Unit Procedure

Specimen Receipt, Tracking and Distribution

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Department: Processing Laboratory

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1. OBJECTIVE

1.1. This Standard Operating Procedure (SOP) describes the procedures used in the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL) for receiving, log-in, log-out, tracking and distribution of samples from the CTSL to study protocol personnel or designee. Sample receipt and tracking is essential to the function of the Indiana CTSI CTSL. The CTSL must maintain records that accurately reflect all significant actions and document processing and storage within conditions identified by study personnel per CTSI-CRC-PL-151 Managing Requests for Sample Processing Support. The samples need to be able to be retrieved from storage upon request in a timely and orderly fashion. Records must document full accountability from receipt to release.

2. SCOPE

2.1. This SOP applies to CTSL personnel who receive samples for processing and/or storage. It defines the procedure for the receiving, tracking (login/out, processing) and distribution of samples managed by the CTSL. The scope also defines the process for communicating the status of samples received to the investigators.

3. RESPONSIBILITIES

3.1. Processing Lab staff is responsible for ensuring bio-specimens are received, logged-in and tracked through the processing and storage lifecycle according to protocol specific requirements and in compliance with all associated safety and regulatory guidelines.

3.2. It is the responsibility of the personnel releasing specimens to ensure that each sample is clearly and properly labeled as well as ensuring that requisite study documentation is completed according to the CTSL sample processing directives for the applicable protocol.

3.3. It is the responsibility of the receiving study personnel to ensure that each sample is checked for accuracy against the specific study requirements. After release, this release document is considered the single authoritative source document for sample release from the CTSL.

4. DEFINITIONS

ICRC: Indiana Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	ID: Identification
IUSM: Indiana University School of Medicine	PI: Principle Investigator
PL: Processing Lab	

SSF: Specimen Storage Facility	SOP: Standard Operating Procedure
WebCAMP: Web Center Administrative Management Program	

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 Document Control and Management
5.2. CTSI-CRC-CLN-030 Handling of SOP Deviations
5.3. CTSI-CRC-CLN-031 Handling of Protocol Deviations
5.4. CTSI-CRC-PL-104 Problem Management and Discrepancy Resolution
5.5. CTSI-CRC-PL-121 General Safety
5.6. CTSI-CRC-PL-151 Management of Requests for Sample Processing Support
5.7. CTSI-CRC-PL-157 Mislabeled/Unlabeled Specimens
5.8. CTSI-CRC-PL-158 Data Sample Management System
5.9. CTSI-CRC-PL-301 Mechanical Refrigeration Units

6. PROCEDURE

6.1. Materials
  6.1.1. Freezer box labels, low temperature and LN_2 resistant (e.g., Cryo-Babies® part no. 9187-1700)
  6.1.2. Storage containers (cryoboxes, Ziploc bags)
  6.1.3. Study specific protocol instructions CTSI-CRC-PL-FM508 Lab Processing Sheet or other protocol directions for processing.
  6.1.4. 4°C/-20°C/-80°C Mechanical Refrigerators/Freezers (CTSI-CRC-PL-301 Mechanical Refrigeration Units).
6.2. Sample Receipt
  6.2.1. Sample acquisition is per CTSI-CRC-PL-FM506 CTSL Sample Management and Protocol Specific Training Form or as protocol requires.
  6.2.2. Sample acquisition methods are:
    6.2.2.1. Study/CRC personnel deliver sample(s) in person or by pneumatic tube delivery system.
    6.2.2.2. Courier service delivers sample(s) to CTSL
    6.2.2.3. CTSL staff retrieves sample(s) from designated areas according to schedule agreed upon by CTSL and study personnel.
6.3. Sample Log-in
  6.3.1. Evaluate whether samples meet acceptance criteria. Samples must be labeled with at least two unique identifiers such as name, MRN, study number, subject ID or other identification that match documentation such as study requisitions, scheduled login entries on CTSI-CRC-PL-LG615 Specimen Receipt Log or protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet(s).
  6.3.2. For samples **that meet** acceptance criteria, proceed with step 6.3.4.
  6.3.3. For samples **failing to meet** acceptance criteria:

