INDIANA CTSI Clinical and Translational Sciences Institute

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

TITLE: Regulatory and Client/User Audit

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-11.07

SUPERSEDES SOP#: N/A

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APPROVAL: _____ DATE: 07-09-2021
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1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Reorganized Sections to align with SF-1-1.
      1.1.2. Step 6.2.4 scope expanded to permit notification of audit scope to SSF Operation Management personnel, removing limitation that only SSF Operations Manager is notified.
      1.1.3. Step 6.2.6 scope expanded to permit SSF Operation Management personnel accompaniment of auditor, removing limitation that the SSF Facility Manager is not permitted to accompany auditor.
      1.1.4. Added Section 10 to align with SF-1-1.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) describes the procedure that is followed during an inspection or audit by facility users/clients, state or federal agencies. A variety of federal, state and local agencies have jurisdiction in the conduct of clinical trials, storage of clinical samples and drug-related products, and the storage and shipment of biologic materials.

   2.2. The SSF shall permit an authorized employee to inspect or audit that part of the facility pertinent to the designated study and to inspect/audit pertinent records and specimens as required by law.

   2.3. Facility users and their designees have the authority to perform an 'on-site' inspection or audit of the SSF for user-related activities.

3. PRINCIPLE
   3.1. The Indiana CTSI Specimen Storage Facility (SSF) is committed to providing a storage facility for Principle Investigators performing bio-banking activities that satisfy all applicable "best practice recommendations".

4. SCOPE
   4.1. The scope of this procedure includes each individual serving in the defined Indiana CTSI SSF roles. This SOP defines SSF Personnel responsibilities applicable to facility audits versus study directed audits.
   4.2. Responsibility for responding to audit findings (to include performance of corrective actions, and any written and/or verbal responses) is limited to facility-related items.
   4.3. Internal audits of the SSF are conducted as defined in SOP SF-1-8 and are not recorded on Appendix A.

5. MATERIALS
   5.1. N/A

6. PROCEDURE
   6.1. HANDLING INSPECTIONS BY FEDERAL, STATE OR LOCAL REGULATORY AGENCIES. This section is applicable only for regulatory agency audits and is not applicable to study representatives.
      6.1.1. Inspector's Arrival
         6.1.1.1. An inspection can be announced or unannounced.
            6.1.1.1.1. If the inspection is announced, the inspector will be instructed to arrive at the R-3 Building, Room C153, 980 W. Walnut Street, Indianapolis IN.
            6.1.1.1.2. If the investigation is unannounced, the inspector will be escorted to the SSF Manager's office (R-3 Building, Room C153, 980 W. Walnut Street, Indianapolis IN) by SSF personnel.
         6.1.1.2. SSF personnel informed of an inspector's arrival direct the inspector to the SSF Director, if available. If the SSF Director is unavailable, the inspector is directed to the Associate Director and/or SSF management personnel. This individual then contacts the SSF Director as soon as possible.
         6.1.1.3. SSF Operation Management personnel are notified.
         6.1.1.4. Quality Compliance personnel are notified.
         6.1.1.5. The Principle Investigator (PI) of the collection being audited is notified and is responsible for managing the audit.
         6.1.1.6. If the PI is not available, The Office of Research Administration (317-274-8289) is notified to manage the audit.

      6.1.2. The Opening Meeting is directed by the PI or representative.

      6.1.3. SSF Personnel Responsibilities During an Inspection
         6.1.3.1. Ensure that the auditor's visit is appropriately documented as defined in SOP SF-2-3: SOP for Controlled Access.
         6.1.3.2. SSF personnel are assigned by the director or designee to escort the inspector during the inspection. The inspector will be accompanied at all times.
         6.1.3.3. Samples taken by the auditor are to be managed by PI study personnel.
         6.1.3.4. The SSF personnel escorting the inspector are responsible for responding to questions or directing a knowledgeable employee to do so.
         6.1.3.5. During the investigation, facility personnel should continue with their respective duties to avoid disruption of facility activities.

      6.1.4. Access to SSF Records
         6.1.4.1. With permission of the PI, the inspector may copy records relevant to the inspection with the following exceptions:

6.1.4.1.1. An inspector is not permitted to inspect or copy financial data, pricing data, personnel data not relevant to qualification of technical and professional personnel of the facility, and research data.
6.1.4.1.2. It is recommended that a list of documents provided for inspection be maintained by the SSF/PI to facilitate any required audit responses.
6.1.4.1.3. The inspector is not permitted to inspect or copy quality assurance unit records related to 1st party or 2nd party audit observations and/or findings, including any corrective actions required or taken.
6.1.4.1.4. Cameras are not permitted unless specifically approved by the Director and PI.

