INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR SSF MANAGED SPECIMENS INTAKE AND RELEASE

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CHAPTER: 1- Administration and Quality Oversight

SOP #: SF-1-14.07

SUPERSEDES SOP #: N/A

AUTHORED BY: ____________ DATE: 9-22-2022
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1. REVISION

1.1. Significant changes incorporated in version include:

- 1.1.1. Step 3.1 revised to reflect that the CTSI processing lab (CTSL) is responsible for managing the Sample Management System (SMS) database(s) unless otherwise directed by SSF Management.
- 1.1.2. Section 6.1.3 revised to reflect CTSL usually enters specimen data into the SMS.
- 1.1.3. Steps 6.1.8.2 and 6.4 have been revised to reflect the requirement of notifying CTSL personnel about sample intake/release for inventories managed by the SMS.
- 1.1.4. Appendix A and B revised to expedite the process of sample intake and release.

2. PURPOSE

2.1. This SOP establishes a procedure for intake and release of specimens by the SSF from or to assignment outside of the SSF. This includes receipt of specimens for SSF storage, placement in a storage unit managed by a PI, and release of specimens from the SSF to an external party. If specimens are returned to the SSF following permanent release, they are managed per directives for receipt of new specimens as described in this SOP.

3. PRINCIPLE

3.1. The SSF is responsible for managing samples according to directives supplied by the authorized study personnel. Authorized study personnel are responsible for all aspects of the protocol, including directives to the SSF for storage and release for distribution by the study personnel. The CTSI processing lab (CTSL) is responsible for managing the Sample Management System (SMS) database(s) unless otherwise directed by Management.

4. SCOPE

4.1. This SOP applies to SSF Personnel receiving specimens for protocols which have arranged for sample storage in the SSF with or without management by the Sample Management System (SMS).

4.2. This SOP applies to SSF Personnel releasing samples from the SSF to comply with investigator directives.

4.3. The scope of this SOP is limited to intake and release of specimens. It is not intended to guide specific use of the SMS.

4.4. SSF-facilitated disposal of any specimens, even at the written request of the study PI, is outside the scope of this SOP. All specimens must be released to study personnel for disposal. However, at the discretion of the SSF director, exceptions may be allowed in extreme cases when there is no one available from the study to whom samples could be released.

4.5. Relocations due to an OOS are managed per SF-1-10 and are outside of the scope of this SOP.

5. MATERIALS

5.1. N/A

6. PROCEDURE

6.1. Samples received for SSF managed storage are entered into the SSF Sample Intake Record (Appendix A) as follows:

6.1.1. Enter the Date to reflect the date the sample arrives in the SSF

6.1.2. Enter the Protocol ID to connect the specimens to a document that defines the SSF responsibility in managing the specimens and the investigator for whom the specimens are managed.

6.1.3. Designate samples as “intake”, “transport”, or “return” as indicated below. A table at the end of Section 6.1.3 summarizes pertinent criteria distinguishing sample types.

6.1.3.1. Samples are designated as “Intake” if the samples are:

6.1.3.1.1. Processed by the CTSL

6.1.3.1.2. Transferred to the SSF by SSF staff

6.1.3.1.3. Placed in the assigned SSF storage location by SSF staff

6.1.3.1.4. Managed by the SMS database(s)

6.1.3.2. Samples are designated as “Transport” if they are:

6.1.3.2.1. Transported to the SSF by SSF staff

6.1.3.2.2. Placed in the assigned SSF storage location by SSF staff

6.1.3.2.3. Are NOT managed by SMS database(s)

6.1.3.3. Samples are designated as “Return” if they are *returned to the SSF* by PI-personnel after removal from the SSF per Section 6.2 of this SOP.

6.1.3.3.1. The returned samples may or may not be managed by the SMS per Sections 6.1.3.1 and 6.1.3.2.

6.1.3.3.2. SMS database updates are managed by CTSL or SSF personnel at sample return, as applicable.

6.1.3.3.3. A freeze/thaw event is recorded in the SMS database, as applicable, when provided.

6.1.3.3.4. Return volume is recorded in the SMS database at PI request.

Summary Table			
	Intake	Transport	Return
Responsibility for transporting samples	SSF Staff	SSF Staff	PI Personnel
Responsibility for entering data into SMS database	Usually CTSL Personnel	N/A	Usually CTSL Personnel
Responsibility for placing samples into storage	SSF Staff	SSF Staff	SSF Staff

6.1.4. Identify the samples received as follows:

  6.1.4.1. Samples may be identified by listing each sample or Container ID on the form, or by describing the group (e.g., bag of blood tubes).

