



**STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility**

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

CHAPTER: 1- Administration and Quality Oversight

SOP #: SF-1-14.03

SUPERSEDES SOP #: N/A

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Issue Date: 01.23.15

Effective Date: 01.30.15

1. REVISION

- 1.1. Significant changes incorporated in version include:
 - 1.1.1. Modified signatory approval section.
 - 1.1.2. Edited Section 6.1.3.2 to include samples that are processed but are not placed in permanent storage.
 - 1.1.3. Added Section 6.1.3.2.1 for distinguishing between frozen samples and fresh samples to be processed in documentation. Revised Appendix A accordingly.
 - 1.1.4. Added Section 6.1.4 to provide directives for documenting collection dates for fresh samples to be processed. Revised Appendix A accordingly.
 - 1.1.5. Included Section 6.1.5.2.2 for clarification on documenting the QC section on Appendix A for samples that are not accompanied by manifests or processing sheets.
 - 1.1.6. Section 6.5.3 was updated to state that documentation of 10% check for transport samples is N/A.
 - 1.1.7. Revised Section 6.1.10 for clarity.
 - 1.1.8. Section 6.1.10.4 was added to clarify that locations for samples to be processed are not entered into the SMS because they are only temporary.
 - 1.1.9. Sections 6.1.11 and 6.2.7 were added for the documentation of comments and, if there are no comments, the acceptance of the comment field being left blank.
 - 1.1.10. Removed the directive from Section 6.2 for documenting the date the sample is removed from permanent storage at the SSF. Updated Appendix B accordingly.
 - 1.1.11. Modified step 6.2.4 to clarify documentation requirements for samples not being moved to an interim location.
 - 1.1.12. Section 6.2.5 was edited to direct documentation of release date and signature of study personnel to whom samples are being released and the documentation of SSF technician initials and date of release. Appendix B updated to reflect changes.

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, or for processing and includes 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, intermediate processing, and release for distribution by the study personnel. The SSF is responsible for tracking the specimens from intake through final release.

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 SSF Sample Management System (SMS) and may or may not include processing by the SSF.

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 sample management system.

4.4. This SOP integrates with SOP SF-4-22: SOP for Receiving, Logging, And Tracking Samples for Processing by the SSF and SOP SF-4-01: SOP for Sample Processing Requests, along with specific processing SOPs, to manage the full scope of SSF sample handling.

4.5. Location naming conventions are managed per SF-4-22

4.6. 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”, “processing” or “transport” as follows:

6.1.3.1. Samples are designated as “Intake” to the SSF if they are managed by SSF Sample Management System (SMS).

6.1.3.2. Samples are designated as “processing” if there is an existing directive for processing upon receipt (Manage per SF-4-1 and SF-4-22).

6.1.3.2.1. Samples designated as “processing” are further described as being fresh (P/F) or frozen (P/Z).

6.1.3.3. Samples are designated as “Transport” if they are not managed by SSF, but are carried from the collection or receipt location (e.g., CTSL) to the SSF and placed in storage.

- 6.1.4. If the sample is to be processed and is fresh (P/F), document the date when the sample was collected by study personnel. Otherwise, document “N/A.”
- 6.1.5. Identify the samples received as follows:
- 6.1.5.1. Samples may be identified by listing each sample on the form either individually or by listing groups of samples from a single study/participant ID and the number of each sample type included (e.g: study 1234, participant abc, visit 1, time point 2, 6 serum samples and 4 plasma samples).
 - 6.1.5.2. Samples for “intake” or “processing” are logged in via (a) recording the sample ID as described in the previous step or (b) identifying a container and attaching either a manifest or processing sheet(s) copy which identifies all samples in the corresponding container.
 - 6.1.5.2.1. If samples are identified by a manifest or copies of processing sheets , SSF personnel document the following on the SSF Sample Intake Record (Appendix A):
 - 6.1.5.2.1.1. 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.
 - 6.1.5.2.1.2. 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 ok column. If in error, describe in comment section with additional documentation as required.
 - 6.1.5.2.2. If samples are not identified by a manifest or copies of processing sheets, SSF personnel document the total number of samples only. The 10% verification box may be checked or documented as “N/A.”
 - 6.1.5.3. Samples for “transport” may be identified by the box ID and total number of samples in the box. The 10% verification box is documented as “N/A.”
- 6.1.6. The person providing the samples is identified in the “Rec’d from” column. If from CTSI, initial the top section of the row that indicates “CTSI”. If not from CTSI, legibly identify the person providing the samples in the bottom section of the row.
- 6.1.7. The SSF personnel receiving the samples and identifying the samples per Section 6.1.5 is identified in the “Rec’d by” column.
- 6.1.8. The SSF personnel placing the specimens into the storage location record the location (unit, shelf, rack and box) and enter technician identification and date.
- 6.1.9. If the samples are to be “processed” after having been placed into storage (categorized as “P/F or P/Z” upon receipt), complete the “Out for Processing” column when the samples are taken from their storage location for processing.
- 6.1.10. If applicable, record when samples are entered into the Sample Management System (SMS)
- 6.1.10.1. If intake samples are received from the CTSI, a manifest listing samples and locations will be provided; therefore, enter “N/A” for SMS entry.
 - 6.1.10.2. If intake samples are received by the SSF directly from an investigator, record date/tech ID when the entry is complete.
 - 6.1.10.3. If transport samples are received, enter “N/A.”

6.1.10.4. Samples designated “processing” are only stored temporarily before they are processed at the SSF, and therefore are not entered in the SMS. Document “N/A” for SMS entry.

Note: Sample management directives for the samples derived from processing are defined in SF-4-1 and documented as described in SF-4-22.

6.1.11. 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. 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.

6.2.2. Identify the samples released as follows:

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

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

6.2.2.3. If samples are identified by a manifest or other document, SSF personnel document the following on the SSF Sample Release Record (Appendix B):

6.2.2.3.1. The total number of samples recorded on the manifest is confirmed by physically examining the container of specimens. If correct, Record the number of samples in the Sample # column. If in error, describe in comment section with additional documentation as required.

6.2.2.3.2. 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 ok column. If in error, describe in comment section with additional documentation as required.

6.2.3. 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 Sample Management System (SMS).

6.2.4. 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.

6.2.5. 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.

6.2.6. If applicable, update the sample status in the SMS.

6.2.7. 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.

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)

SSF Sample Intake Record

Date	Protocol ID	Intake (I) Processing (P/F for fresh or P/Z for frozen)	Collect- ion Date (for P/F samples only)	Sample/Box ID (Multiple samples: Summarize below and attach separate sheet(s) or provide descriptive identification for the group)	QC		Rec'd from	Placed in Storage	Tech / date	Out for Proces- sing (tech/ date)	SMS entered by SSF (tech/date)	Comments
					# of sam- ples	10 % ok (✓) N/A if (T)						
							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_____			
							CTSL		U_____ S_____ R_____ B_____			

SSF Sample Release Record

Protocol ID	Sample/Box ID (Multiple samples: Summarize below and attach separate sheet(s) or provide descriptive identification for the group)	QC		Relocation In Preparation for Final Release			Final Release			SMS updated (tech/date)	Comments
		# of samples	10% ok (✓)	Interim Storage Location	Tech/ Date of relocation	Comments	Date of Release	Released to: (printed name and signature)	Released by: (tech initials)		
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							
				U_____ S_____ R_____ B_____							