BIOSPECIMEN MANAGEMENT CORE (CTSL/SSF) Policies

a) Confidentiality -

All data shared with the BIOSPECIMEN MANAGEMENT CORE, comprised of the Specimen Storage Facility and the Clinical and Translational Support Laboratory, is kept confidential. All samples processed and/or stored in the facilities 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 Specimen Storage Facility (SSF), a written agreement delineating the responsibilities of the investigator and the SSF must be signed. The Clinical and Translational Support Laboratory (CTSL) does not require a written agreement for services but considers payment of fees for services rendered as acceptance of the CTSL's policies and procedures.

SSF - The SSF's main responsibilities regarding confidentiality are defined in the SOP SF-1-4, Managing Storage Space: Section 6.4.3.1 SSF Commitments. General practices of the SSF that ensure confidentiality are as follows:

- Training, controlled access, and alarm response practices have been developed to protect and insure confidentiality of materials stored in the SSF.
- Visitor entry practices include:
  - SOP training required of Collaborating Biobank personnel prior to being granted autonomous access to the facility.
  - Access to sample collections for all other study staff is limited to PI authorized study personnel only.
  - Staff who have not been granted autonomous access to the facility are escorted by CTSI SSF personnel to ensure safety and security of the specimens.
  - Documentation of all visitors via paper log and electronic badge access log is maintained and reviewed periodically by staff.

Management of samples stored in the SSF are the responsibility of the collecting investigator unless the SSF is included in the PI's IRB protocol and SSF responsibilities are defined on the storage agreement. Internal tracking of specimen location is kept distinct from clinical data by (a) using separate Sample Management Systems (SMS) or (b) when using the same SMS, permissions are defined as to not allow SSF access to confidential information. (Refer to SOP SF-1-2: Facility Overview and Scope of Charge)

Policies and procedures regarding the provision of records, files and documentation for audit purposes are defined by SOP SF-1-11 Regulatory and Client/User Audit.

CTSL - The responsibilities of the CTSL regarding confidentiality are defined by U.S. Department of Health and Human Services' HIPAA Privacy and Security Rules and Indiana University's specific privacy policies. Any confidential information viewed by CTSL staff and the dissemination of such information by CTSL staff is governed by these policies.

Specimen identification is defined and managed by the study sponsor/PI and links between the patient/subject and associated specimens is the responsibility of study personnel. Internal tracking (within the CTSL) of specimen location and identification (including links between patient/subject and their associated specimens) is kept distinct from clinical data by the use of CTSL specific logs, processing forms and lab specific specimen tracking systems.

b) Conflict resolution –

SSF – Procedures for conflict resolution are defined in SF-1-04 Managing Storage Space: Section 6.8 and are summarized below:

- Conflict due to inadequate space:
  - Discuss options with the SSF Director.
  - If unresolved, appeal to Chair of Oversight Committee for consideration of priority over existing collections.
- Conflict due to failure to provide active IRB approvals:
  - Appeal to IRB to provide letter of exemption.
  - Request review by Chair of Oversight Committee.
- Conflict due to failure to meet Biosafety requirements
  - 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.
  - Request review by Chair of Oversight Committee.
- If PI has concerns regarding quality, operations, or policies of the SSF:
  - Discuss concerns with SSF Director
  - Request review by Chair of Oversight Committee
- If PI has concerns regarding pricing
  - Discuss concerns with SSF Director
  - Request review by Chair of Oversight Committee
- All decisions may be referred to full review by the Oversight Committee.

CTSL – All conflicts concerning customer relations, billing disputes or any other issue concerning daily operations are to be reported to the CTSL Operations Manager. If an acceptable resolution is not reached, the Operations Manager will report to the Lab Director for further resolution.
Conflicts concerning quality of service or policies of the CTSL are to be reported to the Lab Director for review and response. All decisions and resolutions may be reviewed by the Oversight Committee at the Director's discretion.

BIOSPECIMEN MANAGEMENT CORE (CTSL/SSF) Policies

c) Cost Recovery/Payment Policies –

SSF - Payment for services policies are defined in the SOP for Managing Storage Space: Section 6.4.2 Investigator Commitments and are summarized below:

- The PI agrees to pay user fees in a timely fashion.
- If PI losses funds for biobanking activities, the PI agrees to remove specimens from storage within 30 days of notification.
- The PI 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.)
- 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.

CTSL – Quotes for services are available upon request. Rates are available upon request. Payment for services are billed to the provided account for each study requesting processing and shipping services via the CORES billing system. Billing occurs monthly. Any discrepancies discovered by study staff are to be reported to the Operations Manager for review and resolution. Refunds will be credited back to the study's account via the CORES billing system if reported within 60 days of invoice. Refunds of charges greater than 60 days old will be processed via the university's GEC procedure.

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 funded by NIH/private grant or industry sponsored sources. Lowest priority will be given to external customers who are conducting industry sponsored or commercial work.

e) Publication –

Per Indiana CTSI citation policies: (refer to https://www.indianactsi.org/cite-indiana-ctsi/)

If you are submitting a publication and have received Indiana CTSI funding you are required to include an acknowledgment of CTSA grant support and a disclaimer. This policy is applicable to individuals whose salary, education or research activities are funded all or in part by Indiana CTSI directly or via institutional match funds, and whose work on the cited project is in support of activities related to Indiana CTSI.

Investigators using the **Indiana CTSI Specimen Storage Facility** must ALSO acknowledge NCRR Construction Grant # RR020128

Any peer-reviewed publications must also be listed in PubMedCentral.

Authorship is not expected for services.