INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: Standard Operating Procedure for Deviation Management

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-9.06

SUPERSEDES SOP #: N/A

Issue Date 06.15.2021

Effective Date: 06.22.2021

AUTHORED BY: _____ DATE: 6-7-21
Indiana CTSI SSF Staff

REVIEWED BY: _____ DATE: 06-09-2021
Indiana CTSI SSF Director

QA APPROVAL: _____ DATE: 06.15.2021
Quality Compliance Specialist

1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Step 3.1.3 example revised to improve clarity.
      1.1.2. Section 10, Collaborating Biobank Training Directives, added to align with SF-1-1.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) for documenting, investigating, and logging deviations. This procedure satisfies guidance set forth in ISBER "Best Practices". ISBER Best Practices defines a deviation as an intentional or unintentional event that is a departure from a procedure or normal practice. Section D6.1 of ISBER Best Practices requires that: "Deviation reports are produced for all events that fall outside SOPs".

3. PRINCIPLE
   3.1. Deviations must be fully addressed to include documentation of the event, investigation of the cause(s), and a plan for preventing recurrence. This procedure is designed to address all of these aspects of a deviation through the corrective and preventative actions (CAPA) for continuous improvement approach. Deviations may be discovered through result of an audit, an observation by any SSF personnel or review by a client and are distinctly different from Out of Specification Conditions (OOS); however, OOS conditions may result from or point to a deviation. Examples of occurrences documented as deviations compared to occurrences documented as OOS conditions are provided below.
      3.1.1. Example of an OOS which is NOT a deviation: An SSF freezer is found to read below the acceptance range. The SSF technician addresses the reading according to the SOP.
      3.1.2. Example of an OOS which is ALSO a deviation: SSF personnel monitor a mechanical freezer which has warmed to alarm conditions per SF-3-1, SOP for Mechanical Refrigeration Units. The freezer fails to recover to acceptable temperature within defined parameters, and SSF personnel begin relocating samples to an SSF backup freezer per SF-1-10, SOP for Out of Specification Condition and Notification Management. The SSF personnel relocating samples is called away from the freezer relocation to assist a customer, fails to return to the freezer relocation, and the freezer fails to recover, allowing specimens housed in the freezer to thaw.

3.1.3. Example of a Deviation not related to an OOS: An audit is being conducted and the auditor reviews the SSF visitor log. There are 2 non-SSF-trained personnel in the Mechanical Refrigeration Unit Storage room at the time of the audit, however, there is only 1 visitor logged in for the day.

4. SCOPE

4.1. This SOP defines the actions and responsibilities for all SSF personnel in the event of a deviation. Out of Specification (OOS) conditions are managed per SOP SF-1-10.

5. MATERIALS

5.1. N/A

6. PROCEDURE

6.1. DEFINITIONS

6.1.1. Corrective Action – Action taken immediately to resolve the deviation.

6.1.2. Preventative Action – Steps taken to prevent future occurrences of the same deviation.

6.1.3. Planned Deviation – An intentional departure from normal operation of SOPs.

6.1.4. Root Cause – The most basic reason for an undesirable condition or problem that, if eliminated or corrected, would have prevented an event from occurring.

6.1.5. Unplanned Deviation – An unanticipated error or accident.

6.1.6. Planned/Unplanned Deviations – a deviation which has both an unplanned component and a planned component.

6.2. UNPLANNED DEVIATIONS

Note: An unplanned deviation may occur in conjunction with a planned deviation. Additionally, multiple unplanned deviations which are related (e.g., an additional deviation may be discovered during the investigation of the deviation in question) may be documented together.

6.2.1. Upon discovery, immediately notify SSF Management and QA. Notification needs to take place within 1 working day of discovery.

6.2.2. SSF Management and QA will advise regarding an acceptable immediate corrective action to minimize the adverse impact on stored specimens.

6.2.3. The person discovering the deviation initiates the Deviation Report Form (Appendix A) with the description and record of the immediate corrective action taken within 5 working days of discovery.

6.3. PLANNED DEVIATIONS

6.3.1. Planned deviations are first documented on a Deviation Report Form (Appendix A). Documented approval from SSF Management and QA is required prior to implementation of planned deviations. Copies of planned deviations may be kept with the SSF SOP or applicable form until the revised document is made effective (as applicable).

6.4. DEVIATION PROCESSING AND INVESTIGATION OF IMPACT

6.4.1. Obtain a deviation tracking number from QA.

6.4.1.1. The deviation tracking number is assigned as follows:
D-YY-XX, where:
D – Indicates that the reference number pertains to a Deviation.
YY – Indicates the last two digits of the year in which the deviation is initiated.
XX – Deviation Number (issued consecutively within year of occurrence)

6.4.1.2. If a deviation tracking number is obtained via email, a copy of the correspondence may be added to the deviation logbook as a placeholder for the completed report.