  6.1.4.2. Samples for “intake” are logged in per the previous step.

    6.1.4.2.1. If a Container ID is identified, either a manifest or processing sheet(s) copy, which identifies all samples in the corresponding container, is attached.

      6.1.4.2.1.1. If samples are identified by a manifest or copies of processing sheets, SSF personnel document the following:

        6.1.4.2.1.1.1. The total number of samples recorded on the manifest or copies of processing sheets: This is confirmed by physically examining the container of specimens. Record the number of samples in the Sample # column. If in error, describe in comment section with additional documentation as required.

        6.1.4.2.1.1.2. Confirmation of a 10% verification check: Minimally 10% of the individual specimens are confirmed to correlate with the manifest by physically examining the specimens within the container. If correct, check (✓) the “10% ok” column. If in error, describe in comment section with additional documentation as required.

    6.1.4.2.2. If individual sample IDs are listed on Appendix A, SSF personnel document the total number of samples only. Record “N/A” in the 10% verification box.

  6.1.4.3. Samples for “transport” may be identified by the Container ID and total number of samples in the container. The attachment of a manifest or processing sheet/s is not applicable. The 10% verification box is documented as “N/A.”

  6.1.4.4. Samples for “return” are received per Section 6.1.4.2 or Step 6.1.4.3, depending on whether samples are managed in the SMS database(s).

6.1.5. The person providing the samples is identified in the “Rec’d from” column. If from CTSL, the person must initial the top section of the row that indicates “CTSL”. If not from CTSL, the person must legibly document (at minimum) first initial and last name in the bottom section of the row.

6.1.6. The SSF personnel receiving the samples and identifying the samples per Section 6.1.4 is identified in the "Rec'd by" column.

6.1.7. The SSF personnel placing the specimens into the storage location record the location (unit, shelf, rack, and box) and enter technician identification and date.

6.1.8. SMS database update:

6.1.8.1. When intake samples are received from the CTSL, a manifest listing samples and locations will be provided; therefore, enter "N/A" for SMS entry.

6.1.8.2. When return samples are received by the SSF directly from an investigator, indicate when CTSL personnel have been notified of the sample intake or record date/tech ID when the entry is complete as applicable. .

6.1.8.3. When transport samples are received, enter "N/A."

6.1.9. Enter any comments relative to documenting the management of the intake of samples.

Note: It is acceptable for the *Comment* section to remain blank since Appendix A is considered a "living" document and a comment could be added at any given point.

6.2. When samples are removed from their assigned storage location with the intent to release from the SSF, they are logged out via SSF Sample Release Record (Appendix B) as follows:

6.2.1. Technician Completing Sample Preparation:

6.2.1.1. Enter the Protocol ID to connect the specimens to a document that defines the SSF responsibility in managing the specimens and the investigator for whom the specimens are managed.

6.2.1.2. Identify the samples released as follows:

6.2.1.2.1. Samples may be identified individually by listing each sample on the form.

6.2.1.2.2. Samples may be logged out via identifying a container and attaching a manifest or other document identifying all samples in a particular container.

6.2.1.3. Enter Sample Preparation Info:

6.2.1.3.1. Compile total count of samples being released via physical count, recording the total samples per box on the manifest.

6.2.1.3.2. Complete a 100% check of samples pulled from storage if samples were selected from original boxes and placed in new boxes. OR

6.2.1.3.3. Complete a 10% check for the number of samples pulled from storage if they are being released in their original boxes. Document completion on Appendix B and the manifest, if applicable.

6.2.1.3.4. If samples are being stored in an interim location within the SSF in preparation for final release from the SSF, the SSF technician moving the samples records the location (unit, shelf, rack, and box), technician, and date as well as any pertinent comments. As applicable, update the status in the SMS.

6.2.1.3.5. If samples are NOT being stored in an interim location before being released, document "N/A" in the Relocation in Preparation for Final Release columns.

6.2.2. Technician Performing QC Check:

6.2.2.1. Perform a QC check (to be performed by SSF personnel who did not perform the initial sample preparation/pull):

6.2.2.1.1. Reconcile the total number of samples recorded during Sample Preparation on the manifest by physically examining the container of specimens, recording the total samples per box on the manifest, if applicable. If correct, check (✓) "Yes" on Appendix B in the Sample Count Reconciles column. If in error, check (✓) "No, see comments" and describe in comment section with additional documentation as required.

