



STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility

TITLE: Managing Storage Space

CHAPTER: 1-Administration and Quality Oversight

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1. REVISION

1.1. Significant steps incorporated in this version include:

- 1.1.1. Annex I room name changed from MS B-46 to IB 097/MS-B046 Cage for consistency with other SOPs.
- 1.1.2. Changed Annex III room name from MS B-37 to MS-B037 throughout to maintain consistency with other SOPs. Room map, Appendix M, updated accordingly.
- 1.1.3. Removed all references to UH5049 and Annex II throughout the SOP because UH freezer rooms were decommissioned by the SSF.
- 1.1.4. Removed all references to processing services throughout the SOP, because the SSF ceased processing operations.
- 1.1.5. Section 6.1.5.9, Specimen Specific information regarding infectious agents further defined to require PI to define whether specimens are CDC Category A or CDC Category B or lower. Further define that SSF will not store Category A specimens and that storage requests for Category A specimens will be refused with the PI directed to the SSF's Oversight Committee, if necessary. Section 6.1.5.9 reformatted to better align with Appendix A.
- 1.1.6. Section 6.1.5.10 revised to reflect model of LN₂ and/or -80°C LN₂ freezer versus unit box capacity, due to storage rates and billing changes.
- 1.1.7. Removed processing account designation of "P" in Section 6.2.1 and additional references in Section 6.6.1.
- 1.1.8. Section 6.2.7.4 revised to reflect recording of Study Identifier and define the term to include CRC Protocol number, Study short name, and Study name. All references to Study Name replaced with Study Identifier throughout the SOP.
- 1.1.9. Section 6.2.7.5 revised to reflect that requests to alter Appendix A to reflect addition or existing storage of Category A specimens will result in storage increase denial and/or notification that Category A specimens already stored in the SSF will result in account closure, and the PI must remove specimens from the SSF immediately. Directives added for PI appeal to the SSF's Oversight Committee.
- 1.1.10. Section 6.4.3.2 item 5 revised to correct reference from CTSI to SSF.

- 1.1.11. Section 6.4.3.2 item 8 revised to indicate that PI owner of LN₂ freezer(s) agrees to allow SSF personnel to alter high level alarm point on an LN₂ freezer in the event of an overflow. PI will be notified the following business day, the freezer will continue to be monitored via the alarm system, with low level alarm unaffected and high level alarm point restored when unit reaches acceptable level. Inaccurate reference to removing unit from alarm system removed. Option for PI to decline action removed because the directive is illogical and counterintuitive to sample safety.
- 1.1.12. Section 6.4.6.2 revised as follows:
 - 1.1.12.1. Removed reference to chronologic numbering of racks and boxes, because the term chronologic refers to time. The applicable rack and box numbering references indicate that racks are assigned a number from left to right within freezer and boxes assigned a number from back to front, from top to bottom of rack.
 - 1.1.12.2. Removed reference to chronologic numbering of freezer units within freezer rooms, defining that units are placed in numerical order per applicable directives for each room.
 - 1.1.12.3. Removed reference to chronologic numbering of shelves within freezer units, defining that shelves are numbered numerically from top to bottom.
 - 1.1.12.4. Removed naming/numbering convention for UH 5049
 - 1.1.12.5. Added naming/numbering convention for Mechanical Freezers in C156.
 - 1.1.12.6. Specified in Section 6.4.6.2.4 that LN₂ unit racks may be pre-numbered by the manufacturer or assigned a number numerically by SSF personnel and identified with tags or permanent ink.
- 1.1.13. Section 6.4.6.3 revised to include the option of listing study identifier in addition to PI name on Appendix G for -70°C rental space in an SSF freezer and to remove -20°C freezer and Ambient SSF rental space to Section 6.4.6.4.
- 1.1.14. Due to space limitations on Appendix G, given revisions referenced in the previous step, Section 6.4.6.4 and Appendix K added, defining rental space in SSF -20°C freezers and ambient cabinets. Section 6.4.6.8 revised accordingly.
- 1.1.15. Step 6.4.6.5.1 and Appendix A revised to accommodate the most likely box sizes accommodated by SSF LN₂ rental freezers (25-cell and 100-cell 2" tall boxes).
- 1.1.16. Section 6.4.6.7.1.1 revised to direct SSF personnel to initial and date hand-written Appendix D modifications made by PI.
- 1.1.17. Step 6.6.7 reworded to more clearly direct SSF personnel to review of Section 6.2.7.5, given the defined response to a request to add Category A specimens.
- 1.1.18. Step 7.3 updated to reflect revised location of Category A Specimen definition.
- 1.1.19. Section 9 revised to reflect renamed Appendices G, I, K, and M.
- 1.1.20. Appendix A revised as follows:
 - 1.1.20.1. Denote rental of space accommodating 25-cell and 100-cell 2" tall boxes in an SSF LN₂ rental freezer.
 - 1.1.20.2. Remove reference to UH5049, SSF Annex II.
 - 1.1.20.3. Reflect model of LN₂ and/or -80°C LN₂ versus unit box capacity, due to storage rates and billing changes.
 - 1.1.20.4. Specimen Specific information regarding infectious agents further defined to require PI to define whether specimens are CDC Category A or CDC Category B or lower.
 - 1.1.20.5. Section 6 revised to assess ISBER compliance for samples stored in C156.
- 1.1.21. Appendix D revised as follows:
 - 1.1.21.1. To request Study Identifier instead of Study Name
 - 1.1.21.2. To clarify that "Personnel Authorized for Sample Access" lists authorized personnel in addition to PI, Primary, and Secondary.
 - 1.1.21.3. To update Category A Specimens definition location

- 1.1.21.4. Investigators Commitments Section Item 5 revised to correct reference from CTSI to SSF.
- 1.1.21.5. Investigators Commitments Section Item 8 revised to indicate that PI owner of LN₂ freezer(s) agrees to allow SSF personnel to alter high level alarm point on an LN₂ freezer in the event of an overflow. PI will be notified the following business day, the freezer will continue to be monitored via the alarm system, with low level alarm unaffected and high level alarm point restored when unit reaches acceptable level. Inaccurate reference to removing unit from alarm system removed. Option for PI to decline action removed because the directive is illogical and counterintuitive to sample safety.
- 1.1.22. Appendix G revised to include option of listing study identifier in addition to PI name for -70°C rental space in an SSF freezer. -20°C and Ambient rental space moved to Appendix K due to space limitations on Appendix G.
- 1.1.23. Appendix I revised to reflect Annex I room name change from MS B-46 to IB 097/MS-B046 Cage to maintain consistency with other SOPs.
- 1.1.24. Appendix J “Evaluation of Out of Specification Instance Closeout Completed” revised to state “Out of Specification Instance Closeout Completed”, better fitting with workflow. An N/A option remains.
- 1.1.25. Appendix K, UH5049 map, deleted since UH freezer rooms were decommissioned. Appendix K repurposed as -20°C and Ambient rental space map.
- 1.1.26. Appendix M revised to update Annex III room name from MS B-37 to MS-B037 to maintain consistency with other SOPs.
- 1.1.27. Appendix N revised as follows:
 - 1.1.27.1. Step/Section references corrected throughout
 - 1.1.27.2. Corrected PI signature requirement for Assignment of Replacement Request numbers for administrative change at annual renewal (no storage increase or decrease). PIs are not required to sign Appendix A. Corrected from Y to N/A.
 - 1.1.27.3. Provided directives for revision of Study Identifier and to add the signature types key to page 2 for clarity.

2. PURPOSE

- 2.1. This Standard Operating Procedure (SOP) describes the requirements, process, and considerations for assigning and permitting use of space in the Indiana CTSI Specimen Storage Facility (SSF). It also describes the process and documentation for modifying space request. This procedure satisfies guidance set forth in ISBER and Good Laboratory Practices (21 CFR 58 Subpart C, Facilities).

3. PRINCIPLE

- 3.1. The SSF does not serve as an independent biorepository but provides a facility for storage of specimens in a manner compliant with ISBER Best Practices and Good Laboratory Practices (21 CFR 58 Subpart C, Facilities). The facility provides storage space for a large number of CTSI investigators conducting bio-banking activities. A clearly defined process for requesting and relinquishing storage space in the facility is required. Moreover, the SSF needs assurances that investigators permitted to use the SSF are working in compliance with institutional policies and regulatory requirements and must be able to link stored specimens to the corresponding institutionally or other regulatory authority approved protocols.

4. SCOPE

- 4.1. The scope of this procedure includes all SSF personnel and defines the SSF response to requests received from all principle investigators to use storage space within the SSF. The scope also defines the process for responding to investigators who are denied services, or have concerns regarding operations, pricing, quality or other SSF policies. Forms generated from electronic request systems are preliminary and not controlled documents, therefore, SF-1-4 Appendices, once signed by the Principle Investigator (PI), are considered the master controlled documents for this SOP.

5. MATERIALS

5.1. N/A

6. PROCEDURE

Note: Refer to Appendix L for a flow chart summarizing the process of Storage Space Request Management and Intake.

6.1. Storage Request Submission - PI submit a request to use storage space. The request will be submitted one of the following formats:

6.1.1. Web-based or Email request – Request is printed, and section 6.2 is executed through step 6.2.6 by SSF personnel.

6.1.2. Hard copy

6.1.2.1. A template for a hard-copy form is provided in Appendix A.

6.1.2.2. SSF personnel executes Section 6.2 through Step 6.2.6.

6.1.3. If the request is denied by SSF Director, refer to Step 6.3.

6.1.4. After receiving SSF Director approval of the storage request, a current version of Appendix A is created for each web-based and email request.

