INDIANA CTSI Clinical and Translational Sciences Institute

**STANDARD OPERATING PROCEDURE**
**Indiana CTSI Specimen Storage Facility**

TITLE: WRITING, REVIEWING, AND APPROVING SOPs

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-1.09

SUPERSEDES SOP#: N/A

Issue Date: 04.08.2021

Effective Date: 04.26.2021

AUTHORED BY: _____ DATE: 3-19-21
Indiana CTSI SSF Lab Staff

APPROVAL: _____ DATE: 03-26-2021
IndianaCTSI SSF Director

QA APPROVAL: _____ DATE: 04.08.2021
Quality Compliance Specialist

1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Appendix B revised to reflect Annex IV addition.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) describes the format, enumeration method, and review methods for SOPs developed for the Indiana CTSI Specimen Storage Facility (SSF). This procedure satisfies guidance set forth in ISBER "Best Practices" as related to facility operations.

3. PRINCIPLE
   3.1. In order to maintain continuity within the SOP document system, this SOP describes the procedures to be followed for SOP approval, review, and revision.

4. SCOPE
   4.1. The scope of this procedure includes each individual involved in the development, approval, and review of these SOPs for the SSF. Documentation Control is described in SOP SF-1-6 Controlled Document Management.

5. MATERIALS
   5.1. N/A

6. PROCEDURE
   6.1. SOP FORMATTING
      6.1.1. The header section of each SOP contains the specific page number followed by the total number of pages (excluding appendices). The header appears on each page.
      6.1.2. The footer section contains the SOP number and the SOP title (or abbreviated version of the SOP title). The footer appears on each page.
      6.1.3. The top portion of each SOP's initial page contains the following sections:

6.1.3.1. A section that includes the Indiana CTSI logo and the identification of the facility/laboratory (SSF).

6.1.3.2. A section containing the following: unique title, the title of the chapter in which the SOP can be located, the unique SOP number, the effective date, the superseded SOP number, and the issue date.

6.1.3.3. Below the SOP general information section is a section provided for the individuals (defined in section 6.8) to document authorship and approval by affixing their signatures.

6.1.4. The text sections of each SOP are numbered using a standard outline format as described in Appendix A. SOP sections and section numbering may vary with SOP content.

6.2. SOP TERMINOLOGY

6.2.1. Definitions of status descriptions, frequency terminology, and commonly applicable terms and phrases are defined in Appendix B. Terminology further defined within specific SOPs will take precedence over the definitions contained in this SOP.

6.2.2. Any SOP reference contained in another SOP is understood to be a reference to the most recently approved version.

6.2.3. Any SOP reference to a document included in an SOP appendix is understood to be a reference to the latest form version of the respective document.

6.3. SOP ENUMERATION PROCEDURE

6.3.1. UNIQUE IDENTIFICATION NUMBER

Each SOP is required to have a unique identification number, which cannot be reassigned. These numbers are assigned by SSF Management and recorded in a master index. Each alphanumeric descriptor consists of the 4 fields described below:

AA-X-Y.ZZ

AA - The Alpha field indicating for which laboratory the SOP is valid and is defined as: SF for the Indiana CTSI Specimen Storage Facility

X - The numeral indicating the Chapter of the SOP Manual where the SOP is listed. All SOPs are assigned to a Chapter. The SOP Manual consists of the following chapters:
Chapter 1: Administration and Quality Oversight
Chapter 2: Facility
Chapter 3: Equipment

Y - The numeral assigned to the procedure. Numbers are assigned sequentially.

ZZ -The two-digit version number initially assigned as '01', and increasing sequentially with each revision to the SOP.

6.4. APPENDICES

SOP appendices are used as a means of clarification, identification, or to document information obtained during the SOP execution. Each appendix is associated with a specific SOP, but may be referenced in multiple SOPs.