6.2.2.1.2. Minimally 10% of the individual specimens are confirmed to correlate with the manifest by physically examining the specimens within the container. If correct, check (✓) the "10%" option and initial and date. If in error, describe in comment section with additional documentation as required. Document completion on the manifest, if applicable.

6.2.2.1.3. If samples are identified individually or if the samples are being released in their original boxes, SSF personnel document the total number of samples only. Record "N/A" in the 10% verification box.

6.3. When samples are released from the SSF, enter the date on which the samples were released to study personnel, and the identification (printed name with signature) of the person receiving the samples. The SSF technician releasing the samples enters his/her initials.

6.4. If applicable, notify CTSL personnel of release or record date/tech ID when sample status is updated in the SMS database(s).

6.5. Enter any comments relevant to documenting the management of the release of samples.

Note: It is acceptable for the *Comment* section to remain blank since Appendix B is considered a "living" document and a comment could be added at any given point.

6.6. In cases where a study requests disposal of certain specimens, SSF staff should release the samples to the study personnel and document per all previous steps in Section 6.2. *Disposal of study samples by SSF staff is prohibited except in extreme cases where it is deemed necessary and subsequently approved by the SSF director.*

7. REFERENCES

7.1. ISBER (Current edition)

8. DOCUMENTATION

8.1. Documents are maintained per SF-1-6 Controlled Document Management SOP.

8.2. Deviations are managed per SF-1-9 Deviation Management SOP.

9. APPENDICES

9.1. The current version of each of the following appendices are used to guide and/or implement this SOP:

APPENDIX A: SSF Sample Intake Record (1 page)
APPENDIX B: SSF Sample Release Record (1 page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES

10.1. N/A

SSF Sample Intake Record

Date	Protocol ID	Intake (I) Transport (T) Return (R)	Sample/Container ID (Multiple samples: Identify by either Container ID or description of group, and attach separate sheet(s) which itemizes all sample IDs. Itemized list is N/A for (T) samples)	QC		Rec'd from	Rec'd and Documented by:	Placed in Storage		SMS update*
				# of samples	10% ok (✓) *N/A if (T)*			Storage (U/S/R/B)	Tech/ date	
						CTSL 		U______ S______ R______ B______		
						CTSL 		U______ S______ R______ B______		
						CTSL 		U______ S______ R______ B______		
						CTSL 		U______ S______ R______ B______		
						CTSL 		U______ S______ R______ B______		
						CTSL 		U______ S______ R______ B______		

Comments:

* Indicate N/A for Intake/Transport from CTSL, or record ① to reference footnote below for sample return. For sample return, record the date CTSL personnel were notified along with the initials/date of the technician who notified CTSL personnel. If SSF personnel are performing SMS update, SSF personnel record only their initials and date when the SMS entries are made.

①Inventory managed by CTSL. CTSL personnel were notified of sample return on the date indicated.

Reviewed by (Initials/Date): ________________________

SSF Sample Release Record

Protocol ID:

Sample/ Container ID (Multiple samples: Identify by either Container ID or description of group and attach separate sheet(s) which lists all sample IDs)	Sample Preparation				QC			Release		*SMS Updated, if applicable
	Number of Samples	100% ✓ (selected samples) or 10% ✓ (original boxes)	Interim Storage Location	Initials/ Date	Sample Count Reconciles	10% ✓ (selected samples) or N/A (original boxes)	Initials/ Date	Released to:	Released by / Release Date (Initials/ Date)	
		☐ 100% ☐ 10%	U______ S______ R______ B______		☐ Yes ☐ No, see comments	☐ 10% ☐ N/A		Signature: Name (print):		
		☐ 100% ☐ 10%	U______ S______ R______ B______		☐ Yes ☐ No, see comments	☐ 10% ☐ N/A		Signature: Name (print):		
		☐ 100% ☐ 10%	U______ S______ R______ B______		☐ Yes ☐ No, see comments	☐ 10% ☐ N/A		Signature: Name (print):		
		☐ 100% ☐ 10%	U______ S______ R______ B______		☐ Yes ☐ No, see comments	☐ 10% ☐ N/A		Signature: Name (print):		
		☐ 100% ☐ 10%	U______ S______ R______ B______		☐ Yes ☐ No, see comments	☐ 10% ☐ N/A		Signature: Name (print):		

Comments:

* Record ① to reference footnote below for sample release, and record the date CTSL personnel were notified along with the initials/date of the technician who notified CTSL personnel. If SSF personnel are performing SMS update, SSF personnel record only their initials and date when the SMS entries are made.

① Inventory managed by CTSL. CTSL personnel were notified of sample release on the date indicated.

Reviewed by (Initials/Date): ______________________