6.1.4.1. Complete Appendix A, using PI-provided storage information (Section 6.1.6), SSF Request number (step 6.2.1), and space assignment (Section 6.2.4).

6.1.4.2. Evaluate PI-submitted hard copy (if applicable) for version. If obsolete version was submitted, create Appendix A per Step 6.1.5.1.

6.1.5. The Storage Request includes the following information:

6.1.5.1. Date of Request

6.1.5.2. Name, institution and contact information for the investigator

6.1.5.3. Primary contact name, role and contact information.

6.1.5.4. Protocol regulatory approval information including the following:

6.1.5.4.1. Approved IRB Protocol Institution and number, if pertaining to human research

6.1.5.4.2. IBC number, if applicable

6.1.5.4.3. Exempt status, if exempt per IRB and IBC regulations

6.1.5.5. Study(ies) Name / ID(s)

6.1.5.6. Protocol information for all studies of a storage type (GLP, Non-GLP) stored in the SSF should be listed under Study(ies) in Section 1 of Appendix A and above Section 1 of Appendix D.

6.1.5.7. Date requested to begin using the SSF. If for future funding proposal, note anticipated date of award.

6.1.5.8. Anticipated duration of SSF space use

6.1.5.9. Nature of specimens to be submitted:

6.1.5.9.1. Status regarding specimen de-identification (identified or de-identified)

6.1.5.9.2. Biosafety Considerations:

6.1.5.9.2.1. Storage of Human Blood, Body Fluid, or Tissue

6.1.5.9.2.2. Infectious Agent Level: CDC Category A –OR– CDC Category B or lower

6.1.5.9.2.3. NOTE: CDC Category A specimens may not be stored in the SSF. Requests to store Category A specimens will be denied, and the PI may appeal to the SSF's Oversight Committee per Section 6.8.1.3.

6.1.5.9.3. Other Safety Considerations:

6.1.5.9.3.1. Recombinant DNA (rDNA)

6.1.5.9.3.2. Radiation Safety considerations (Refer to SF-1-7 Appendix G for IUPUI Radiation Safety Office guidance safety guidance.)

6.1.5.9.3.3. GLP Study

6.1.5.9.4. Other Safety Considerations, explained

6.1.5.10. **Space Requested**

- 6.1.5.10.1. Space for PI owned mechanical freezer
 - 6.1.5.10.1.1. # of Chest or upright units
 - 6.1.5.10.1.2. Size of unit (physical footprint)
- 6.1.5.10.2. Space for PI owned Liquid Nitrogen freezer
 - 6.1.5.10.2.1. Size of unit / model (physical footprint)
- 6.1.5.10.3. Space for PI owned -80°C Liquid Nitrogen freezer
 - 6.1.5.10.3.1. Size of unit / model (physical footprint)
- 6.1.5.10.4. Space within SSF Mechanical Freezer: minimum space is 1/2 rack
 Note: ½ rack accommodates ~648 2ml cryovials or ~68 5-10 ml tubes.
 Note: 1 rack accommodates ~1296 2 ml cryovials or ~137 5-10 ml tubes.
- 6.1.5.10.5. Space within SSF Ambient Storage: minimum space is 1 drawer
 Note: 1 drawer accommodates ~1296 2 ml cryovials or ~137 5-10 ml tubes.
- 6.1.5.10.6. Space within SSF Liquid Nitrogen Storage Unit: minimum space is 1 LN₂ storage box

- 6.1.6. PI signature on Appendix A is not required. PI authorization for the storage request is confirmed when they sign the storage agreement, Appendix D of this SOP.

6.2. SSF personnel log the request into the Master Study Log (Appendix B template hard copy form and electronically) and performs preliminary assessment of the request.

- 6.2.1. Assign an SSF request number per the following convention:

SSF Request #: YY - NNN - A

YY is final 2 digits of the Calendar Year

NNN is the Chronological assignment within the calendar year

A = O for non-GLP studies

A = OG for GLP studies (refer to SOP SF-1-13: Housing GLP Collections, for additional information).

- 6.2.1.1. Each PI is assigned one or more Request numbers per request type, i.e. GLP Collection (G), Non-GLP Collection (O).

- 6.2.1.1.1. Studies with identical specimen safety requirements (Section 3 of Appendix A) may be assigned the same request number.
- 6.2.1.1.2. Studies with varying specimen safety requirements (Section 3 of Appendix A) would be assigned unique request numbers.

- 6.2.2. SSF personnel review request for completeness, taking into account the request for immediate space vs. commitment in support of a funding application. If the documents are incomplete, SSF personnel informs the PI who is then responsible to provide the missing information.

- 6.2.3. Based on the completed request, SSF personnel make a preliminary determination as to PI eligibility for facility use.

- 6.2.4. **Space Determination Evaluation** - If the request is for immediate space, SSF personnel determine if sufficient space is available. If available, a proposed space assignment is identified.

- 6.2.4.1. If proposed space assignment is for mechanical refrigeration units in R3-C156, determine from PI whether samples require ISBER Best Practices compliance for room temperature.

- 6.2.4.1.1. If samples require ISBER compliance, determine alternate storage location.

- 6.2.4.1.2. If alternate location is unavailable, proceed per Step 6.8.1.1.

- 6.2.4.2. Denote findings on Appendix A, Section 6 as Y, N, or N/A.

- 6.2.4.3. **Freezer Intake Guidelines** - Requests to store a PI-owned freezer must comply with SSF intake guidelines, as follows:

- 6.2.4.3.1. Freezers already in service and housing samples:

- 6.2.4.3.1.1. Must be in good working order, with no known mechanical defects.

- 6.2.4.3.1.2. Must accommodate racks no larger than those with capacity to hold 16-25 two inch boxes.
- 6.2.4.3.1.3. PI must have all samples contained in racks or bins to facilitate specimen relocation during freezer defrost.
- 6.2.4.3.2. New (empty) freezers:
 - 6.2.4.3.2.1. Must accommodate racks no larger than those with capacity for 16-20 two inch boxes – OR -
 - 6.2.4.3.2.2. Unit may be acceptable if it can be reconfigured to comply with Step 6.2.4.3.2.1 by purchasing an additional shelf and shelf brackets. PI will purchase additional shelf and shelf brackets.
 - 6.2.4.3.2.3. Any samples placed in freezer must be contained in PI-provided racks or bins to facilitate specimen relocation during freezer defrost.
- 6.2.4.4. **NOTE:** Utilize Intake of New, Repaired, or Replacement Freezers and Freezer Relocations form (Appendix J) for freezer intake. Appendix J is an optional, suggested tool *for use on intake of PI-Owned and SSF-Owned freezers.*
- 6.2.4.5. **Freezer Preventive Maintenance (PM) Evaluation and Testing at Freezer Intake:**
 - 6.2.4.5.1. For brand new, empty MRU units:
 - 6.2.4.5.1.1. Startup unit after required rest period per SF-3-1.
 - 6.2.4.5.1.2. Once freezer has reached acceptable temperature per SF-3-1, complete quarterly maintenance per SF-3-1 using SF-3-1 Appendix D.
 - 6.2.4.5.1.3. Document results on SF-3-1 Appendix D.
 - 6.2.4.5.1.4. Complete annual preventive maintenance per SF-3-1 using SF-3-1 Appendix B.
 - 6.2.4.5.1.5. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix K.
 - 6.2.4.5.1.6. Document results on SF-3-1 Appendix B.
 - 6.2.4.5.1.7. The next Quarterly PM will be scheduled per SF-1-1, not to exceed 3 months.
 - 6.2.4.5.1.8. Input / confirm set points defined by PI per Appendix D.
 - 6.2.4.5.1.9. Assign annual and bi-annual preventive maintenance due dates, per SF-1-1, and based on when the unit is placed in service (i.e unit meets acceptance for safely holding samples, has been successfully alarm tested and is being actively monitored by SSF staff per SF-3-1).
 - 6.2.4.5.1.10. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.1.11. Follow SF-1-4 Appendix L to place unit in service.
 - 6.2.4.5.1.12. Document results on SF-1-4 Appendix J, as applicable.
 - 6.2.4.5.1.13. Guidelines listed in table format at the end of Section 6.2.4.5.
 - 6.2.4.5.2. If MRU freezer is in service / not new:
 - 6.2.4.5.2.1. Complete annual preventive maintenance per SF-3-1 using SF-3-1 Appendix B.
 - 6.2.4.5.2.2. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix K.
 - 6.2.4.5.2.3. Document results on SF-3-1 Appendix B.
 - 6.2.4.5.2.4. Input / confirm set points defined by PI per Appendix D.
 - 6.2.4.5.2.5. Complete quarterly maintenance per SF-3-1 using SF-3-1 Appendix D.
 - 6.2.4.5.2.6. Document results on SF-3-1 Appendix D.
 - 6.2.4.5.2.7. The next Annual PM is scheduled per SF-1-1.

