

Work Instruction for caHUB Data Entry at BSS

IT-0001-W1

Ver. 02.00

Effective Date: 01/11/2012

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1.0 PURPOSE

This work instruction provides the steps for entering candidate and biospecimen information into the systems that support the collection, handling, shipping, and storage of biospecimen and candidate data for the caHUB (cancer Human Biobank) program. This work is performed by staff at each participating Biospecimen Source Site (BSS) and associated biorepositories, as described in the **caHUB Data Entry Procedure (IT-0001)**.

2.0 ENVIRONMENTAL HEALTH & SAFETY

Not applicable

3.0 MATERIALS & EQUIPMENT

- 3.1 Computer station with either of the following installed: Windows XP (or higher)
- 3.2 Internet access
- 3.3 CDR Data Services is a web application. It has been tested with the following PC-based browsers: Internet Explorer 8 and 9; Google Chrome 13; and Firefox 3.5x, 4, and 5
- 3.4 Certified browser (Internet Explorer 7.0, Mozilla Firefox 2.0.0.14, or Safari 3.1)

4.0 PROCEDURE

The following table is an overview of the steps from consent to completion of BSS work on a collection event.

BSS Action Events	Comment
Obtain consent. Determine eligibility.	Refer to PM-0003-F4, GTEx Donor Eligibility Criteria Form to determine the eligibility.
Create candidate in CDR	Refer to IT-9001 CDR Data Services User's Guide.
Enter informed consent verification and eligibility	Screen failures must be entered within two business days of candidate approach. Consented donors must be entered within two business days of collection. Refer to IT-9001 CDR Data Services User's Guide.
Enter data from paper TRF into Bio4D PDF	If PDF problems occur, contact the CBR.
Log into Bio4D to prepare shipment and attach or email the PDF	
Hand off biospecimens to couriers	Refer to OP-0001, GTEx Kit Receipt, Supplies, and Shipping Procedure.
Link candidate to case in CDR	Refer to IT-9001 CDR Data Services User's Guide.
Enter TRF into CDR and upload scanned paper copy	Candidate linking and TRF entry and upload must occur within two business days of collection. Refer to IT-9001 CDR Data Services User's Guide.
Enter clinical case report form (CRF) into CDR	The CRF must be entered within ten business days of collection. Refer to IT-9001 CDR Data Services User's Guide
Change CDR case status to DATA ENTRY COMPLETE	Upon completion of data entry by the BSS, the Case Status should be changed to "Data Entry Complete".
Perform review of data	Perform local review of electronic data and correct data entry errors noted.

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BSS Action Events	Comment
Change CDR case status to BSS QA REVIEW COMPLETE	After completing the local QA review and making updates to the CDR Data Services system, the BSS should update the Case Status to " BSS QA Review Complete ". <i>After this point, the record is locked. To request reopening for data entry, email CDR.</i> Refer to IT-9001 CDR Data Services User's Guide

4.1 Preconditions

Prior to performing the steps in this procedure, two activities must be complete:

- 4.1.1 For the donor candidate, enter the appropriate Informed Consent and Eligibility Forms. Refer to IT-9001, the CDR Data Services User's Guide for instructions.
- 4.1.2 Complete the collection of the biospecimens and associated data using the appropriate SOPs. The Tissue Recovery Form, in particular, must be used to collect biospecimen data. This form is attached to the **CRF Completion SOP (PM-0003)**.

4.2 Candidate Identification & Initial Data Entry

Once the appropriate paperwork has been completed and the biospecimen collection has occurred, within two business days the following steps must occur.

- 4.2.1 Log in to the CDR DS system and create a new candidate record.
- 4.2.2 Enter verification of Informed Consent information and eligibility.

4.3 Biospecimen Collection & Case Creation

NOTE: The following steps must be completed for each biospecimen collection shipment.

- 4.3.1 Complete the PDF Bio4D GTEEx Tissue Data Collection Form (surgical or postmortem/OPO specific) using the data from the Tissue Recovery Form and upload to the Bio4D system. Note: There might be a delay of up to 10 minutes before the case appears in the CDR DS system.

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4.3.1.1 Upon completion of biospecimen collection and Bio4D data entry, data entry into the CDR Data Services system can begin. Newly uploaded cases that are not linked to a specific candidate have a Case Status of "**Collected**". This means that the tissue collection is complete and the Bio4D data has been received. Candidates in the "**Collected**" status cannot be edited or modified by the BSS.

4.3.2 Pack and ship the kit(s) to the appropriate biorepositories (e.g., LDACC, Brain Bank, CBR, etc.), using the **GTEx Kit Receipt, Supplies, and Shipping Procedure (OP-0001)**.

4.3.3 Enter shipping and tracking information into Bio4D.

4.4 Final Data Entry

This procedure must begin within two business days and be completed within ten business days of the collection.

4.4.1 **Within two business days of the collection event**, log into the CDR DS system

4.4.1.1 Enter previously obtained informed consent and donor eligibility information.

4.4.1.2 Link the candidate to the case.

4.4.1.2.1 Upon completion of the Consent Verification and Donor Eligibility Criteria, a candidate can be linked to a case. Once linked, the Case Status automatically becomes "**Data Entry Underway**". The BSS is able to enter, edit and modify data in the "**Data Entry Underway**" status.

4.4.1.3 Enter the TRF form data for that candidate.

4.4.1.4 Upload the paper TRF form to CDR DS.

4.4.2 **Within ten business days of the collection event**, log into the CDR DS system and:

4.4.2.1 Enter the Clinical Case Report Form (CRF) data for that candidate.



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4.4.2.2 When all data entry has been completed by the BSS, the Case Status should be changed to "**Data Entry Complete**". While in this status, the BSS can perform simple/complex reviews of the data. Cases in the "**Data Entry Complete**" can be edited or modified by the BSS.

4.4.2.3 After completing the BSS initiated Quality Assurance review and making updates to the CDR Data Services system, the BSS should update the Case Status to "**BSS QA Review Complete**". All cases must be placed in the "**BSS QA Review Complete**" status prior to being accepted for review by caHUB (GTEx Project). Cases in the "**BSS QA Review Complete**" are locked from further data entry and cannot be edited or modified by the BSS.

4.5 If data entry errors are identified, and the case is locked, please contact the GTEx Data Management team. Cases requiring edits or modifications to the data entered in the CDR Data Services system by the BSS will be placed in the Case Status "**Remediation**". Cases identified by the "**Remediation**" status have been unlocked by caHUB (GTEx Project) for data corrections by the BSS..

If the error involves the TRF, please refer to the **GTEx Data Correction Form (PM-0004-F1)** for instructions.

5.0 Help Desk Support: If you have questions or technical problems while using the CDR DS application, contact the CDR help desk.

6.0 REFERENCES

- 6.1 caHUB Data Entry Procedure, IT-0001
- 6.2 CRF Completion SOP, PM-0003
- 6.3 GTEx Kit Receipt, Supplies, and Shipping Procedure, OP-0001
- 6.4 GTEx Data Correction Form, PM-0004-F1