INDIANA CTSI Clinical and Translational Sciences Institute	**STANDARD OPERATING PROCEDURE** **Indiana CTSI Specimen Storage Facility**

TITLE: Facility Overview and Scope of Charge

CHAPTER: 1-Administration and Quality Oversight

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1. REVISION
   1.1. Sections reconfigured and Collaborating Biobank Training (Section 10) added to align with SF-1-1.
   1.2. Added directives for management of the SSF group email account in Section 6.3.4.
   1.3. Added University Information Technology Services (UITS) website address to References Section 7.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) provides an overview and defines the general purpose of the Indiana CTSI Specimen Storage Facility (SSF).

3. PRINCIPLE
   3.1. The Indiana CTSI Specimen Storage Facility has been created to provide a site for storage of research specimens generated during translational research. Such specimens include, but are not limited to:
      3.1.1. Clinical samples and samples generated during the conduct of clinical trials that should conform to Guidances such as the ISBER "Best Practices". The specimens are to have been collected under an IRB Approved Protocol and in compliance with all applicable policies.
      3.1.2. Clinical materials generated in relation to clinical trials that are collected and stored in accordance with FDA or other federal Guidances or regulations.
      3.1.3. Drugs, Biologic Agents, or other material used in Investigational New Drug Applications that requires storage and monitoring in accordance with US FDA Good Laboratory Practices or other relevant regulations or Guidances.

4. SCOPE
    4.1. This SOP describes the general structure of a facility that will provide services to a large number of Principle Investigators (PI) at Indiana University, Purdue University, University of Notre Dame and other institutions participating in the Indiana CTSI.
    4.2. The SSF is by definition a storage facility. The facility provides an environment where material may be stored in a controlled, secure environment. SSF administration works with PIs to ensure that storage is compliant with the appropriate regulatory requirements.

5. MATERIALS
    5.1. N/A

6. PROCEDURE
    6.1. CHARGE OF THE FACILITY
        6.1.1. The SSF is a physical location for storage of specimens. **The material stored within the facility will remain the property of the PI who will be solely responsible for the oversight of specimen collection, distribution, and management.**
        6.1.2. The facility will request assurance from each PI that the respective sample collection and storage is in compliance with the appropriate regulatory guidances. This process is defined in SF 1-4 SOP for Managing Storage Space.
        6.1.3. The facility operates under defined SOPs to ensure the following:
            6.1.3.1. Specimens are maintained at monitored storage conditions as requested by the PI.
            6.1.3.2. Storage conditions are continuously monitored, and emergency response procedures are defined for addressing equipment malfunctions.
            6.1.3.3. Deviations from SOPs are documented per SF-1-09 SOP for Deviation Management.
            6.1.3.4. Deviations from acceptable conditions (OOS conditions) are documented per SF-1-10 SOP for Out of Specification Condition and Notification Management.
            6.1.3.5. PIs are notified about OOS occurrences deemed relevant to them; however, if further reporting of such events is required, it is the responsibility of the PI to provide the appropriate authorities with the reports.

        6.1.4. The facility maintains SOPs that describe the security system and defines the measures used to ensure the integrity and confidentiality of stored specimens. Access is limited to CTSI SSF and collaborating personnel (as defined in SF-2-3, SOP for Controlled Access Operations) and persons escorted by trained personnel per SOP SF-2-3.
        6.1.5. The SSF operates as a recharge center. User costs are developed by the facility director and require approval by Indiana University.

    6.2. STRUCTURE
        6.2.1. The Facility is managed by the Indiana CTSI which appoints the Facility Director. The IU Simon Cancer Center will appoint an associate director to provide facility oversight.
        6.2.2. The SSF organizational structure is defined in SF-1-3, SOP for Organization: Directorship, Staffing, and Oversight Committee.