- 6.2.4.5.2.8. The next Quarterly PM will be scheduled per SF-1-1, not to exceed 3 months.
 - 6.2.4.5.2.9. Evaluate freezer for necessity of defrost (bi-annual preventive maintenance), assigning due date within one year.
 - 6.2.4.5.2.10. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.2.11. Follow SF-1-4 Appendix L to place unit in service.
 - 6.2.4.5.2.12. Document results on SF-1-4 Appendix J, as applicable.
 - 6.2.4.5.2.13. Guidelines listed in table format at the end of Section 6.2.4.5.
- 6.2.4.5.3. For brand new, empty LN₂ units:
- 6.2.4.5.3.1. Freezer startup is often completed by vendor.
 - 6.2.4.5.3.2. Once freezer has reached acceptable temperature after startup (per SF-3-2), SSF personnel ensure probes are properly positioned:
 - 6.2.4.5.3.2.1. Top probe (Temp A) depth is as near as possible to the top of tallest rack, unless otherwise defined by PI.
 - 6.2.4.5.3.2.2. Bottom probe (Temp B) is submerged in LN₂, if probe is long enough to submerge and unless otherwise defined by PI.
 - 6.2.4.5.3.3. Obtain desired set points from PI, defined per SF-3-2 Appendix C, and input into freezer.
 - 6.2.4.5.3.4. Complete semi-annual and annual maintenance per SF-3-2 using SF-3-2 Appendix B.
 - 6.2.4.5.3.5. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix J.
 - 6.2.4.5.3.6. Document results on SF-3-2 Appendix B.
 - 6.2.4.5.3.7. The unit's first Quarterly PM is due per SF-1-1, not to exceed 3 months.
 - 6.2.4.5.3.8. The next Annual and Semi-Annual PMs are scheduled per SF-1-1.
 - 6.2.4.5.3.9. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.3.10. Follow SF-1-4 Appendix L to place unit in service.
 - 6.2.4.5.3.11. Document results on SF-1-4 Appendix J, as applicable.
 - 6.2.4.5.3.12. Guidelines listed in table format at the end of Section 6.2.4.5.
- 6.2.4.5.4. If LN₂ freezer is in service / not new:
- 6.2.4.5.4.1. Freezer set up is often completed by vendor.
 - 6.2.4.5.4.2. Once freezer has reached acceptable temperature (per SF-3-2), SSF personnel ensure probes are properly positioned:
 - 6.2.4.5.4.2.1. Top probe (Temp A) depth is as near as possible to the top of tallest rack, unless otherwise defined by PI.
 - 6.2.4.5.4.2.2. Bottom probe (Temp B) is submerged in LN₂, if probe is long enough to submerge and unless otherwise defined by PI.
 - 6.2.4.5.4.3. Confirm desired set points with PI, defined per SF-3-2 Appendix C, and verify freezer set points.
 - 6.2.4.5.4.4. Complete quarterly, semi-annual, and annual preventive maintenance per SF-3-2 and SF-3-2 Appendix B.
 - 6.2.4.5.4.5. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix J.
 - 6.2.4.5.4.6. Document results on SF-3-2 Appendix B.

- 6.2.4.5.4.7. The next Quarterly PM is scheduled per SF-1-1, not to exceed 3 months. The next Semi-Annual PM (defined in SOP SF-3-2) is due six months from completion date recorded on SF-3-2 Appendix B.
 - 6.2.4.5.4.8. The next Annual PM (defined in SOP SF-3-2) is due one year from earliest annual component completion date recorded on SF-3-2 Appendix B.
 - 6.2.4.5.4.9. Evaluate for necessity of defrost per SF-3-2.
 - 6.2.4.5.4.10. Semi-annual and annual preventive maintenance due dates are entered on SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.4.11. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.4.12. Follow SF-1-4 Appendix L to place unit in service.
 - 6.2.4.5.4.13. Document results on SF-1-4 Appendix J, as applicable.
 - 6.2.4.5.4.14. Guidelines listed in table format at the end of Section 6.2.4.5.
- 6.2.4.5.5. For brand new, empty -80°C LN₂ units:
- 6.2.4.5.5.1. Freezer startup is often completed by vendor.
 - 6.2.4.5.5.2. Once freezer has reached acceptable temperature after startup (per SF-3-16), SSF personnel ensure probes are properly positioned:
 - 6.2.4.5.5.2.1. Top probe (Temp A) depth is as near as possible to top of tallest rack level, unless otherwise defined by PI.
 - 6.2.4.5.5.2.2. Bottom probe (Temp B) is as near as possible to bottom of rack level, unless otherwise defined by PI.
 - 6.2.4.5.5.3. Obtain desired set points from PI, defined per SF-3-16 Appendix C, and input into freezer.
 - 6.2.4.5.5.4. Complete annual maintenance per SF-3-16 using SF-3-16 Appendix B.
 - 6.2.4.5.5.5. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix J.
 - 6.2.4.5.5.6. Document results on SF-3-16 Appendix B.
 - 6.2.4.5.5.7. The unit's first Quarterly PM is due per SF-1-1, not to exceed 3 months.
 - 6.2.4.5.5.8. The next Annual PM (defined in SOP SF-3-16) is due one year from earliest annual component completion date recorded on SF-3-16 Appendix B.
 - 6.2.4.5.5.9. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
 - 6.2.4.5.5.10. Follow SF-1-4 Appendix L to place unit in service.
 - 6.2.4.5.5.11. Document results on SF-1-4 Appendix J, as applicable.
 - 6.2.4.5.5.12. Guidelines listed in table format at the end of Section 6.2.4.5.
- 6.2.4.5.6. If -80°C LN₂ freezer is in service / not new:
- 6.2.4.5.6.1. Freezer set up is often completed by vendor.
 - 6.2.4.5.6.2. Once freezer has reached acceptable temperature (per SF-3-16), SSF personnel ensure probes are properly positioned:
 - 6.2.4.5.6.2.1. Top probe (Temp A) depth is as near as possible to top of tallest rack level, unless otherwise defined by PI.
 - 6.2.4.5.6.2.2. Bottom probe (Temp B) is as near as possible to bottom of rack level, unless otherwise defined by PI.

- 6.2.4.5.6.3. Confirm desired set points with PI, defined per SF-3-2 Appendix C, and verify freezer set points.
- 6.2.4.5.6.4. Complete quarterly and annual preventive maintenance per SF-3-16 and SF-3-16 Appendix B.
- 6.2.4.5.6.5. Alarm Testing MUST BE completed per SF-2-4, utilizing SF-2-4 Appendix J.
- 6.2.4.5.6.6. Document results on SF-3-16 Appendix B.
- 6.2.4.5.6.7. The next Quarterly PM will be scheduled per SF-1-1, not to exceed 3 months.
- 6.2.4.5.6.8. The next Annual PM (defined in SOP SF-3-16) is due one year from earliest completion date recorded on SF-3-16 Appendix B.
- 6.2.4.5.6.9. Evaluate for necessity of defrost per SF-3-16.
- 6.2.4.5.6.10. Annual preventive maintenance due dates are entered on SSF's shared calendar and tracked using the calendar.
- 6.2.4.5.6.11. Maintenance due dates are entered on the SSF's shared calendar and tracked using the calendar.
- 6.2.4.5.6.12. Follow SF-1-4 Appendix L to place unit in service.
- 6.2.4.5.6.13. Document results on SF-1-4 Appendix J, as applicable.

Required Maintenance – Freezers Intake					
Freezer Type	Set Points Eval.	Quarterly	Semi-Annual	Annual	Defrost Evaluation
MRU					
---new	X	X		X	
---in service	X	X		X	X
LN ₂ Freezer					
---new	X		X	X	
---in service	X	X	X	X	X
-80°C LN ₂					
---new	X			X	
---in service	X	X		X	X

6.2.4.5.7. **NOTE: PM evaluation is applicable to both PI-owned and SSF-owned freezers.**

- 6.2.5. If request is for a commitment in support of a funding application, SSF staff draft a letter of provisional acceptance. (See Appendix C for template)
- 6.2.6. The SSF Director reviews eligibility and space assignments, and a final disposition of the request is documented on the Master Study Log.
 - 6.2.6.1. **SSF Director and PI Signatory Requirements** are summarized in Appendix N (SSF Director and PI Signatory Guidelines).
- 6.2.7. **Modifications to Appendix A**, for revisions to existing protocols, with no new Request number assigned, are performed when the following changes are applicable:
 - 6.2.7.1. Staffing Change of Primary personnel – *upon receipt of revised Appendix D, signed by the PI:*
 - 6.2.7.1.1. Prepare current version of Appendix A, including data from the effective agreement, revising primary contact information per signed Appendix D.
 - 6.2.7.1.2. Select reason for revision in Section 5.
 - 6.2.7.1.3. Record the date Appendix D was signed by the PI on the Effective Date line in Appendix A Section 6, initials and date.
 - 6.2.7.1.4. On the now obsolete Appendix A, record the Obsolete Date, which is one calendar day prior to the date the PI signed Appendix D, on the Obsolete Date line, initials and date.
 - 6.2.7.1.5. SSF Director approval is not required
 - 6.2.7.1.6. PI signature on Appendix A is not required.

