

## **Specimen Storage Facility Policies**

### **a) Confidentiality -**

All data shared with the SSF is kept confidential. All samples stored in the facility are the property of the investigator and will not be shared unless specific written direction is provided by the owner. Prior to storing material in the SSF, a written agreement delineating the responsibilities of the investigator and the SSF must be signed.

The responsibilities of the SSF are defined in the SOP for Managing Storage Space: Section 6.4.3.1 SSF Commitments, excerpts relevant to this section of this application are copied below. (Refer to SOP SF-1-4 Managing Storage Space Appendix C-2)

#### **6.4.3.1 SSF Commitments**

- 1 The SSF maintains an oversight committee that reviews policies and advises the SSF.
- 2 The SSF maintains a set of Standard Operating Procedures that describes the policies and directs the staff of the SSF. The critical policy SOPs are reviewed by the SSF Oversight Committee. SOPs include the following policies and procedures pertinent to this agreement:
  - a The scope and charge of the SSF
  - b The management structure of the SSF
  - c Operating practices of the facility.
  - f Maintenance and monitoring procedures for the SSF and the storage equipment within the SSF
  - h Training, controlled access, and alarm response practices developed to protect and insure confidentiality of materials stored in the SSF.
  - i Non-CTSI staff SSF entry practices including escorts for investigator personnel to access their specimens.
- 3 The SSF maintains the facility in compliance with current ISBER and GLP guidances relevant to facilities for storage.
- 4 Access is limited to CTSI SSF personnel and authorized study personnel who are escorted by CTSI SSF personnel for safety and security of the specimens
- 7 This agreement limits SSF activity to facility maintenance, equipment oversight, study personnel escort, and emergency specimen transfer unless defined in a separate agreement.

Samples stored in the SSF are managed by the collecting investigator unless the SSF is included in the PI's IRB protocol. Internal tracking of specimen location is kept distinct from clinical data by (a) using separate Sample Management Systems (SMS) or, if the investigator has selected the same SMS as the SSF (CaTissue) permissions are defined to not allow SSF access to confidential information. (Refer to SOP SF-1-2: Facility Overview and Scope of Charge Appendix C-3)

No information about the tissue bank client list is provided to an outside group with the exception of extramural grant applications, or as required by law. (Refer to SOP SF-1-11 Regulatory and Client/User Audit Appendix C-4)

To protect specimens and insure confidentiality of materials that may have patient

identifiers, a special security system was designed for the facility. The system is described below in the facility section.

b) Conflict resolution – The process involved in resolution of conflicts depends on the nature of the concern/conflict and are defined in the SOP for Managing Storage Space: Section 6.8 copied below and included in the appendices. (Refer to SOP SF-1-4 Managing Storage Space Appendix C-2)

6.8. *Process for responding to investigators who are denied services, or have concerns regarding operations, pricing, quality or other SSF policies. SSF personnel refer the investigator as follows:*

6.8.1. *If services are denied*

6.8.1.1. *Due to inadequate space:*

6.8.1.1.1. *Discuss options with the SSF Director.*

6.8.1.1.2. *If unresolved, appeal to Chair of Oversight Committee for consideration of priority over existing collections*

6.8.1.2. *Due to failure to provide IRB approvals*

6.8.1.2.1. *Appeal to IRB to provide letter of exemption*

6.8.1.2.2. *Request review by Chair of Oversight Committee*

6.8.1.3. *Due to failure to meet Biosafety requirements*

6.8.1.3.1. *Appeal to IUPUI Health and Safety for letter of confirmation that specimens do not provide a risk to SSF personnel greater than that of standard human blood and body fluid managed per Universal Precautions for Blood Borne Pathogens*

6.8.1.3.2. *Request review by Chair of Oversight Committee*

6.8.2. *If PI has concerns regarding quality, operations, or policies of the SSF*

6.8.2.1. *Discuss concerns with SSF Director*

6.8.2.2. *Request review by Chair of Oversight Committee*

6.8.3. *If PI has concerns regarding pricing*

6.8.3.1. *Discuss concerns with SSF Director*

6.8.3.2. *Request review by Chair of Oversight Committee*

6.8.4. *All decisions may be referred to full review by the Oversight Committee.*

c) Cost Recovery/Payment Policies - Payment for services policies are defined in the SOP for Managing Storage Space: Section 6.4.3.2 Investigator Commitments, relevant excerpts of which are copied below. (Refer to SOP SF-1-4 Managing Storage Space Appendix C-2)

6.4.3.2 Investigator Commitments:

- 3 The PI agrees to pay user fees in a timely fashion.
- 4 If PI loses funds for biobanking activities, the PI agrees to remove specimens from storage within 30 days of notification.
- 9 Agrees to accept charges for use of the SSF back-up freezer (if required) at approved recharge rates if the back-up freezer is used for greater than 14 days. (This does not apply to users leasing SSF freezer space.)

- 12 Failure to comply with these responsibilities results in oversight of the specimens being transferred to the investigator's home Institution. Specimens may not be accessed except by authorization of the institutional representative.

d) Prioritization of work – Priority is given to extramurally funded projects and projects assigned by the CTSI Project Development Teams. Second priority is given to IU, Purdue, and Notre Dame investigators who are providing funds from internal sources. Lowest priority will be given to industry sponsored or commercial work.

e) Publication All publications resulting from samples and/or processing provided by the SSF must acknowledge the CTSI in all publications. Authorship is not expected for services.

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*Publications must comply with the CTSI publication policy and ensure that any peer-reviewed publications are included in PubMedCentral.*