INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: MANAGING GOOD LABORATORY PRACTICE (GLP) SPECIMENS

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-13.07

SUPERSEDES SOP #: N/A

Issue Date: 11.22.2022

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AUTHORED BY: _____ DATE: 11-22-22
Indiana CTSI SSF Staff

APPROVAL: _____ DATE: 11-22-2022
Indiana CTSI SSF Director

QA APPROVAL: _____ DATE: 11.22.2022
Quality Compliance Specialist

1. REVISION
   1.1. Significant revisions incorporated in this version include:
      1.1.1. Section 6.5.2 significantly revised to:
         1.1.1.1. Redefine procedures for use of Appendix A such that PI approval is not required on Appendix A, since PI approval to add/remove collaborating biobank personnel (CBP) from sample access authorization is received via SF-2-3 Appendix E signed by the PI, and a signed SF-1-4 Appendix D indicates PI approval to add/remove non-CBP sample access authorization.
         1.1.1.2. Define training procedures for non-CBP, since all personnel utilizing any of the optional appendices must be trained per this SOP and SF-1-5 SOP for Personnel Training.
         1.1.1.3. Define that signature attribution is per the personnel's SF-1-5 Appendix A. SSF personnel print or type the personnel's name and initials on SF-1-13 Appendix A.
      1.1.2. Appendix A significantly revised to facilitate Section 6.5.2 procedure revisions defined in Section 1.1.1.
2. PURPOSE
   This Standard Operating Procedure (SOP) describes the requirements, process, and considerations for managing specimens in support of protocols requiring compliance with 21 CFR 58 Good Laboratory Practices (GLP) in the Indiana CTSI Specimen Storage Facility (SSF).
3. PRINCIPLE
   The Indiana CTSI SSF provides a facility for storage of specimens in a manner compliant with ISBER Best Practices. Certain modifications of the Indiana CTSI SSF SOPs may be required to satisfy Good Laboratory Practices (21 CFR 58 Subpart C, Facilities: Sec. 58.51 Specimen and data storage facilities. "Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.")
4. SCOPE

The scope of this procedure includes all SSF personnel and defines the SSF procedures which are applicable to GLP specimen collections including enhanced (a) access control, (b) monitoring and (c) data recording. The procedures identified in this SOP are implemented "in addition to" all other SSF SOPs when the investigator notifies the SSF that the collection being stored must comply with GLP. Additionally, this SOP applies to any GLP study personnel who choose to document on the optional appendices within.

5. MATERIALS
   5.1. N/A

6. PROCEDURE
   6.1. The Principle Investigator (PI) submits a request to use storage space per the Specimen Management procedure defined in SF-1-4 SOP for Managing Storage Space. The investigator includes in the "Specimen Information" Section that the request is for specimens that must be maintained per Good Laboratory Practices.
      6.1.1. Space Requested is completed per SF-1-4.

   6.2. SSF personnel log the request into the Master Study Log per SF-1-4 and perform a preliminary assessment of the request.
      6.2.1. An SSF request number is assigned per the convention defined in SF-1-4 with a "G" (signifying GLP) added after the previously final alpha character "O".
      6.2.2. SSF personnel review the request and make a preliminary determination, the SSF Director reviews, and response and documentation is per SF-1-4.

   6.3. If the request is approved and is for immediate use, a Storage Agreement is initiated per SF-1-4 AND any access control, monitoring, and data reporting other than the standard SSF practices is noted (See Section 6.4).

   6.4. Once a storage agreement is in place, a GLP Supplementary Requirements Reporting Form (Appendix C) is jointly completed by SSF Management and PI study personnel. This form details directives mandated by the GLP study for the SSF, in addition to other pertinent information. A new Appendix C is submitted whenever there are any additions or changes. The form documents the following information (as applicable):
      6.4.1. PI Request/Special Instructions, including standard SSF freezer maintenance the PI would like to omit or modify.
         6.4.1.1. Annual alarm testing is critical and MUST BE CONDUCTED on all units in the facility. Thus, this procedure cannot be waived by PI directives.
      6.4.2. Comments
      6.4.3. Optional SSF Forms Requested (See Section 6.5)