- 6.2.7.2. Billing account revision – upon receipt of new account number(s) from PI, Primary Contact, or other personnel designated by the PI (likely the PI Department’s fiscal officer or Accounting personnel):
 - 6.2.7.2.1. Revise billing account number(s) on current, effective Appendix A.
 - 6.2.7.2.2. Alternately, prepare current version of Appendix A, including data from the effective agreement, revising account number(s).
 - 6.2.7.2.3. Select reason for revision in Section 5.
 - 6.2.7.2.4. Record the date the revised account number(s) was/were provided on the Effective Date line in Appendix A Section 6, initials and date.
 - 6.2.7.2.5. If applicable, on the now obsolete Appendix A, record the Obsolete Date, which is one calendar day prior to the date the revised account number(s) was/were provided, on the Obsolete Date line, initials and date.
 - 6.2.7.2.6. Documentation of account number(s) revision is attached to the Appendix D, per step 6.4.6.5.1.5.
 - 6.2.7.2.7. SSF Director approval is not required
 - 6.2.7.2.8. PI signature on Appendix A is not required.
- 6.2.7.3. Storage Spaces Added or Removed (Existing Studies / Protocols)
 - 6.2.7.3.1. Revise Appendix A per Section 6.1 & Appendix D per Section 6.4.
 - 6.2.7.3.2. Select reason for revision in Section 5.
 - 6.2.7.3.3. Record the date Appendix D was signed by the PI on the Effective Date line in the revised Appendix A Section 6, initials and date.
 - 6.2.7.3.4. On the now obsolete Appendix A, record the Obsolete Date, which is one calendar day prior to the date the PI signed Appendix D, on the Obsolete Date line, initials and date.
 - 6.2.7.3.5. SSF Director approval is not required for addition and removal on existing protocols.
 - 6.2.7.3.6. PI signature on Appendix A is not required.
 - 6.2.7.3.7. NOTE: The addition of specimens with a new Study, Protocol, and/or Specimen Information require a new SSF Request Number, Appendix A (see Section 6.1), and Appendix D (see Section 6.4). Appendix A revisions are not applicable.
- 6.2.7.4. Study Identifier or IRB / IBC / Exempt status revision – upon receipt of new Study Identifier and/or IRB/IBC number(s) or Exempt status from PI or Primary Contact:
 - 6.2.7.4.1. Study Identifiers are CRC Protocol number, Study short name, or Study name.
 - 6.2.7.4.2. Revision per directives in this Section are *not applicable* when a new protocol is introduced, and SSF personnel must proceed per Section 6.6.1.2. Section 6.2.7.4 is *only applicable* to updates on existing protocols.
 - 6.2.7.4.3. Revise Study Identifier and/or IRB/IBC number(s) or Exempt status on current, effective Appendix A.
 - 6.2.7.4.4. Alternately, prepare current version of Appendix A, including data from the effective agreement, revising Study Identifier and/or IRB/IBC number(s) or Exempt status.
 - 6.2.7.4.5. Select reason for revision in Section 5.
 - 6.2.7.4.6. Record the date the revised Study Identifier and/or IRB/IBC number(s) or Exempt status was/were provided on the Effective Date line in Appendix A Section 6, initials and date.
 - 6.2.7.4.7. If applicable, on the now obsolete Appendix A, record the Obsolete Date, which is one calendar day prior to the date the revised Study Identifier and/or IRB/IBC number(s) or Exempt status was/were provided, on the Obsolete Date line, initials and date.
 - 6.2.7.4.8. Documentation of Study Identifier and/or IRB/IBC number(s) or Exempt status revision is attached to the Appendix D, per step 6.4.6.5.1.6.
 - 6.2.7.4.9. SSF Director approval is not required

- 6.2.7.4.10. PI signature on Appendix A is not required.
- 6.2.7.5. Specimen Information revision – upon receipt of new specimen information (e.g. human blood, body fluid, or tissue; infectious agents) from PI or Primary Contact:
 - 6.2.7.5.1. If the Appendix A requiring revision contains more than one Study, *revision* of Appendix A for update of Specimen Information *is only applicable* when all of the studies on that request # still have the same Specimen Information after update.
 - 6.2.7.5.1.1. If revision would result in multiple studies with differing Specimen Information on the same request number, a new request number must be assigned to the study(ies) requiring Specimen Information revision. Proceed per Section 6.6.1.2.
 - 6.2.7.5.2. Revise Specimen Information on current, effective Appendix A.
 - 6.2.7.5.2.1. If Specimen Information revision includes adding or revising Infectious Agent Level to reflect storage of CDC Category A specimens in the SSF, advise PI that CDC Category A specimens may not be stored in the SSF.
 - 6.2.7.5.2.1.1. Requests to add Category A specimens will be denied.
 - 6.2.7.5.2.1.2. Notification that Category A specimens are stored in the SSF will result in account closure, and the PI must remove specimens from the SSF immediately.
 - 6.2.7.5.2.1.3. The PI may appeal to the SSF's Oversight Committee per Section 6.8.1.3.
 - 6.2.7.5.3. Alternately, prepare current version of Appendix A, including data from the effective agreement, revising Specimen Information.
 - 6.2.7.5.4. Select reason for revision in Section 5.
 - 6.2.7.5.5. Record the date the revised Specimen Information was provided on the Effective Date line in Appendix A Section 6, initials and date.
 - 6.2.7.5.6. If applicable, on the now obsolete Appendix A, record the Obsolete Date, which is one calendar day prior to the date the revised Specimen Information was provided, on the Obsolete Date line, initials and date.
 - 6.2.7.5.7. Documentation of Specimen Information revision is attached to Appendix A.
 - 6.2.7.5.8. SSF Director approval is not required
 - 6.2.7.5.9. PI signature on Appendix A is not required.
- 6.2.7.6. Other - The following revisions to Appendix A are initialed and dated by SSF staff and an explanation and/or any relevant information is denoted in a comment:
 - 6.2.7.6.1. Physical relocation of PI-owned freezers and SSF rented racks per section 6.4.6.5.1.8.
 - 6.2.7.6.2. Typographical errors (e.g., a location, serial number, or email address was recorded incorrectly).
 - 6.2.7.6.3. SSF Director approval is not required.
 - 6.2.7.6.4. PI signature on Appendix A is not required.
- 6.2.7.7. Appendix A **revisions** are not applicable to PI modification. Follow directives in section 6.2.8.
- 6.2.7.8. **Study Closure** – Removal of all PI units/samples
 - 6.2.7.8.1. Denote study closure and date of closure on the comments line in Section 6 of Appendix A, and
 - 6.2.7.8.2. Record the Obsolete Date on that line in Section 6, initials and date.
 - 6.2.7.8.3. The SSF must receive notification of study closure from the PI. Email notification is acceptable.

- 6.2.7.8.4. SSF Director approval is not required.
- 6.2.7.9. SSF Director and PI Signatory guidelines are summarized in Appendix N.
- 6.2.8. **Modifications to the Master Study Log (Appendix B)**
 - 6.2.8.1. Denote date of storage increase and/or decrease in “Date Appendix A Revised for Storage Revision” column for the applicable request number, and initial and date.
 - 6.2.8.1.1. No modifications to PI are allowed unless a new request (Appendix A) is completed for the new PI per Section 6.1. **A new SSF request number must be assigned.**
 - 6.2.8.1.2. The following Appendices D / A revisions are not recorded on Appendix B:
 - 6.2.8.1.2.1. Primary and Secondary contact revisions
 - 6.2.8.1.2.2. “Personnel Authorized for Sample Access” revisions
 - 6.2.8.1.2.3. Billing account number revisions
 - 6.2.8.1.3. Appendix A modifications are defined in Section 6.2.7.
 - 6.2.8.1.4. Appendix D modifications are defined in Section 6.4.6.5.1.
 - 6.2.8.2. Record removal date and initial when all freezers for a given SSF request number are removed from the facility.
 - 6.2.8.2.1. Follow Section 6.2.7.3 to modify the number of units in the facility if only some of the freezers are removed.
 - 6.2.8.3. Manage the transfer of ownership of units/samples by modifying (per 6.2.7.3) or closing (per 6.2.7.8) the original PI SSF request, as applicable, and opening a request by the new PI per the following:
 - 6.2.8.3.1. Transfer of ownership of *all* PI units/samples is managed by closing (per 6.2.7.8) the original PI SSF request and opening a new request number for the new PI.
 - 6.2.8.3.2. Written approval (e-mail acceptable) is obtained from PI transferring ownership (unless PI is unavailable to provide signature), the PI assuming ownership (may be indicated by signature on storage agreement), and the SSF Director.
 - 6.2.8.3.3. Copies of approval documentation is be filed with the most recent storage agreement for the closed request and the new storage agreement for the new request number.
 - 6.2.8.3.4. See Appendix N for signatory guidelines.
- 6.2.9. **Re-assignment of SSF request numbers for active storage accounts:**
 - 6.2.9.1. Every 3-5 years, at the discretion of SSF Management, if needed in order to consolidate active requests on the Master Study Log (Appendix B).
 - 6.2.9.1.1. Completed at Annual Renewal per Section 6.4.6.7.
 - 6.2.9.1.2. SSF Director approval is not required.
 - 6.2.9.1.3. Refer to Appendix N, signatory guidelines.
 - 6.2.9.2. When the amount of storage increases and/or decreases exceeds the “Date Appendix A Revised for Storage Revision” (per step 6.2.8.1) spaces available on the hard copy of SF-1-4 Appendix B for the assigned SSF request number.
 - 6.2.9.3. Initiate an Appendix D for the new request number (per section 6.4), referencing the previous request number in the defined space in the top section of Appendix D.
 - 6.2.9.4. Initiate an Appendix A for the new request number (per section 6.1).
 - 6.2.9.5. Upon receipt of the signed Appendix D, complete the following:
 - 6.2.9.5.1. Record date of closure and new request number on the obsolete Appendix D.
 - 6.2.9.5.2. Make the most recently effective version of Appendix D obsolete.
 - 6.2.9.5.3. On the Section 6 comments line of the now obsolete version of Appendix A, indicate the request for closure, the closure date and the new SSF request number in the designated space.
 - 6.2.9.5.4. Record the Obsolete Date, which is one calendar day prior to the date the PI signed Appendix D, on that line in Section 6 of Appendix A, initials and date.

