

- 7.1 Work Instruction for Data Entry at BSS, IT-0001-W1
- 7.2 caHUB Candidate and Specimen Data Entry Process Flow, IT-0001-P1



INITIATION/REVISION HISTORY

REV #	DESCRIPTION OF CHANGE	AUTHOR	EFFECTIVE DATE