6.3.3.1. Unlabeled/mislabeled specimens will be held until identification can be determined per CTSI-CRC-PL-157 Unlabeled/Mislabeled Specimens.
6.3.3.2. Note any other discrepancies on corresponding processing form(s), and/or any other study related documentation.
6.3.3.3. Immediately notify the study coordinator of discrepancies.
6.3.3.4. If unable to reach the study coordinator, refer to the CTSL Management for direction.
6.3.3.5. Do not destroy the sample unless written directives (e-mail is acceptable) are received from study personnel.
6.3.3.6. Record all actions in investigating/resolving discrepancies on corresponding processing form(s), as applicable.
6.3.3.7. Document final resolution on CTSI-CRC-PL-FM508 Lab Processing Sheet, CTSI-CRC-PL-FM511 Unlabeled-Mislabeled Specimen Form and/or any other study related documentation as applicable.

6.3.4. Compare any other study related documentation, if provided, with the samples received.
6.3.4.1. If there are no discrepancies, proceed with processing and/or storage as noted.
6.3.4.2. If there are discrepancies, proceed with resolution steps described under 6.3.3.

6.3.5. Log in samples with the following information, as applicable, on the CTSI-CRC-PL-LG615 Specimen Receipt Log that was prepared per CTSI-CRC-PL-152 Protocol Visit Setup and Labeling.
6.3.5.1. Study/Protocol Name
6.3.5.2. Sample/Subject ID
6.3.5.3. Visit Time point
6.3.5.4. Collection Time: Include date if not drawn on same date of log.
6.3.5.5. Received time
6.3.5.6. Received by
6.3.5.7. Total number of tubes
6.3.5.8. Number of each type/color of tube
6.3.5.9. Indicate if urine was received and type of container (J=jug, C=cup)
6.3.5.10. Note any other pertinent information as needed in comments section or by footnote.

6.3.6. Multiple collection visits (MCV)
6.3.6.1. Specimens received for study visits that have multiple collection time points are logged into CTSI-CRC-PL-LG616 Multiple Collection Visit Specimen Receipt Log.

6.3.6.2. A notation of MCV will be entered on the appropriate study visit line on the CTSI-CRC-PL-LG615 Specimen Receipt Log if the visit was scheduled.

6.3.6.3. If the multiple collection visit is not found on the CTSI-CRC-PL-LG615 Specimen Receipt Log, an entry on the applicable CTSI-CRC-PL-LG615 Specimen Receipt Log will be made with the notation of "MCV" placed in the collection time box.

6.3.7. File CTSI-CRC-PL-LG615 Specimen Receipt Logs (except MCV logs), dated with the current year, together in the CTSL Specimen Log-In forms folder.

6.3.8. File all MCV logs in the MCV study specimen log binder.

6.3.9. If logging in samples via a printed spreadsheet or other manifest, enter a single line entry on the applicable CTSI-CRC-PL-LG615 Specimen Receipt Log.

6.3.9.1. Spreadsheets or other manifest type documents will be printed and attached to the date specific CTSI-CRC-PL-LG615 Specimen Receipt Log. A notation on the single line log entry will be entered referring to the attachment.

6.3.10. Electronically scan all study specific CTSI-CRC-PL-FM508 Lab Processing Sheets and save in a study-specific folder:

6.3.10.1. CRC studies (studies that have a 4 digit identifier and schedule visits on the CRC) - save scanned documentation in study specific folders found in O:\PCIR\Lab

6.3.10.2. Non-CRC studies (studies that have a 6 digit identifier such as P##-### or designated by a study name) - save scanned documentation in study specific folders found in O:\DMCT\CTSIProcessingLabs\CTSL_Overall\Non-CRC Protocols

6.3.11. Return original copies of CRC numbered protocol documents to the CRC for filing by administrative staff or return directly to coordinator any non-CRC protocol documentation.

6.4. Equipment/Sample Tracking

6.4.1. Freezers, refrigerators and centrifuges that are utilized during sample processing and storage will be recorded on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.4.2. Each Freezer, refrigerator and centrifuge has a unique letter/number ID.

6.4.3. Record the ID of the centrifuge utilized during the process of each sample in its corresponding processing time box along with the centrifuge start time on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.4.4. Record the freezer/refrigerator ID of unit where finished specimens are being stored on the protocol specific CTSI-CRC-PL-FM508 Lab Processing Sheet, if applicable.

NOTE: Freezer ID entries on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet indicates the initial location of the samples

after processing. All subsequent relocations of samples may be recorded on sample release logs or specimen logs designated for specific backup locations. Update of the initial entry on protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet is not required.