- 6.2.9.5.5. Record the date Appendix D with the new request number was signed by the PI on the Effective Date line in Appendix A Section 6, initials and date.
- 6.2.9.5.6. Post new Appendix D on applicable Freezer(s).

6.2.9.6. Refer to Appendix L, page 2, the Administrative SSF Request Number Update Flow Chart.

6.2.10. Increases/decreases in storage space do not require SSF Director approval. See Appendix N, for signatory guidelines.

6.3. If the request is denied, the PI is provided a written response (e-mail acceptable) explaining the factors leading to denial. The response includes the mechanism for rebuttal (see Section 6.8).

6.4. **Storage Agreement (Appendix D) Initiation** - If the request is approved and is for immediate use:

- 6.4.1. A Storage Agreement is initiated to include directives defined in steps 6.4.3.1 through 6.4.6.5: (See SSF Storage Agreement (Appendix D) for template)
- 6.4.2. Note the date Appendix D was signed by the PI on the Effective Date line in Section 6 of Appendix A and initial and date.
- 6.4.3. If Appendix A was revised to reflect edits to the previous request (e.g., increase in storage space), record the date Appendix D was signed by the PI on the Effective Date line in Section 6 of Appendix A of the new request, initials and date, and the Obsolete Date, initials and date, on that line of the previous request.

***NOTE:** Annual storage agreement renewals are managed per SF-1-2 and Section 6.4.6.7 of this SOP.*

6.4.3.1. SSF Commitments

- 1 *The SSF maintains an oversight committee that reviews policies and advises the SSF.*
- 2 *The SSF maintains a set of Standard Operating Procedures that describes the policies and directs the staff of the SSF. The critical policy SOPs are reviewed by the SSF Oversight Committee. SOPs include the following policies and procedures pertinent to this agreement:*
 - a *The scope and charge of the SSF*
 - b *The management structure of the SSF*
 - c *Operating practices of the facility.*
 - d *Safety practices for the SSF staff and users*
 - e *Conditions maintained for each type of storage provided by the SSF and notifications if these conditions are exceeded.*
 - f *Maintenance and monitoring procedures for the SSF and the storage equipment within the SSF*
 - g *Notifications to investigators if conditions vary outside of the established parameters*
 - h *Training, controlled access, and alarm response practices developed to protect and insure confidentiality of materials stored in the SSF.*
 - i *Non-CTSI SSF staff entry practices including escorts for investigator personnel to access their specimens.*
- 3 *The SSF maintains the facility in compliance with current ISBER and GLP guidances relevant to facilities for storage.*
- 4 *Access is limited to CTSI SSF personnel and authorized study personnel who are escorted by CTSI SSF personnel for safety and security of the specimens.*
- 5 *If requested, the SSF will provide SOPs to the IUPUI IRB and other relevant IRBs and regulatory oversight groups.*
- 6 *The SSF functions as a recharge center and costs for services are determined by Indiana University.*
- 7 *This agreement limits SSF activity to facility maintenance, equipment oversight, study personnel escort, and emergency specimen transfer unless defined in a separate agreement.*
- 8 *SSF liability is limited to that associated with research activities at Indiana University.*

6.4.3.2. Investigator Commitments:

- 1 *The user is a PI with primary responsibility for the material to be stored in the facility.*
- 2 *The collection, storage and distribution of the stored material satisfy applicable regulatory agencies, e.g., IRB, IBC.*
- 3 *The PI agrees to pay user fees in a timely fashion.*

- 4 *If PI loses funds for biobanking activities, the PI agrees to remove specimens from storage within 30 days of notification.*
- 5 *PI agrees that all project-related personnel must provide the SSF with a request for access escort at least 2 working days in advance.*
- 6 *The PI provides and maintains current contact information for the study specimens.*
- 7 *Authorizes SSF personnel to move specimens to a back-up freezer in the event of primary unit failure.*
 - a *Provides clear directives for managing notification of relocation of cataloged samples.*
 - b *Agrees that, while the SSF will, in the event that transfer to a back-up unit is required, take all reasonable measures to place specimens into the back-up unit in a similar organizational pattern, no warranty of specimen location is made except for specimen protocols managed by CTSI Sample Management software.*
- 8 *PI owner of LN₂ freezer(s) agrees to allow SSF personnel to alter high level alarm point on an LN₂ freezer in the event of an overflow. PI will be notified the following business day, the freezer will continue to be monitored via the alarm system (low level alarm will not be affected) and high level alarm point will be restored when unit reaches acceptable level.*
- 9 *Agrees to accept charges for use of the SSF back-up freezer 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.)*
- 10 *The PI agrees to renew the SSF Storage Agreement annually to ensure continued regulatory approvals for samples stored in the SSF. This process is initiated by the SSF.*
- 11 *The PI agrees to certify annually during Storage Agreement renewal (point 10) that they are not housing any CDC Category A specimens in the SSF.*
- 12 *The PI agrees to inform SSF of all biohazard or other safety changes to the initial application safety statement and keep current all safety related designations for the specimens being stored. This includes biohazard level and all other safety considerations and practices.*
- 13 *The PI agrees to inform the SSF of studies which regulatory bodies have closed or placed on hold.*
- 14 *The PI agrees to contain samples in PI-provided racks, bins, or other storage receptacles to facilitate specimen relocation to a backup freezer in the event of an emergency.*
- 15 *The PI agrees to promptly inform the SSF of all personnel requiring de-activation of access authorization.*
- 16 *PIs storing freezers in the SSF agree to comply with the following freezer intake requirements:*
 - a *Freezers already in service and housing samples:*
 - i *Must be in good working order, with no known mechanical defects.*
 - ii *Must accommodate racks no larger than those with capacity to hold 16-25 two-inch boxes.*
 - iii *PI must have all samples contained in racks or bins to facilitate specimen relocation during freezer defrost.*
 - b *New (empty) freezers:*
 - i *Must accommodate racks no larger than those with capacity for 16-20 two-inch boxes –OR–*
 - ii *Unit may be acceptable if it can be reconfigured to comply with step 15.b.i by purchasing an additional shelf and shelf brackets. PI will purchase additional shelf and shelf brackets.*
 - iii *Any samples placed in freezer must be contained in PI-provided racks or bins to facilitate specimen relocation during freezer defrost.*
- 17 *If the SSF determines that the PI has failed to comply with these responsibilities:*
 - a *The SSF's Oversight Committee Chair will be notified, and discussion with other Oversight Committee members will be at Chair's discretion.*
 - b *Actions may include the following:*
 - i *Retraining, if applicable*
 - ii *Increased storage fees based on the non-subsidized rate*
 - iii *Escalation of issue to PI's department chair*
 - iv *Cancellation of storage agreement*
 - v *Oversight of specimens being transferred to the investigator's home Institution. Specimens may not be accessed except by authorization of the institutional representative.*
- 18 *PI concerns regarding pricing, quality, operations, or policies of the SSF may be discussed with the SSF Director and/or the Chair of the SSF's Oversight Committee.*

6.4.4. Study Personnel Information:

6.4.4.1. PI Name and Contact information

- 6.4.4.2. Alternate names and contact information for problems and/or alarm response (minimum of one [1] PI-alternate required).
 - 6.4.4.2.1. Primary contact (may be the PI)
 - 6.4.4.2.2. Secondary contact
- 6.4.4.3. Names of all additional personnel authorized for sample access
- 6.4.4.4. Signatory Authority may be designated by the PI at the PI's discretion.
- 6.4.5. Freezer unit information (complete all information for PI owned units; however, for SSF owned units, the only required information is the SSF Location Room Space assignment per 6.4.5.10 below.)
 - 6.4.5.1. Unit number
 - 6.4.5.2. Manufacturer/Model
 - 6.4.5.3. Serial #
 - 6.4.5.4. Power requirements/configuration
 - 6.4.5.5. Study personnel notification via alarm system (yes or no)
 - 6.4.5.6. Set point specifications for PI-owned ultra-low freezers, if other than SSF standard of Cold alarm, -90°C; Warm alarm, -60°C; and Set point -80°C.
 - 6.4.5.6.1. Set point specifications for PI-owned LN₂ freezers are defined in SOP for LN₂ Freezers (SF-3-2), Appendix C.
 - 6.4.5.6.2. Set point specifications for PI-owned -80°C LN₂ freezers are defined in SOP for -80°C LN₂ Freezers (SF-3-16), Appendix C.
 - 6.4.5.7. Key for emergency access (yes or no)
 - 6.4.5.8. Copy of current warranty or service contract (yes or no)
 - 6.4.5.9. Special information for emergency transfer to back-up (Optional) may be defined in the Comments section at the bottom of Appendix D.:
 - 6.4.5.9.1. If the samples are cataloged, provide guidance regarding process for notation if transfer to a back-up freezer unit.
 - 6.4.5.9.2. If not electronically cataloged, the SSF places specimens into a back-up unit in a similar organization manner.
 - 6.4.5.9.3. If investigator directives are not defined, the SSF places specimens into a back-up unit in a similar organization manner.
 - 6.4.5.10. Storage location (additional description of naming conventions are provided in section 6.4.6):
 - 6.4.5.10.1. PI Owned Freezer – Specify room and location for each freezer (e.g. C135-F1).
 - 6.4.5.10.2. Rack in SSF Rental Freezer – Specify freezer name, storage room and freezer location, and location within freezer (ex. SSF (or CTSI) Freezer 1, C135-A10, Shelf 4, Rack 2).
 - 6.4.5.10.3. Half-Rack in SSF Rental Freezer – Specify freezer name, storage room and freezer location, location within freezer, and boxes assigned (ex. SSF (or CTSI) Freezer 1, C135-A10, Shelf 4, Rack 2, Boxes 1-8).
 - 6.4.5.10.4. Space in SSF Ambient Cabinet – Specify room, cabinet name/number, and drawer (e.g. C135, Ambient Cabinet 1, Drawer 1).
 - 6.4.5.10.5. Space in SSF LN₂ Rental Freezer – Specify freezer name, storage room and freezer location, rack number(s), and box number(s) (ex. SSF (or CTSI) LN₂ Freezer 1, C156-B3, Rack 13, Boxes 1-4).
 - 6.4.5.11. Account number for charges
 - 6.4.5.12. Fields not applicable for space rented in an SSF ambient cabinet, ultra-low freezer, or LN₂ freezer should be marked N/A or something similar.