    6.3. MONITORING, REPORTING, AND NOTIFICATIONS
        6.3.1. Prior to acceptance of material for storage in the facility, the submitting PI must sign an agreement (per SOP SF-1-4) that defines the relationship with the facility, the responsibility of the PI, and the responsibility of the SSF.
        6.3.2. Annually, a current copy of the Storage Agreement(s) (SOP SF-1-4 Appendix D) is sent to each investigator for review/revision as defined in SOP SF-1-4. Although PI response time is undefined, it is expected to be timely. During the interim period between SSF initiation of the renewal process and the PI's provision of the signed agreement to the SSF, PI payment

of the SSF-generated invoices is considered sufficient to permit the SSF to continue to manage the specimens per the last signed agreement on file. A perceived lack of PI response is handled as defined in SOP SF-1-4.

6.3.3. If IRB or other regulatory agencies initiate actions which impact samples stored in the facility (ex. study closure), the SSF personnel will manage the samples according to the University directives.

6.3.4. SSF GROUP EMAIL ACCOUNT

    6.3.4.1. SSF personnel utilize a group email account (ictsissf@iupui.edu), at minimum, to facilitate customer contact and customer access and receive door alarm notifications per SOP SF-2-3.

    6.3.4.2. IU's University Information Technology Services (UITS) is responsible for directing the E-mail systems utilized by the University and for assigning all e-mail addresses and associated procedural requirements. As such, UITS facilitates the use of the systems it provides, including Exchange email.

    6.3.4.3. Procedures utilized to manage the SSF's email account using a tool such as Exchange email, are not SSF SOP-defined.

    6.3.4.4. The SSF Director, Facility Manager (or SSF personnel with the permission of the SSF Director or Facility Manager) are permitted to apply ONLY the rules listed below to the SSF group email account. The SSF Director must explicitly direct any other rules applied.

        6.3.4.4.1. Forwards all group emails to the respective SSF personnel IU individual email accounts.

        6.3.4.4.2. Forwards all Door Alarm email notifications, except "Point Inactive" alerts to the SSF primary pager.

        6.3.4.4.3. Forwards all Door Alarm email notifications to the respective SSF personnel IU individual email accounts.

        6.3.4.4.4. Forwards Point Inactive events to the respective SSF personnel IU individual email accounts for informational purposes only since Point Inactive events do not require investigation per SOP SF-2-3.

    6.3.4.5. Upon adding or removing SSF personnel from the rule forwarding all emails received by ictsissf@iupui.edu to respective SSF personnel IU individual email accounts, as soon as possible:

        6.3.4.5.1. Send a test email to ictsissf@iupui.edu and ensuring the message forwards to applicable SSF personnel.

        6.3.4.5.2. Retaining documentation of testing is not required.

    6.3.4.6. Upon effecting any change to forwarding rules aside from the change defined in Section 6.3.4.5, testing is completed as soon as possible. At minimum, testing includes:

        6.3.4.6.1. Sending a test email to ictsissf@iupui.edu and ensuring the message forwards to applicable SSF personnel.

        6.3.4.6.2. Generating a Door Alarm, and ensuring notification is received by (1) SSF personnel IU email accounts and (2) the SSF primary pager by the ictsissf@iupui.edu forwarding rule. Door alarm response is managed per SOP SF-2-3.

        6.3.4.6.3. Retaining documentation of testing, aside from that required by SF-2-3 directives, is not required.

6.4. SAMPLE PROCESSING

6.4.1. Samples stored in the SSF requiring processing pre/post-storage are processed by non-SSF personnel contracted by the PI since the SSF has ceased processing operations.

7. REFERENCES
    7.1. ISBER Best Practices (Current Version)
    7.2. University Information Technology Services (UITS) – https://uits.iu.edu

8. DOCUMENTATION
    8.1. N/A

9. APPENDICES
    9.1.   No Appendices are applicable to this SOP.

10. COLLABORATING BIOBANK TRAINING DIRECTIVES
    10.1. N/A