6.4.1. Identification of Appendices

6.4.1.1. Every document included in an SOP as an appendix contains a footer identifying the SOP number from which it originated. The footer of each document also includes a form version number to distinguish the version number of the appendix from the version number of the SOP containing it. Each

form version number begins at "01", and increases sequentially each time a revision is made to it.

6.4.1.2. Every SOP appendix will include a header that identifies the Appendix designation (A, B, etc.) and the pagination for the individual Appendix.

6.4.2. Revisions to an approved Appendix:

6.4.2.1. Each time revisions are made to a document identified as an SOP appendix, the SOP to which it is attached must also be reviewed for consistency. The Appendix may be revised independently of the respective SOP if the SOP contents do not conflict with the appendix content changes.

6.4.2.2. Appendices are revised independently from the SOP by incorporating the content changes in the body of the appendix and by increasing the form version in the footer of the revised appendix. For an appendix comprised of multiple pages, the form version is increased on all pages even if the content is modified on only one page.

6.4.2.2.1. To facilitate completion of logs for which daily entries are required (e.g., monthly equipment logs), it is acceptable for technicians to "grey-out" fields adjacent to "non-working" days for the respective month. It is also acceptable for technicians to electronically complete fields for month/year, etc.

6.4.2.2.2. Changes described above are incorporated electronically during the next SOP revision.

6.4.2.3. Alternately, a revision to an SOP which does not result in a change to the form version number in the footer of the appendix may occur if no change is made to the appendix.

6.4.3. Appendix modifications must be accompanied by a Document Change Control Form if they are not incorporated in an SOP change. The Change Control Form and instructions for completing the Change Control form are provided in SOP SF-1-6 Controlled Document Management.

6.5. INITIATION OF A NEW SOP

6.5.1. The request to initiate a new SOP can be made by anyone in the SSF or the supporting QA Unit. SSF Management will provide a new SOP number to the requester.

6.5.2. When a new SOP incorporates significant content from a retired SOP(s), the SOP number(s) of the retired SOP(s) is listed in the field designated as "SUPERSEDES SOP: _____" in the appropriate section on the first page of the SOP.

6.5.3. Initiation of new SOPs must be accompanied by the Change Control Form. The Change Control Form and instructions for completing the Change Control form are provided in SOP SF-1-6 Controlled Document Management.

6.6. REVISION TO AN EXISTING DOCUMENT

6.6.1. The process for initiating a revision to an existing SOP or Appendix can be initiated by anyone in the SSF or the supporting QA Unit.

6.6.2. Revisions to these documents must be accompanied by the Change Control Form. The Change Control Form and instructions for completing the Change Control form are provided in SOP SF-1-6 Controlled Document Management.

6.6.3. Critical revisions are defined as any revision that directly affects an essential element of the document. This would include a change in the materials, the order of operations, the reporting methods, documentation, equipment, etc. When critical revisions are warranted

for a particular SOP, the required revisions are detailed individually in the section on the revised SOP titled: "SECTION 1. – REVISION".

6.6.4. Appendices with critical changes will either be accompanied by a revised SOP or the Change Control form will be appended with a list of critical revisions.

6.6.5. Non-Critical revisions are defined as any revision to SOP formalities (i.e.: spelling, grammar, punctuation, or updated contact information). The incorporation of non-critical revisions can be postponed until a revision of critical components is deemed necessary. When incorporated, these changes are not required to be listed in the "Revision Section" of the revised SOP.

6.7. RETIREMENT OF EXISTING SOPs

6.7.1. The process for retirement of existing SOPs may be initiated by anyone in the SSF or the supporting QA Unit and must be accompanied by an approved Document Change Control Form. The Document Change Control Form and instructions for completing the Document Change Control form are provided in SOP SF-1-6 Controlled Document Management.

6.8. APPROVALS

6.8.1. The electronic copy of the document must be distributed to QA along with the Change Control Form with the appropriate completed sections. QA will distribute a hard copy of the new or revised document for signatures.