6.4.6. Freezer Assignment and Postings

- 6.4.6.1. The freezer space is assigned by SSF Management and the assigned freezer space is noted on Appendix D. Naming Conventions are further defined in the table below:

	Freezer Name Ex: CTSI Freezer1	Storage Room Ex: C135	Freezer Location Ex: E9	Freezer S/N Ex: X01M-601443- XM
Purpose	Provide consistency in labeling operations	Specify a particular room within the SSF entity	Specify an outlet/alarm to which a freezer is connected in a given room	Uniquely identify a specific freezer
Note 1	Names are assigned by SSF, CTSI or PI as applicable	Room IDs are traceable through the SSF validation documents	Outlet/alarm IDs are assigned as specified in the section below	Assigned by the freezer manufacturer
Note 2	Names are re-used as needed and are used primarily to distinguish a freezer from others owned by the same PI/group	A specific MRU may be relocated to a different room as needed	A freezer may be relocated to a different alarm/outlet as needed	Applicable primarily to equipment logs for the purpose of uniquely identifying a freezer regardless of the room or location within a room
Note 3	Identifiable on Maps in Appendices E-I, K & M	Identifiable on Maps in Appendices E-I, K & M	Identifiable on Maps in Appendices E-I, K & M	Not identifiable on Maps in Appendices E-I, K & M

6.4.6.2. Naming and numbering convention for the freezer outlets are as follows, and the freezers are given a location name according to their outlet connections (except in IB 097/MS-B046 Cage and MS-B037, where freezers are given a location name according to their alarm point ID):

6.4.6.2.1. Mechanical Freezers Room (C135)-refer to Appendix F:

- 6.4.6.2.1.1. Rows from east to west are lettered alphabetically
- 6.4.6.2.1.2. Outlets are assigned numbers numerically from south to north within each row.
- 6.4.6.2.1.3. Units occupying the same row of outlets are placed in numerical order from east to west, and then from south to north within each row of outlets. Shelves are assigned a number numerically from top to bottom within each unit.
- 6.4.6.2.1.4. Racks are assigned a number from left to right within each shelf of the unit.
- 6.4.6.2.1.5. Boxes within each rack are assigned numbers from back to front followed by top to bottom where the box that is most towards the top and back of a rack is #1.

6.4.6.2.2. Mechanical Freezers Room Annex (IB 097/MS-B046 Cage) –Refer to Appendix I:

- 6.4.6.2.2.1. Alarm points/freezers in the eastern most row are labeled from north to south with the letters A through L.
- 6.4.6.2.2.2. Alarm points/freezers in the western most row are labeled from south to north with the letters M through T.
- 6.4.6.2.2.3. Alarm points/freezers the center row are labeled from north to south with the letters U through Y.

- 6.4.6.2.2.4. Racks are assigned a number from left to right within each shelf of the unit.
- 6.4.6.2.2.5. Boxes within each rack are assigned numbers from back to front followed by top to bottom where the box that is most towards the top and back of a rack is #1.
- 6.4.6.2.3. Mechanical Freezers Room Annex III (MS-B037) –refer to Appendix M:
 - 6.4.6.2.3.1. Freezers are grouped around 7 alarm points, labeled clockwise from the southwest corner of room MS-B037.
 - 6.4.6.2.3.1.1. West to east oriented groups (points A-D) are labeled by alarm point and numerically (e.g. A1, A2, A3) from west to east.
 - 6.4.6.2.3.1.2. North to south oriented groups (points E-G) are labeled by alarm point and numerically from north to south.
 - 6.4.6.2.3.2. Racks are assigned a number from left to right within each shelf of the unit.
 - 6.4.6.2.3.3. Boxes within each rack are assigned numbers from back to front followed by top to bottom where the box that is most towards the top and back of a rack is #1.
- 6.4.6.2.4. Liquid Nitrogen Freezers (C156) –Refer to Appendix E:
 - 6.4.6.2.4.1. Rows from south to north are lettered alphabetically
 - 6.4.6.2.4.2. Units within each row are assigned numbers from west to east.
 - 6.4.6.2.4.3. Racks within each unit may be pre-numbered by the manufacturer, or may be assigned a number numerically by SSF personnel and identified with tags or permanent ink.
 - 6.4.6.2.4.4. Boxes within each rack are numbered numerically from top to bottom.
- 6.4.6.2.5. Mechanical Freezers (C156) – Refer to Appendix E:
 - 6.4.6.2.5.1. Rows from south to north are lettered alphabetically
 - 6.4.6.2.5.2. Units within each row are numerically assigned numbers from west to east.
 - 6.4.6.2.5.3. Racks are assigned a number from left to right within each shelf of the unit.
 - 6.4.6.2.5.4. Boxes within each rack are assigned numbers from back to front followed by top to bottom where the box that is most towards the top and back of a rack is #1.
- 6.4.6.3. Space in an SSF Rental ultra-low freezer is assigned by SSF Management, and the assigned rental space is noted on Appendix D.
 - 6.4.6.3.1. Rental space is assigned by rack or half-rack.
 - 6.4.6.3.2. The name of the PI assigned the defined rental space is noted on Appendix G, which is posted on all rental freezers.
 - 6.4.6.3.3. Study Identifier may also be recorded to distinguish multiple spaces assigned to a PI.
 - 6.4.6.3.4. Due to the necessity of multiple MRU freezers to be managed concurrently and possibly exceeding the capacity of Appendix G, multiple Appendix G postings, each denoting unique freezers, may be managed independently with effective and obsolete dates managed independently. An overall governing spreadsheet is used to manage these freezers, locations, effective and obsolete dates as defined in Appendix G.
- 6.4.6.4. Space in an SSF Rental -20°C freezer or ambient cabinet is assigned by SSF Management, and the assigned rental space is noted on Appendix D.

- 6.4.6.4.1. Rental space is assigned by rack or half-rack (freezer) or drawer (ambient cabinet).
- 6.4.6.4.2. The name of the PI assigned the defined rental space is noted on Appendix K, which is posted on all rental freezers.
- 6.4.6.4.3. Study Identifier may also be recorded to distinguish multiple spaces assigned to a PI.
- 6.4.6.4.4. Due to the necessity of multiple MRU freezers and ambient cabinets to be managed concurrently and possibly exceeding the capacity of Appendix K, multiple Appendix K postings, each denoting unique freezers, may be managed independently with effective and obsolete dates managed independently. An overall governing spreadsheet is used to manage these freezers, locations, effective and obsolete dates as defined in Appendix K.
- 6.4.6.5. Space in an SSF LN₂ freezer or -80°C LN₂ freezer is assigned by SSF Management and the assigned rental space is noted on Appendix D.
 - 6.4.6.5.1. Rental space is assigned by 2" tall box, with the most likely box sizes housing 25-cells or 100-cells.
 - 6.4.6.5.2. The name of the PI assigned the defined rental space is noted on Appendix H, which is posted on all rental freezers and at the entry to C156.
 - 6.4.6.5.2.1. Specify freezer name, storage room, and freezer location on Appendix H (ex. SSF (or CTSI) LN₂ Freezer 1, C156-B3).
 - 6.4.6.5.3. Due to the need for multiple LN₂ freezers to be managed concurrently but independently via Appendix H, each respective freezer may therefore have a corresponding Appendix H with effective and obsolete dates managed independently. An overall governing spreadsheet is used to manage these freezers, locations, effective and obsolete dates as defined in Appendix H.
- 6.4.6.6. PI signature on Appendix D is required. SSF Director and PI Signatory guidelines are summarized in Appendix N.
- 6.4.6.7. A copy of Appendix D is posted on each applicable Freezer to be available as a reference of ownership and personnel authorized to access the units/contents. Alternately, copies of Appendix D can be maintained in a common area on a clipboard inside, or immediately outside, the controlled area.
 - 6.4.6.7.1. **Modifications to Appendix D** for revisions to existing protocols, with no new Request number assigned, are performed & documented as follows:
 - 6.4.6.7.1.1. Staffing Changes for non-Collaborating Biobank Customers and Collaborating Biobank Primary or Secondary personnel
 - 6.4.6.7.1.1.1. Add additional staff information by writing on original copy.
 - 6.4.6.7.1.1.2. PI initials and dates modification.
 - 6.4.6.7.1.1.3. SSF personnel initials and dates modification.
 - 6.4.6.7.1.1.4. Post new copy on applicable Freezer.
 - 6.4.6.7.1.1.5. Alternately, submission of a new form, signed by the PI, is acceptable.
 - 6.4.6.7.1.2. Staffing Changes for Collaborating Biobank Personnel Authorized for Sample Access (excluding PI, Primary and Secondary Contacts)
 - 6.4.6.7.1.2.1. Refer to Step 6.4.6.6.1.1 to revise Collaborating Biobank Primary or Secondary personnel and 6.2.8.1.1 if Collaborating Biobank PI replacement is required.
 - 6.4.6.7.1.2.2. SF-2-3 Appendix E (Collaborating Biorepository Staff Access Form) signed by the PI *must have been received by the SSF*.