6.5. Sample Storage

6.5.1. Samples may be either placed into bags, typically sorted by visit, or in cryoboxes. Refer to the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet for storage requirements.

6.5.2. Bagged samples

6.5.2.1. Samples that are not requiring long term storage may be place in zip-lock bags.

6.5.2.2. Bags must contain a copy of the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet or the bag must be labeled with the study specific identification such as study number/name, participant name, date of visit and/or subject ID as applicable.

6.5.3. Boxed samples

6.5.3.1. Boxes will be labeled per CTSI-CRC-PL-FM506 CTSL Sample Management and Protocol Specific Training Form or as protocol requires.

6.5.3.1.1. Each box from a specific study will have a unique identifier (ID) as to ensure multiple samples do not acquire an identical storage location.

6.5.3.1.2. Short term storage boxes may be given IDs based on sample type, participant ID, study visit or any other parameter requested by the study personnel.

6.5.3.1.3. Long term storage box IDs are based on their pending location within the Specimen Storage Facility. Labels will indicate freezer, shelf, rack and box number (ex: HF1-2-3-4 indicates box will be stored in Freezer HF1, shelf 2, rack 3 and it is the 4th box of the rack)

6.5.3.2. Boxed samples will be given designated locations (cell number) within a storage box and the location will be recorded on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.5.3.2.1. Locations (cells) within the box are numbered by row and column. Ex: An 81 cell box starts with row 1 then column 1 (designated 1.1) in the top left corner cell while the bottom right corner cell is designated as 9.9. Row numbers increase from top to bottom and column numbers increase from left to right.

6.5.3.2.2. Oversized samples (such as whole blood tubes) may be laid down in the box rather than standing in individual cells.

When this occurs, each individual sample is given a location number based on number of samples per box. Location number represents layer (or row) and location within the layer. Ex: A PaxGene tube may have the location 2.3 which indicates the tube is in the second layer and is the third sample in the layer counting from left to right.

6.5.3.2.3. Avoid leaving cells empty in order to optimize freezer storage space.

6.5.4. Temporary (short term) sample storage

6.5.4.1. Samples may be stored in the CTSL for up to 1 week following receipt/processing. This may be extended on a per protocol basis by management.

6.5.4.2. Refer to step 6.9 and 6.10 for sample release procedures.

6.5.5. Long term sample storage

6.5.5.1. Unfilled, in-process boxes are stored in designated locations in CTSL freezers/refrigerators. Refer to either location charts posted on designated freezers or study specific CTSI-CRC-PL-FM508 Lab Processing Sheet for in-process box locations.

6.5.5.2. Completed boxes (filled and partially filled/end of study) are to be relocated to a designated "hold" location within the CTSL freezers/refrigerators. Refer to section 6.10.2 for box verification and release procedures.

6.6. Sample Receipt/Release Confirmation Record Requests

6.6.1. A copy of any logs described in this procedure may be provided for review at the request of study personnel.

6.7. Sample Release Request

6.7.1. Study personnel can submit a request via ctslab@iupui.edu with a scheduled time/date for sample pick up or call the lab prior to pick up.

6.7.2. The following information should be provided by study personnel to aid in preparing pickup of samples:

6.7.2.1. Protocol number(s)

6.7.2.2. Study ID/Patient ID(s)

6.7.2.3. Study visit ID(s)

6.8. Preparation of specimens for release

6.8.1. CTSL staff will confirm samples are correctly labeled and have been stored according to processing directives.

6.8.2. Samples shall remain in the study defined storage condition until study personnel arrive for pick up.

6.8.3. CTSL staff will complete the CTSI-CRC-PL-LG617 Specimen Release Log with the following information.

6.8.3.1. Study name/protocol
6.8.3.2. Subject ID/box ID
6.8.3.3. Number of samples of each storage type
6.8.3.3.1. Ambient (A)
6.8.3.3.2. Refrigerated (R)
6.8.3.3.3. Frozen (F)
6.8.4. Enter any comments that are necessary for further identification of samples to be released.