6.8.2. Signatures

6.8.2.1. Before any SOP can be implemented, the Author, the SSF Director or Associate and a member of QA Unit are required to sign and date the Approval Section located on the first page of each SOP. If the SSF Director or Associate is author, the only additional required signature is QA.

6.8.3. An accompanying Change Control Form per SOP SF-1-6 Controlled Document Management must also be completed and signed. The signatures required and meaning of these signatures are defined below.

6.8.3.1. Author approval signifies that the content of the SOP accurately reflects the desired practice for the process described in the SOP.

6.8.3.2. SSF Director/Associate Director approval signifies the document is accurate and complete and provides agreement with the justification and rationale for change and for providing the tools and resources necessary to implement the procedure.

6.8.3.3. Quality Assurance Unit approval signifies agreement with the justification for change and that the procedure complies with pertinent regulatory requirements and is consistent with applicable policies and procedures.

6.8.3.4. When all of the appropriate signatures have been obtained, an issue date can be assigned. When the Director or QA is author, their signature as author signifies approval as well as authorship.

6.8.4. Effective dates

6.8.4.1. The effective date is defined to be the date upon which the procedures described in the SOP are implemented in the SSF.

6.8.4.2. The effective date is assigned based on anticipated training time. The period of time between the issue date and the assigned effective date must be sufficient to allow for SSF personnel to be trained in the procedure. This period of time may vary with the degree of SOP technicality and need.

6.8.5. The SOP with the original signatures is considered the "ORIGINAL" and is maintained by the SSF Operations or Facility Manager. Distribution and maintenance of controlled copies for implementation is defined in SOP SF-1-6 Controlled Document Management.

6.8.6. Issue dates

6.8.6.1. The issue date is defined to be the date upon which the procedure is issued for training or validation, but prior to the effective date.

6.8.6.2. The issue date is assigned after all of the appropriate signatures have been obtained and Change Control Form is completed.

6.9. PERIODIC DOCUMENT REVIEW

6.9.1. SOPs are reviewed on a periodic basis (as defined below) to ensure that they remain an accurate representation of existing operations. Changes dictated by need should be initiated immediately.

6.9.2. Anyone in the SSF or supporting QA Unit may suggest that an SOP be reviewed at any time if new scientific evidence is presented, new regulatory requirements are instituted, or for process improvement and clarification.

6.9.3. The periodic review process for SOPs and their associated appendices is administered by Quality Assurance based on the assigned effective dates of the SOP using the periodicity defined below:

6.9.3.1. Technical – Biennially

6.9.3.2. Administrative – Biennially

6.9.4. Administrative SOPs are defined as follows
Chapter 1: Administration and Quality Oversight

6.9.5. Technical SOPs are defined as follows:
Chapter 2: Facility
Chapter 3: Equipment

6.9.6. SSF Management will provide the author with the specific document numbers due for periodic review.

6.9.6.1. The review of each SOP is conducted by the author. If the SOP author is not available, the SSF Director will assign the responsibility to an alternate SSF team member. The review is typically due within 1 month of notification.

6.9.6.2. The assigned reviewer initiates a Change Control Form for each document assigned for periodic review. (The Change Control Form may be initiated by any trained individual). Instructions for completing the Change Control form are provided in SF-1-6 Controlled Document Management.

6.9.6.2.1. If no changes are necessary, it is so noted on the Change Control Form, which is subsequently forwarded to QA and circulated for approvals.

6.9.6.2.2. When changes are necessary, follow Section 6.6 of this SOP.

7. REFERENCES

7.1. ISBER Best Practices- current version

7.2. SOP SF-1-6 Controlled Document Management

8. DOCUMENTATION

8.1. Master copies of SOPs are maintained in the Quality Compliance Archive files according to 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 implement this SOP:
   Appendix A: SOP FORMAT SECTIONS (1 Page)
   Appendix B: SSF SOP TERMINOLOGY (1 Page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES
   10.1. N/A

# SOP FORMAT SECTIONS

SECTION 1 - REVISION
This section contains any information pertaining to a critical revision of an SOP. If there is no relevant information to include in this section, note "N/A" under the section header to denote "not applicable".

