INDIANACTSI
Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: Standard Operating Procedure for Housing Good Laboratory Practice Collections

CHAPTER: 1--Administration and Quality Oversight

SOP #: SF-1-13.05

SUPERSEDES SOP#: N/A

Issue Date: 08.30.16

Effective Date: 09.16.16

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Indiana CTSI SSF Staff

APPROVAL: _____ DATE: 8-25-2016
Indiana CTSI SSF Director

QA APPROVAL: _____ DATE: 08.30.16
Quality Compliance Specialist

1. REVISION
   1.1. Significant revisions incorporated in this version include:
      1.1.1. Reorganized procedural section to more accurately describe the process, providing directives for the submission of Appendix C for any and all PI requests regarding the SSF's role in monitoring and maintenance of applicable units.
      1.1.2. Section 6.4 edited to remove ambiguity pertaining to the identity and uses of Appendix C.
      1.1.3. Section 6.5 added to incorporate use of Appendices A and B as optional, as directed by the completed Appendix C.
      1.1.4. Appendix B was modified and Appendix D was created to separate the monitoring portion from the access log on the previous version of Appendix B. Section 6.5 was updated accordingly.
      1.1.5. Section 6.5.4 added to state that PI forms may be utilized, and if SSF staff are instructed to utilize them, training is deferred to the PI.
      1.1.6. Section 6.5.5 added to instruct a PI who does not wish to utilize the optional SSF appendices to specify this preference on Appendix C.
      1.1.7. Section 6.5.6 added to mandate training on this SOP for any study personnel intending to document on optional SSF appendices. Section 4 was updated to include said personnel.
      1.1.8. Appendix A updated to include a field for personnel to print name.
      1.1.9. Appendix C edited to provide fields for documenting PI requests, comments, and whether or not optional SSF appendices are to be utilized.

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 CTSI Specimen Storage Facility (SSF).

3. PRINCIPLE

The CTSI SSF provides a facility for storage of specimens in a manner compliant with ISBER Best Practices. Certain modifications of the 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. Principle Investigators (PI) submits a request to use storage space per the Specimen Management procedure defined is SF-1-4-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 Managing Storage Space.

6.2. SSF personnel log the request into the Master Study Log per SF-1-4 Managing Storage Space 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 Managing Storage Space EXCEPT that a G (signifying GLP) is added after the previously final alpha character (P if accompanied by a processing request and O if no processing).

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

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 or Designee on Appendix C, the following additional practices may be initiated:

6.5.1. A separate GLP Access Authorization Form (Appendix A) may be provided by the GLP Study Director or Designee and is assigned to each individual GLP storage unit.

6.5.1.1. The names of SSF personnel and PI study personnel who have access to the GLP collection are listed.

6.5.1.2. An updated GLP Access Authorization Form is provided by the GLP Study Director or Designee when personnel authorizations change.

6.5.1.3. The current version is posted at the applicable unit and the outdated versions are retained with the SSF records relative to the GLP Study.

6.5.2. A GLP Access Log may be (upon request of PI) be created (Appendix B) to documents access to the storage unit.

6.5.3. A GLP Access Authorization Form (Appendix A) must be submitted in conjunction with the use of this log. A GLP Monitoring Log may be created (Appendix D) 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 Study-PI defined:

6.5.3.1. Parameter to be monitored

6.5.3.2. Frequency of monitoring

6.5.3.3. Acceptable range

6.5.3.4. Notification directives

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

6.5.4. 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.

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

6.5.6. If the GLP Study PI wishes to use any of the optional appendices, then training on this SOP is mandated for any personnel providing documentation on these forms. All training is managed per SF-1-5 Personnel Training.

6.6. Directives are approved by both the GLP Study 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 are 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 study 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 Authorized Access 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)

SSF GLP Access Authorization Form

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

The following personnel satisfy the prerequisites for being granted entry into the GLP storage unit indicated on this form:

Signature	Name Printed	Initials	Affiliation	Comments

Date Effective _____

Approved by _____
GLP Director or Designee

Date Retired_____

Retired by_____
SSF Director

GLP Access Log **Month**_____ **Year**_____

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

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:_____