- 6.4.6.7.1.2.3. On original copy of the Collaborating Biobank's Appendix D, select "ONLY Authorized Collaborating Biobank Personnel updated per SF-2-3, Appendix E" in Section 1 of SF-1-4 Appendix D.
- 6.4.6.7.1.2.4. Add and/or remove access for personnel authorized for sample access by writing on original copy of the Collaborating Biobank's Appendix D.
- 6.4.6.7.1.2.5. Alternately, a new Appendix D may be created.
- 6.4.6.7.1.2.6. In the "For internal use only:" area of Appendix D Section 5, record the date Appendix D was updated, initial and date.
- 6.4.6.7.1.2.7. PI signature not required with the addition or removal of access for Collaborating Biobank Personnel Authorized for Sample Access is the ONLY modification to Appendix D, AND the SSF has received an SF-2-3 Appendix E (Collaborating Biorepository Staff Access Form) signed by the PI.
- 6.4.6.7.1.2.8. Post new copy on applicable freezer.
- 6.4.6.7.1.2.9. *Copies of the revised Appendix D will be sent to the PI upon request.*
- 6.4.6.7.1.3. Storage Spaces Added or Removed (Existing Studies / Protocols)
 - 6.4.6.7.1.3.1. Refer to Sections 6.4.6.6.1.4 and 6.4.6.6.1.5 for transfer of ownership of specimens.
 - 6.4.6.7.1.3.2. Add additional freezer information by writing on original copy. Line out freezer information for units that are removed or replaced.
 - 6.4.6.7.1.3.3. PI initials and dates modification.
 - 6.4.6.7.1.3.4. SSF Director approval not required.
 - 6.4.6.7.1.3.5. Post new copy on applicable Freezer.
 - 6.4.6.7.1.3.6. Alternately, submission of a new form, signed by the PI, is acceptable.
- 6.4.6.7.1.4. Manage the transfer of ownership of *some, but not all* units as follows:
 - 6.4.6.7.1.4.1. Modify (per 6.2.8.1) the transferring PI's Appendix D accordingly.
 - 6.4.6.7.1.4.2. PI initials and dates modification
 - 6.4.6.7.1.4.3. Alternately, submission of a new form, signed by the PI, is acceptable.
 - 6.4.6.7.1.4.4. Open a request by the new PI, per Section 6.1, noting transfer of units and previous request number on Appendix D of newly assigned request number.
 - 6.4.6.7.1.4.5. PI signature required on new Appendix D.
 - 6.4.6.7.1.4.6. Written approval (e-mail acceptable) is obtained from PI transferring ownership (unless PI is unavailable to provide signature) and the PI assuming ownership (may be indicated by signature on storage agreement).

- 6.4.6.7.1.5. Manage the transfer of ownership of *all units* as follows:
 - 6.4.6.7.1.5.1. Document closure (per 6.4.6.6.1.6 and 6.2.7.8) of the original PI SSF request on Appendix D.
 - 6.4.6.7.1.5.2. Open a request by the new PI, per Section 6.1, noting transfer of units and previous request number on Appendix D of newly assigned request number.
 - 6.4.6.7.1.5.3. PI signature required on new Appendix D.
 - 6.4.6.7.1.5.4. Written approval (e-mail acceptable) is obtained from PI transferring ownership (unless PI is unavailable to provide signature) and the PI assuming ownership (may be indicated by signature on storage agreement).
- 6.4.6.7.1.6. SSF Request Number Closures (i.e., all units removed from facility or transferred to another PI within the facility)
 - 6.4.6.7.1.6.1. Section 6 is filled out by SSF management denoting the reason for the closure, the new SSF request number if the unit(s) is/are being transferred, and the PI notification date.
 - 6.4.6.7.1.6.2. SSF Director approval is not required.
 - 6.4.6.7.1.6.3. PI signature on Appendix A is not required.
- 6.4.6.7.1.7. Billing Account Number Revised
 - 6.4.6.7.1.7.1. Billing account number updates are received from the PI, Primary Contact, or other personnel designated by the PI (likely the PI Department's fiscal officer or Accounting personnel).
 - 6.4.6.7.1.7.2. The account number(s) is/are updated on the Appendix D, initialed and dated by SSF personnel.
 - 6.4.6.7.1.7.3. Correspondence denoting the new account number(s) is attached to the Storage Agreement.
 - 6.4.6.7.1.7.4. PI signature is not required.
- 6.4.6.7.1.8. Study Identifier or IRB / IBC / Exempt status revisions
 - 6.4.6.7.1.8.1. Study Identifier and/or IRB/IBC number(s) or Exempt status revisions are received from the PI or Primary Contact.
 - 6.4.6.7.1.8.2. The Study Identifier and/or IRB/IBC number(s) or Exempt status is/are updated on the Appendix D, initialed and dated by SSF personnel.
 - 6.4.6.7.1.8.3. Correspondence denoting the revision is attached to the Storage Agreement.
 - 6.4.6.7.1.8.4. PI signature is not required.
- 6.4.6.7.1.9. Other - The following may be changed at the discretion of SSF Management without prior PI approval. Changes are initialed and dated by SSF staff and an explanation and/or any relevant information is denoted in a comment.

The PI is notified of any sample moves via e-mail, with SSF personnel documenting the date of notification on Appendix D. Unless specifically requested by the PI, SSF personnel will not send the PI copies of the updated Appendix D:

- 6.4.6.7.1.9.1. Physical location of PI owned freezers and SSF rented racks, with the restriction that the new location is within the same room of the facility.
 - 6.4.6.7.1.9.1.1. Movement of freezers/racks to a different room: PI's initials and date of submission of a new form requested, however PI approval via email is acceptable.
 - 6.4.6.7.1.9.1.2. SSF Director approval is not required for freezer / sample relocation described in points 6.4.6.6.1.9.1 or 6.4.6.6.1.9.1.1.
- 6.4.6.7.1.9.2. Typographical errors (e.g., a location, serial number, or email address was recorded incorrectly).
- 6.4.6.7.1.10. SSF Director and PI Signatory guidelines are summarized in Appendix N.
- 6.4.6.8. Master Storage Assignment records (Appendix E-I, K, and M) are maintained in the SSF. For each storage assignment revision (as applicable) proceed as follows:
 - 6.4.6.8.1. Post current version of Appendix E in the Liquid Nitrogen Freezer Room (C156). Alternately, it can be placed on a clipboard inside, or immediately outside, the critical area.
 - 6.4.6.8.2. Post current version of Appendix F in the Mechanical Freezer Room (C135).
 - 6.4.6.8.3. Post current version of Appendix G in the Mechanical Freezer Rooms on the SSF Freezers (C135 / C156).
 - 6.4.6.8.4. Post current version of Appendix H in the Liquid Nitrogen Freezer Room on the SSF LN₂ or -80°C LN₂ Freezer(s) (C156). Alternately, it can be placed on a clipboard inside, or immediately outside, the critical area.
 - 6.4.6.8.5. Post current version of Appendix I in the Mechanical Freezer Room (IB 097/MS-B046 Cage).
 - 6.4.6.8.6. Post current version of Appendix K in the Mechanical Freezer Room on SSF Freezers / Ambient Cabinets (C135)
 - 6.4.6.8.7. Post current version of Appendix M in the Mechanical Freezer Room (MS-B037).
- 6.4.6.9. Process for **Annual Renewal of Storage Agreements**:
 - 6.4.6.9.1. Annually (to coincide with the 1 year anniversary date of PI's signature on the prior SSF storage agreement), storage agreement renewal is initiated per the following procedure:
 - 6.4.6.9.2. Prepare current version of Appendix D for the renewing storage request, including data from the effective agreement.
 - 6.4.6.9.3. Ensure account number(s) listed in Section 4 of Appendix D is the account currently billed for storage fees per non-SOP-defined SSF billing practices, selecting the appropriate yes/no option in Section 4.
 - 6.4.6.9.4. Save a pdf or image (such as jpg) copy of the new storage agreement.
 - 6.4.6.9.5. Email the revised agreement to the PI or Primary (if differing from PI) contact on the storage agreement, requesting that they review and revise the following:
 - 6.4.6.9.5.1. IRB / IBC / Exempt status of study(ies) listed on the agreement
 - 6.4.6.9.5.2. Contact information of PI / Primary / Secondary contacts
 - 6.4.6.9.5.3. Personnel authorized to access samples
 - 6.4.6.9.5.4. Billing account number(s)