SECTION 2 – PURPOSE
This section describes the reason for writing the SOP.

SECTION 3 – PRINCIPLE
This section describes background details and/or provides scientific information needed to clarify the specific topic involved.

SECTION 4 – SCOPE
This section describes the relevant time points or specific conditions affected by the SOP, and it defines who is responsible for implementing the SOP.

SECTION 5 – MATERIALS
This section contains a list of the materials required to perform the SOP. It may include the following as applicable:

- Supplies (quantity, description, product identification)
- Equipment (maintenance, quality control procedures)
- Additional SOP-specific items (Personal Protective Equipment [PPE], etc.)

SECTION 6 – PROCEDURE
This section provides a detailed list of the step-by-step directions to be followed. Also included are the precautions to be taken, any required preparations to be completed, calculations to be performed, interpretations, criteria for acceptance (if applicable) and expected results. Equipment SOPs should generally include sections for describing procedures for operation, cleaning, function verification, maintenance, and calibration.

SECTION 7 – REFERENCES
This section lists the appropriate scientific, technical, regulatory and/or SOP references.

SECTION 8 – DOCUMENTATION
This section lists the documentation requirements to be completed during the implementation of this SOP, and describes the appropriate archiving requirements. This section may include (at the author's discretion) a listing of specific items to be documented as well as the corresponding form(s) on which these items are to be recorded and notes that deviations are managed per SOP SF-1-9 Deviation Management.

SECTION 9 – APPENDICES
This section may be included at the author's discretion, and contains a list of the attached appendices that are used to implement the SOP. The title of each appendix listed is preceded by an alpha character corresponding to the identification of the actual appendix attached to the SOP. The list is alphabetized according to the character preceding the title of the appendix. The appendices are attached to the SOP in alphabetic order according to the identification character.
Appendices may be revised separate from the SOP by either (1) replacing the current version with an updated version and noting the date and director approval or handwritten edits may be made if initialed and dated and appropriate approval is signified by the director.

SECTION 10 – COLLABORATING BIOBANK TRAINING DIRECTIVES
This section may be included in SOPs for which Collaborating Biorepository Personnel (CBP) training is required, compiling training directives specific to CBP to Section 10 of the SOP.

SSF SOP TERMINOLOGY

| | Term | Definition |
|---|---|---|
| 1 | may | Is permitted |
| 2 | Daily | Each working day |
| 3 | Weekly | Not to exceed seven (7) working days or ten (10) calendar days, whichever is longest |
| 4 | Monthly | Not to exceed 36 calendar days |
| 5 | Quarterly | Not to exceed 16 weeks and does not represent calendar quarters |
| 6 | Semi-annually | Not to exceed 7 months |
| 7 | Annually | Not to exceed 13 months |
| 8 | Biennially | Not to exceed 25 months |
| 9 | Policy | Procedure |
| 10 | Mechanical Freezer Room | • R3-C135, DNA and Serum Bank, Mechanical Refrigeration Unit Storage Room<br>• IB 097/MS-B046 Cage, Annex I<br>• MS-B037, Annex III<br>• TK 246, Annex IV -80°C Freezer Room |
| 11 | Liquid Nitrogen Freezer Room | • R3-C156, Cell Repository<br>• TK 252, Annex IV $LN_2$ Freezer Room |
| 12 | Annex I | IB 097/MS-B046 Cage |
| 13 | Annex III | MS-B037 |
| 14 | Annex IV | TK 246, TK 250, TK 252, and TK 258 |
| 15 | M10 BiOS Room | TK 258, Annex IV |

Effective Date_____

Obsolete Date_____