   6.5. Optionally, per the request of the GLP Study Director / PI, or Designee on Appendix C, the following additional practices may be initiated:
      6.5.1. If a GLP PI wishes to use any of the following optional appendices, then training on this SOP is mandated for any personnel providing documentation on these forms, including the PI. All training is managed per SF-1-5 Personnel Training.
      6.5.2. A separate GLP Access Authorization Form (Appendix A) may be assigned to each individual GLP storage unit.
         6.5.2.1. All PI study personnel authorized to access the GLP collection are listed on Appendix A.
         6.5.2.2. SF-1-13 Appendix A is utilized along with SF-1-5 Appendix A, the Prerequisite Training and Signature Form (Signature Form), as follows:
         6.5.2.3. SSF-trained Collaborating Biobank Personnel (CBP)
            6.5.2.3.1. Addition of CBP to SF-1-13 Appendix A:
               6.5.2.3.1.1. For all CBP for whom freezer room access is requested via an SF-2-3 Appendix E (Collaborating Biorepository Staff

Access to Controlled Areas – Request or Rescind) signed by the GLP PI or Designee, SSF personnel type or print full name and initials of the newly trained CBP on SF-1-13 Appendix A.

6.5.2.3.1.2. In lieu of obtaining wet signature on SF-1-13 Appendix A, the CBP's SF-1-5 Appendix A (Signature Form), completed during SSF training, is utilized for the CBP's signature attribution.

6.5.2.3.1.3. SSF personnel document effective date, initials and date on SF-1-13 Appendix A. The effective date is the date freezer room training was completed.

6.5.2.3.1.4. Training requirements also apply to the GLP PI.

6.5.2.3.2. Removal of CBP from SF-1-13 Appendix A:

6.5.2.3.2.1. SF-1-13 Appendix A is updated by SSF personnel upon receipt of an SF-2-3 Appendix E signed by the GLP PI or Designee and upon rescinding CBP freezer room access. SSF personnel lineout the fields for printed name and initials, assign an obsolete date (date the SF-2-3 App. B is executed), initial and date.

6.5.2.3.3. Addition and removal of CBP for whom a signed SF-2-3 App. E is received does not require GLP PI or Designee approval on SF-1-13 Appendix A.

6.5.2.4. Non-Collaborating Biobank Personnel and/or CBP untrained for SSF freezer room access

6.5.2.4.1. Addition of personnel to SF-1-13 Appendix A:

6.5.2.4.1.1. At the addition of personnel to a GLP PI's signed SF-1-4 Appendix D (Storage Agreement), SSF personnel initiate training on the following procedures:

6.5.2.4.1.1.1. SF-1-13 SOP for Managing GLP Specimens

6.5.2.4.1.1.2. Good Documentation Practices per SF-1-5 SOP for Personnel Training

6.5.2.4.1.1.3. Training requirements also apply to the GLP PI.

6.5.2.4.1.2. Signatory verification is maintained in the SSF per SF-1-5 SOP for Personnel Training.

6.5.2.4.1.3. Training documents are maintained in the SSF per SF-1-6 SOP for Controlled Document Management.

6.5.2.4.1.4. Upon effecting SF-1-5 Appendix A, SSF personnel type or print full name and initials of the newly trained personnel on SF-1-13 Appendix A.

6.5.2.4.1.5. In lieu of obtaining wet signature on SF-1-13 Appendix A, the SF-1-5 Appendix A (Signature Form), completed during SSF training, is utilized for signature attribution.

6.5.2.4.1.6. SSF personnel document effective date, initials and date. The effective date is the date training was completed.

6.5.2.4.2. Removal of personnel from SF-1-13 Appendix A:

6.5.2.4.2.1. At GLP PI or Designee request to rescind personnel sample access authorization per a signed SF-1-4 Appendix D, SSF

personnel lineout the fields for printed name and initials on SF-1-13 Appendix A.

6.5.2.4.2.2. SSF personnel assign an obsolete date based on the date SF-1-4 Appendix D was signed. SSF personnel reference the signed SF-1-4 Appendix D on SF-1-13 Appendix A.

6.5.2.4.3. Addition and removal of personnel reflected on a signed SF-1-4 Appendix D does not require GLP PI or Designee approval on SF-1-13 Appendix A.

6.5.2.5. All SSF personnel trained on the following SOPs and procedures have authority to document on the GLP Access Log, SF-1-13 Appendix B, and are not required to be listed on Appendix A:

6.5.2.5.1. SF-1-13 SOP for Managing GLP Specimens

6.5.2.5.2. Good Documentation Practices per SF-1-5 SOP for Personnel Training

6.5.2.5.3. MRU and/or LN_2 room access per SF-2-3 SOP for Controlled Access Operations, as required per the applicable GLP study's freezer and/or ambient storage location.