6.9. Specimen Release
6.9.1. Study Personnel:
6.9.1.1. It is recommended that study personnel confirm samples are properly labeled and that the information documented by CTSL personnel is correct.
6.9.1.2. Receiver of specimens will be requested to print and sign their name on the appropriate line on the CTSI-CRC-PL-LG617 Specimen Release Log.
6.9.1.3. If study personnel refuse to sign the CTSI-CRC-PL-LG617 Specimen Release Log, CTSL personnel will record the name and department of the study personnel and document study personnel's refusal on the log.
6.9.2. CTSL Staff:
6.9.2.1. Confirm all information entered on the CTSI-CRC-PL-LG617 Specimen Release Log is complete and correct for the specimens being released.
6.9.2.2. Enter CTSL personnel initials, time and date of release.

6.10. Transfer of specimens to the Specimen Storage Facility
6.10.1. Whole blood for DNA processing
6.10.1.1. Place specimens designated for DNA extraction in refrigerator (2-8°C).
6.10.1.2. CTSL personnel - Enter the following information on the CTSI-CRC-PL-LG617 Specimen Release Log:
6.10.1.2.1. Study name/protocol
6.10.1.2.2. Subject ID
6.10.1.2.3. Number of refrigerated (R) samples
6.10.2. Specimen boxes for long term storage
6.10.2.1. Protocols requiring data entry
6.10.2.1.1. Place full specimen storage boxes in the designated hold area of a CTSL freezer.
6.10.2.1.2. Upon completion of data entry for all specimens located in the box placed on hold, print a manifest of the box from the data management system.

6.10.2.1.3. Perform a 10% quality check of the box, indicating which specimens were verified with a check mark next to the specimen ID on the manifest. Make two copies of the manifest (one for attachment to the CTSI-CRC-PL-LG617 Specimen Release Log and one to present to the SSF personnel upon transfer).

6.10.2.1.4. If there are no errors, place the box in the designated release area of a CTSL freezer and enter the following on the CTSI-CRC-PL-LG617 Specimen Release Log:

6.10.2.1.4.1. Study name/protocol

6.10.2.1.4.2. Box ID

6.10.2.1.4.3. Number of frozen (F) samples in the box.

6.10.2.1.5. If any errors are found during the initial 10% quality check, a full 100% inventory of the box will be performed and any discrepancies will be rectified.

6.10.2.1.5.1. Print a new manifest and attach to the original manifest and attach them to the the CTSI-CRC-PL-LG617 Specimen Release Log.

6.10.2.1.5.2. Prepare another copy to present to the SSF personnel at transfer

6.10.2.1.5.3. Enter information on the CTSI-CRC-PL-LG617 Specimen Release Log as noted in step 6.10.2.1.4

6.10.2.1.6. SSF personnel will verify specimen information then print and sign their name on the appropriate line on the CTSI-CRC-PL-LG617 Specimen Release Log

6.10.2.1.7. CTSL personnel will enter initials, time and date of release to SSF personnel on the CTSI-CRC-PL-LG617 Specimen Release Log.

6.10.2.2. Protocols not requiring data entry

6.10.2.2.1. Place the box in the designated release area of a CTSL freezer and enter the following on the CTSI-CRC-PL-LG617 Specimen Release Log:

6.10.2.2.1.1. Study name/protocol

6.10.2.2.1.2. Box ID

6.10.2.2.1.3. Number of frozen (F) samples in the box

6.10.2.2.1.4. Notation in the comments section indicating no manifest available.

6.10.3. SSF personnel- verify specimen information then print and sign their name on the applicable line of the CTSI-CRC-PL-LG617 Specimen Release Log.

6.10.4. CTSL personnel- enter initials, time and date of release to SSF personnel on the applicable line of the CTSI-CRC-PL-LG617 Specimen Release Log.

6.11. Documentation

6.11.1. Documents are maintained per CTSI-CRC-QA-003 Document Control and Management.

6.11.2. Deviations are managed per CTSI-CRC-CLN-030 Handling of SOP Deviations and per CTSI-CRC-CLN-031 Handling of Protocol Deviations.

6.11.3. Requests for sample processing support are managed per CTSI-CRC-PL-151 Management of Requests for Sample Processing Support

6.11.4. Mislabeled/Unlabeled samples are managed per CTSI-CRC-PL-157 Mislabeled/Unlabeled Specimens

6.11.5. Data/Sample Management Systems are maintained per CTSI-CRC-PL-158 Data Sample Management System

7. REFERENCES

None

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	NA
Amendment Request by:	NA
Change Control No, if applicable:	NA
Details of Amendment:	NA