6.1.5. The on-site Inspection
6.1.5.1. Safety precautions and facility entry procedures are provided to the inspectors prior to entry. It is the SSF personnel's responsibility to ensure that the inspector adheres to all applicable SSF procedures.
6.1.5.2. If the inspector points out observations and/or findings during an inspection, SSF personnel inform the Director and, if possible, perform the necessary corrective action.

6.1.6. Closing meeting
6.1.6.1. At the closing meeting, the inspector may present a list of any findings to the PI.
6.1.6.2. If any observations/findings noted during the inspection were corrected prior to the close-out meeting, inform the inspector of the corrective actions taken.
6.1.6.3. The SSF assists the investigator in responding to facility-related findings noted during the inspection.
6.1.6.4. Proposed responses to any audit findings generated by the SSF are reviewed by the SSF Director and QA prior to submission.
6.1.6.5. If provided, proposed responses to any audit findings generated by the PI/Study Team are reviewed by the SSF Director and QA prior to submission.
6.1.6.6. Copies of any audit responses generated by the SSF are retained as defined in the SOP for Controlled Document Management, SOP SF-1-6.
6.1.6.7. If provided to the SSF, any audit responses generated by the PI/Study team are retained as defined in the SOP for Controlled Document Management, SOP SF-1-6.

6.2. HANDLING AUDITS BY USERS AND THEIR DESIGNEES This section is applicable only for visits formally defined as audits and is not applicable to study representatives who have requested to be toured through the storage facility.
6.2.1. A facility user will **formally** notify SSF management personnel of their intention to perform an **audit** of the SSF. The audit scope is provided and a mutually agreeable date and time are arranged.
6.2.2. QA is notified as soon as possible of the audit plan.
6.2.3. If the user is designating a third party to perform the audit, the nature of the relationship between the user and the third party should be stated.
6.2.4. SSF Operation Management personnel and the Quality Compliance Specialist are informed of the audit scope. If the Quality Compliance Specialist is not on-site, electronic notification is acceptable.
6.2.5. A list of facility-related documents requested by the auditor prior to the visit is provided by the auditing entity. A copy of these documents is provided to the user and a copy of the list and a copy of each document provided to the auditor is maintained by the SSF to facilitate any audit response. The original documents are maintained at the SSF.

6.2.6. The SSF Director or SSF Operation Management personnel and Quality Compliance Specialist (if available) will accompany the auditor. Not more than 2 total user representatives/auditors may participate in the audit.
6.2.7. Ensure that the auditor's visit is appropriately documented as defined in SOP SF-2-3: SOP for Controlled Access.
6.2.8. Safety precautions and facility entry procedures are provided to the auditors prior to entry. It is the SSF personnel's responsibility to make sure the auditors adhere to all procedures followed at the SSF.
6.2.9. A user is allowed to audit only the data relevant to their studies. Any information regarding studies for other users will not be disclosed during these audits.
6.2.10. The user's findings and recommendations should be formalized in a written document and submitted to the SSF Director and QA for review.
6.2.11. The SSF personnel, SSF Director, and QA evaluate the audit findings/recommendations to determine proper corrective action.
6.2.12. The SSF Director and QA ensure that a formal response (to include objective evidence) is provided within the time frame agreed upon with the user.
6.2.13. Copies of all audit-related documents including audit responses are retained as defined in the SOP for Controlled Document Management, SOP SF-1-6.

**6.3. SSF Personnel document pertinent audit details in the SSF Record of Audits (Appendix A) maintained in the SSF Operations Office. The following information is recorded on the log:**
6.3.1. Date of Audit
6.3.2. Focus of Audit (SSF or PI protocol)
6.3.3. Type of Audit (Regulatory or User)
6.3.4. Specific auditing entity
6.3.5. Auditor Identification
6.3.6. SSF response required (Yes or No)
6.3.7. If yes, define

7. REFERENCES
7.1. ISBER Best Practices (Current Version)

8. DOCUMENTATION
8.1. Master copies of SOPs are maintained in the Quality Compliance Archive files according to the SOP for Controlled Document Management.
8.2. The Record of Audits is retained according to SOP SF-1-6 (SOP for Controlled Document Management).
8.3. Deviations to this SOP are managed per SOP SF-1-9 Deviation Management.

9. APPENDICES
9.1. The current version of each of the following appendices is used to implement this SOP:
Appendix A: SSF Record of External Audits (1 page)

10. COLLABORATING BIOBANK PERSONNEL (CBP) TRAINING DIRECTIVES
10.1. N/A

## Indiana CTSI Specimen Storage Facility Record of External Audits Year: _____

| Audit Date | Focus of Audit (SSF or define PI Study) | Regulatory or SSF User | Auditing Entity | Auditor Identification | SSF Response Required (Yes*/ No) *(* Define)* | Recorded By/date | Comments |
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