6.5.2.5.4. Signatory verification and training documents for SSF personnel are maintained in the SSF per SF-1-5 SOP for Personnel Training and SF-1-6 SOP for Controlled Document Management.

6.5.2.6. The current versions are posted at the applicable unit, and the outdated versions are retained with the SSF records relative to the GLP study.

6.5.3. A GLP Access Log (Appendix B) may, upon request of PI, be created to document access to the storage unit. A GLP Access Authorization Form (Appendix A) must be utilized in conjunction with the use of Appendix B and per directives in Section 6.5.2.

6.5.4. A GLP Monitoring Log (Appendix D) may be created for use either by the GLP study personnel or the SSF (as described in the completed Appendix C) to include documented record of observations for PI-defined:

6.5.4.1. Parameter to be monitored

6.5.4.2. Frequency of monitoring

6.5.4.3. Acceptable range

6.5.4.4. Notification directives

6.5.4.5. If parameters are modified per submission of a new Appendix C, a revised monitoring log is developed and implemented.

6.5.5. Alternatively, data reporting documentation supplied by the PI and used per his/her directives may be employed. The SSF defers training for any SSF use, as applicable, and retention of these documents to the PI.

6.5.6. If the PI wishes not to utilize the SSF optional appendices, this request should also be documented on Appendix C.

6.6. Directives are approved by both the PI and the SSF Director.

6.7. Process for responding to investigators who are denied services, or have concerns regarding operations, pricing, quality or other SSF policies, is managed per SF-1-4 Managing Storage Space.

7. REFERENCES

7.1. Good Laboratory Practices 21 CFR 58 Subpart C: Facilities

8. DOCUMENTATION

8.1. Original Records of GLP Study Specific Logs are reviewed by the SSF Director and given to the PI, and copies are retained per SOP SF-1-6 Controlled Document Management.

8.2. Deviations 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 guide and/or implement this SOP:
   Appendix A: GLP Access Authorization Form (1 page)
   Appendix B: GLP Access Log (1 page)
   Appendix C: GLP Supplementary Requirements Reporting Form (1 page)
   Appendix D: GLP Monitoring Log (1 page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVE
   10.1. Collaborating biobank personnel required to complete SF-1-13 training are directed to read SOP SF-1-13 and all its appendices in its entirety.

SSF GLP Access Authorization Form

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SSF# _____

GLP Unit ID _____ **Page** _____ **of** _____

Location _____

PI / Study Director _____ Biobank Affiliation _____

Personnel listed below satisfy the prerequisites for being granted entry into the GLP storage unit indicated on this form. Personnel signatures and initials are documented on SF-1-5 Appendix A.

PI Personnel*			SSF		SSF	
Printed Name	Initials	Effective Date	Initials / Date	Obsolete Date	Initials / Date	Comments

GLP Access Log **Month_____ Year_____**

INDIANA CTSI Clinical and Translational Sciences Institute

GLP Access Log SSF#_____
GLP Unit ID_____ Location _____
PI or Study Director_____

Date	Record of Entry (Authorized Signature or Initials – Record Additional on Reverse and Include Date)						
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Reviewed by / Date:_____

GLP Supplementary Requirements Reporting Form

INDIANA CTSI Clinical and Translational Sciences Institute

GLP Supplemental Requirements Log SSF#____

GLP Unit ID_____ Location _____

PI or Study Director_____

Supplementary Requirements and Reporting

	PI Request/Special Instructions	Comments	Optional SSF Forms Requested
1	By Date	By Date	For Authorization: SF-1-13, Appendices A and B? ☐Yes ☐No For Enhanced Maintenance: SF-1-13, Appendix D? ☐Yes ☐No Comments:
2	By Date	By Date	
3	By Date	By Date	
4	By Date	By Date	

Approvals

I certify that I have reviewed and agreed to the Supplementary Requirements and Reporting as described above:

PI Signature_____ **Date**_____

SSF Director Signature_____ **Date**_____

Date Effective:

_____

Date Retired_____ Retired by_____
SSF Director

GLP Monitoring Log **Month_____ Year_____**

GLP Monitoring Log SSF#_____
GLP Unit ID_____ Location _____
PI or Study Director_____

Date	Parameter: Frequency: Range: Notification Directive*:		Parameter: Frequency: Range: Notification Directive*:		Parameter: Frequency: Range: Notification Directive*:		
	Tech	*Observation*	Tech	*Observation*	Tech	*Observation*	*Comment /Action*
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* Additional Information Regarding Directives:_____

Reviewed by / Date:_____