6.4.2. SSF personnel initiate a Deviation Report Form (Appendix A).

6.4.3. QA personnel record the deviation tracking number on the Deviation Report Log (Appendix B).

6.4.4. SSF Personnel proceed with completion of Sections 1-5 of the Appendix A form as indicated in the table below:

Section	Description	Sequence/Timing	Responsible Party
	Deviation Tracking Number - Assigned as defined in Step 6.4.1.1	Request deviation number assignment from QA as soon as possible after discovery. Subsequent sections may be completed while awaiting QA number assignment.	Person who discovered the deviation or designated alternate.
1	Document the following information as defined below: Event Date - The actual date on which the event occurred Approximate Duration – The time elapsed from the apparent beginning to the end of the deviation. *Note: Deviations which have gone undetected for a long period should include an investigation to determine if potential quality system improvements are needed. Include attachment of investigative reports as needed* Planned or unplanned - Designate as appropriate Planned/Unplanned – Delineate both the planned component and the unplanned component separately within the deviation. Date of QA Number Assignment – The date on which the deviation tracking number was assigned by QA	Complete as soon as possible after deviation is discovered.	Person who discovered the deviation or designated alternate.
2	Answer each of the items as completely as possible. Applicable SOPs - Enter the SOP number and version that was not followed. This may include 1 or more entries. Description of the deviation and immediate response to remedy an existing situation and to lessen potential impact includes what, who and when for each point. Indicate the impacted area(s) as those presumed to be affected by the deviation. Document as "none" if there is no associated impact. Obtain and attach (with pagination) supporting documentation and reference the deviation number on associated SSF documentation, as appropriate.	Complete as soon as possible after Section 1 is complete	Person who discovered the deviation or designated alternate.
3	Document the results of the Investigation and Root Cause Analysis The *root cause* is determined by asking the question "Why" repeatedly. For example: non	Complete Section 3 after Section 2 is complete and as the investigation progresses. There may be multiple entries on	Person who discovered the deviation or

	authorized personnel were permitted access to a specimen storage unit. • "Why": The SSF tech didn't know the person wasn't authorized for access.	different dates to reflect the history and analysis of the deviation.	designated alternate.
Section	Description	Sequence/Timing	Responsible Party
3	• "Why": The SSF tech didn't review the SF-1-4 submission form. • "Why": (a) The SF-1-4 form was not available on the unit and (b) the SSF tech didn't go locate the form. • "Why": (a) The SSF Operations Manager didn't know that the form was required to be posted immediately and (b) the technician failed to follow defined protocol. • Root Cause: (a) Inadequate SOP and (b) personnel need to be retrained. *If multiple deviations are discovered during the course of the root cause analysis, include an investigation to determine if potential quality system improvements are needed. Include attachment of investigative reports* as *needed.* Obtain and attach (with pagination) supporting documentation and reference the deviation number on associated SSF documentation, as appropriate.	Complete Section 3 after Section 2 is complete and as the investigation progresses. There may be multiple entries on different dates to reflect the history and analysis of the deviation.	Person who discovered the deviation or designated alternate.
4	Document the final assessment of impact and applicable additional response as defined by discussion to include the SSF staff completing the form, SSF Operations Manager and SSF Director. When applicable, the SSF Director notifies investigator/owner of the specimens. Obtain and attach (with pagination) supporting documentation and reference the deviation number on associated SSF documentation, as appropriate.	Complete after the SSF staff investigation is complete and applicable parties have discussed and reached consensus.	Person who discovered the deviation or designated alternate.
5	Document the preventive action and follow-up plan to include the date set for completion and responsible party. Not all deviations require preventative actions and/or follow-up. The frequency, severity, impact and cause of the deviation are reviewed to determine if preventative actions are required. Follow-up is only required where the timeframe for the completion of the preventative actions extends beyond the desired close-out date. Obtain and attach (with pagination) supporting documentation and reference the deviation number on associated SSF documentation, as appropriate.	Complete after the SSF staff investigation is complete and applicable parties have discussed.	Person who discovered the deviation or designated alternate.
6	Document the date the report draft was completed and prepared for SSF Staff	Complete after Sections 1-5 are complete.	Person who discovered the deviation or

	(excluding Operations Manager, Director, and QA Consultant) review.		designated alternate.

Note: Documentation managed by the controlled document system (e.g., SOPs, training forms) is typically not attached to a deviation. Consult with QA for guidance.

6.4.5. Complete Section 7 with signatures when signatory personnel agree to the following:
- 6.4.5.1. Accuracy and completeness of the deviation description
- 6.4.5.2. Completeness of the investigation
- 6.4.5.3. Attribution of impact
- 6.4.5.4. Appropriateness of the corrective actions (immediate & long-term)
- 6.4.5.5. Need for follow-up
- 6.4.5.6. Both the appropriateness of the follow-up actions specified and the appropriateness of the time specified for completion.

6.4.6. Upon documentation of all signatory approvals, submit to QA for final close-out once all follow-up actions (as appropriate) have been completed. Provide evidence of completion of follow-up activities (as appropriate) to QA.

6.4.7. QA personnel complete the Deviation Report Log (Appendix B)

Column	Description	Sequence/Timing
Event Date	Date of occurrence	As soon as known
Deviation #	The reference number assigned	As soon as known
Assigned By	QA Initials and date assigned	
Description	Summary Description of the event, actions, and reported duration.	After Completion of Section 2 of Deviation Report Form by SSF Personnel or upon receipt of notification of the event
Final Impact	Equipment, Facility, Specimen, etc	After final assessment by SSF personnel or upon receipt of report for signature
Close Out	Date of QA signature on Section 7 of Deviation Report Form	Following signature by SSF personnel or upon receipt of report for signature
Follow-up Req'd	Enter Yes/No to correspond to section 5 of Deviation Report	As above
Follow-Up complete	Enter either "N/A" or enter the date completed (from Section 8) and QA initials	Upon receipt of evidence that follow-up is complete
> 60 days	Enter Yes/No to correspond to elapsed time between deviation number assignment by QA and QA close-out signature.	Upon receipt of notification that follow-up is complete
Comment	Clarifying or reference information	As needed

6.4.8. Complete close-out of deviations within 60 calendar days unless the scope is such that it is not feasible to do so. When this occurs, note the reason in the deviation documentation.

6.4.9. All open deviations are reviewed in SSF meetings and may continue review until the recommended actions have been completed.

6.4.10. Once completed, the official date of deviation close-out is listed on Appendix B by QA and is determined once all corrective and preventive actions have been completed and documented as required. Supporting documentation may be added as it becomes available (as applicable). QA verifies completion of Close Out and Follow-up by signing/dating Section 8 of Appendix A.

7. REFERENCES
   7.1. ISBER Best Practices (current version)

8. DOCUMENTATION
   8.1. Documents are retained in the SSF Facility Management Office per the SOP for Controlled Document Management (SF-1-6).

9. APPENDICES
   9.1. The current version of each of the following appendices is used to implement this SOP:
   APPENDIX A: Deviation Report Form (1 Page)
   APPENDIX B: Deviation Report Log (1 Page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES
    10.1. N/A

INDIANA CTSI Clinical and Translational Sciences Institute

Deviation Report Form

Tracking Number (*D-yy-xx*) _____

1. Reporting Information:

Event Date:	Approx. Duration:	☐ Planned ☐ Unplanned	Date of QA Number Assignment:

2. Description of Deviation:

2.1 Applicable SOP(s):

2.2 Describe the Deviation:

2.3 Describe the Immediate Response:

2.4 Make an Initial Impact Assessment:

Specimens	☐ No	☐ Yes (Describe)
Facility	☐ No	☐ Yes (Describe)
Equipment	☐ No	☐ Yes (Describe)
Other	☐ No	☐ Yes (Describe)

Reported By / Date		Attachments	☐ No ☐ Yes (# of pages)____

3. Investigation and Root Cause Analysis:

Documented By / Date		Attachments	☐ No ☐ Yes (# of pages)____

4. Impact Assessment and Additional Response:

☐ Assessment of impact unchanged from initial. No Additional Response required.

☐ Modification of initial assessment and/or additional response required as described below.

Documented By / Date		Attachments	☐ No ☐ Yes (# of pages)____

5. Preventative Actions and Follow-up Plan (as applicable):

5.1 What will be done to prevent a recurrence?

When will this be completed? Who is responsible?

5.2 What documentation will demonstrate completion?

When will this be completed? Who is responsible?

Documented By / Date		Attachments	☐ No ☐ Yes (# of pages)____

6. Initial Report Completed

Date of completion (Sections 1-5), pending review:	

7. Approval Section	Signature / Date
SSF Operations Management	
SSF Director	
Quality Compliance	

8. Close-Out and Follow-Up Completed

QA Verified/Date:

INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

SSF DEVIATION REPORT LOG

YEAR_____ **PAGE**_____

	Event Date	Deviation # Assigned (*D-yy-xx*)	Assigned By/Date:	Applicable SOP (s)	Deviation Description	Final Impact	Close Out Date / By	Follow-Up Req'd	Follow-Up Complete Date/By	>60 Days	Comment
1		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
2		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
3		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
4		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
5		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
6		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
7		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
8		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
9		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	
10		D-_ _ - _ _						❑ No ❑ Yes	❑ N/A Completion Date: QA ID:	❑ No ❑ Yes	