- 6.4.6.9.6. If the PI determines that any of the items referenced in Section 6.4.6.8.5 require revision, the following are permissible:
 - 6.4.6.9.6.1. The PI will notify SSF personnel renewing the storage agreement, and SSF personnel will revise the agreement, save the new version as a pdf or image, and return it to the PI for signature.
 - 6.4.6.9.6.2. The PI will print the agreement, make the necessary changes on the agreement in wet ink, sign in wet ink, and return the original electronically or in-person to the SSF.
 - 6.4.6.9.6.3. The PI will make any necessary changes (such as contact information) using Adobe typewriter or similar function on a pdf version of the storage agreement, sign and return the form to the SSF per signatory guidelines summarized in Appendix N.
- 6.4.6.9.7. If storage increase or decrease coincides with renewal due date (exempting account closure), proceed per section 6.6.1.
- 6.4.6.9.8. Annual renewal of storage agreement is not applicable if account closure (removal of all samples and PI-owned freezers stored in the SSF) coincides with renewal due date.
- 6.4.6.9.9. Appendix A revision is not required if the following remain unchanged:
 - 6.4.6.9.9.1. Billing account number
 - 6.4.6.9.9.2. Primary contact
 - 6.4.6.9.9.3. PI
 - 6.4.6.9.9.4. Storage amounts and locations
 - 6.4.6.9.9.5. IRB/IBC # or Exempt study status

6.5. PI personnel manage the freezer and/or specimen relocation to the SSF in coordination with SSF personnel.

6.6. Summary of Modifications to Storage Appendices:

- 6.6.1. Upon receipt of a request for additional space per Section 6.1, proceed as follows:
 - 6.6.1.1. For requests with the same PI, study type (GLP or non-GLP), and specimen safety considerations:
 - 6.6.1.1.1. Update Appendix A per Section 6.2.7.3.
 - 6.6.1.1.2. Update Appendix B per Section 6.2.8.1.
 - 6.6.1.1.3. Update Appendix D per Section 6.4.6.5.1.3.
 - 6.6.1.1.4. Update Appendix E, F, G, H, I, K, or M as required per Section 6.4.6.
 - 6.6.1.2. For requests with a new PI, a new study type (GLP or non-GLP) with the same PI, or a new study with new specimen safety considerations with the same PI:
 - 6.6.1.2.1. Create Appendix A per Section 6.1.
 - 6.6.1.2.2. Log Request on Appendix B per Section 6.2.1-6.2.6.
 - 6.6.1.2.3. Create Appendix D per Section 6.4.
 - 6.6.1.2.4. Update Appendix E, F, G, H, I, K, or M as required per Section 6.4.6.
- 6.6.2. Upon receipt of request to remove units, proceed as follows:
 - 6.6.2.1. If all units are to be removed:
 - 6.6.2.1.1. Close Appendix A per Section 6.2.7.8.
 - 6.6.2.1.2. Update Appendix B per Section 6.2.8.2.
 - 6.6.2.1.3. Close Appendix D per Section 6.4.6.5.1.4.
 - 6.6.2.1.4. Update Appendix E, F, G, H, I, K, or M as required per Section 6.4.6.
 - 6.6.2.2. If only a portion of the total number of units are to be removed:
 - 6.6.2.2.1. Update Appendix A per Section 6.2.7.3.
 - 6.6.2.2.2. Update Appendix B per Section 6.2.8.1.
 - 6.6.2.2.3. Update Appendix D per Section 6.4.6.5.1.3.
 - 6.6.2.2.4. Update Appendix E, F, G, H, I, K, or M as required per Section 6.4.6.

- 6.6.3. Upon receipt of request to transfer ownership of a unit, manage as modification or closure of the original SSF request number, as applicable, open a new request (per Section 6.1), and revise appendices as follows:
 - 6.6.3.1. Update Appendix B per Section 6.2.8.3.
 - 6.6.3.2. Update Appendix D per Section 6.4.
 - 6.6.3.3. Update Appendix E, F, G, H, I, K, or M as required per Section 6.4.6.
- 6.6.4. Upon receipt of request to update contacts and authorized personnel:
 - 6.6.4.1. For requests with a new PI, proceed per Step 6.6.1.2.
 - 6.6.4.2. For requests to revise primary personnel:
 - 6.6.4.2.1. Update Appendix A per Section 6.2.7.1.
 - 6.6.4.2.2. Update Appendix D per Section 6.4.6.5.1.1.
 - 6.6.4.3. For requests to revise secondary personnel, update Appendix D per Section 6.4.6.5.1.1.
 - 6.6.4.4. For Non-Collaborating Biobank requests to revise "Personnel Authorized for Sample Access", update Appendix D per Section 6.4.6.5.1.1.
 - 6.6.4.5. For Collaborating Biobank requests to revise "Personnel Authorized for Sample Access", update Appendix D per Section 6.4.6.5.1.2.
 - 6.6.4.6. Appendix A revisions are not applicable to Steps 6.6.4.3 – 6.6.4.5.
- 6.6.5. Upon receipt of request to update billing account number:
 - 6.6.5.1. Update Appendix A per Section 6.2.7.2.
 - 6.6.5.2. Update Appendix D per section 6.4.6.6.1.5.
- 6.6.6. Upon receipt of request to update Study Identifier or IRB/IBC/Exempt status:
 - 6.6.6.1. Update Appendix A per Section 6.2.7.4.
 - 6.6.6.2. Update Appendix D per Section 6.4.6.5.1.6.
- 6.6.7. Upon receipt of request to update Specimen Information, refer to Section 6.2.7.5 regarding Appendix A revision. An Appendix D revision is not applicable.
- 6.7. Procedures for requesting **Designation as an SSF Collaborating Biorepository**:
 - 6.7.1. Definition: SSF Collaborating Biorepositories are organizations that have established biorepository policies and a demonstrated track record of compliance with accepted biorepository principles with special emphasis on security of the specimens.
 - 6.7.2. Process to become an SSF Collaborating Biorepository: If an investigator would like to have his/her biorepository organization designated as an SSF Collaborating Biorepository she/he should:
 - 6.7.2.1. Contact the SSF Director to request consideration and provide a brief history of previous biorepository efforts and summary of on-going activities as related to biorepository and SSF activities.
 - 6.7.2.2. The SSF Director will forward the request to the SSF's Oversight Chair/Committee for consideration.
 - 6.7.2.3. The SSF Director will relay the decision of the SSF's Oversight Committee to the requesting PI.
 - 6.7.2.4. Requests for reconsideration of the committee decision may be made to the SSF Oversight Committee Chair.
 - 6.7.3. Removal from status as an SSF Collaborating Biorepository is at the discretion of the SSF Oversight Committee.
 - 6.7.4. SSF Collaborating Biorepository Permissions and Responsibilities:
 - 6.7.4.1. Permission for access to SSF "critical areas" without accompaniment by an SSF staff member is permitted according to SOP SF-2-3 (Controlled Access).
 - 6.7.4.2. The PI must provide a list of personnel to be trained for access per SOP SF-2-3.
 - 6.7.4.3. The listed personnel must complete training as defined in SOP SF-2-3.

- 6.7.4.4. Collaborating biobank personnel may access any storage units for which they have leased space without SSF oversight.
- 6.7.4.5. Collaborating biobank personnel may access SSF-owned freezer space *hosting temporarily relocated samples AND containing the collaborating biobank's samples* without SSF personnel accompaniment.
 - 6.7.4.5.1. NOTE: A general physical location map or signage indicating that samples were relocated to SSF backup freezer in PI-defined storage schema *must* be posted by SSF Staff on any SSF backup freezer containing relocated samples from multiple PIs.
- 6.7.4.6. Authorized access is reviewed annually and managed per SF-2-3. Collaborating Biorepositories are identified in SF-2-3.
- 6.8. **Service Denial** - Process for responding to investigators who are denied services, or have concerns regarding operations, pricing, quality or other SSF policies. SSF personnel refer the investigator as follows:
 - 6.8.1. Determine rationale for service denial and proceed as follows:
 - 6.8.1.1. Due to inadequate space:
 - 6.8.1.1.1. Discuss options with the SSF Director.
 - 6.8.1.1.2. If unresolved, appeal to Chair of Oversight Committee for consideration of priority over existing collections.
 - 6.8.1.2. Due to failure to provide IRB approvals:
 - 6.8.1.2.1. Appeal to IRB to provide letter of exemption.
 - 6.8.1.2.2. Request review by Chair of Oversight Committee.
 - 6.8.1.3. Due to failure to meet Biosafety requirements:
 - 6.8.1.3.1. 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.
 - 6.8.1.3.2. Request review by Chair of Oversight Committee.
 - 6.8.2. If PI has concerns regarding quality, operations, or policies of the SSF:
 - 6.8.2.1. Discuss concerns with SSF Director
 - 6.8.2.2. Request review by Chair of Oversight Committee
 - 6.8.3. If PI has concerns regarding pricing:
 - 6.8.3.1. Discuss concerns with SSF Director
 - 6.8.3.2. Request review by Chair of Oversight Committee
 - 6.8.4. All decisions may be referred to full review by the Oversight Committee.
- 6.9. Process for managing **Expired / Revoked IRB/IBC Approvals**
 - 6.9.1. The SSF may act on any information deemed reliable with regard to a perceived expired/revoked IRB/IBC approval.
 - 6.9.2. The SSF notifies the SSF's Oversight Committee Chair of a perceived expired/revoked IRB/IBC approval, and discussion with other Oversight Committee members may occur at the Chair's discretion.
 - 6.9.3. Resultant actions for the respective PI may include, but are not limited to the following:
 - 6.9.3.1. Increased storage fees based on the non-subsidized rate
 - 6.9.3.2. Escalation of issue to PI's department chair
 - 6.9.3.3. Cancellation of storage agreement
- 6.10. Process for managing **Lack of PI Response**
 - 6.10.1. Any perceived lack of response from a PI to requests made by the SSF will result in escalation to the SSF's Oversight Committee Chair. Common SSF requests include, but are not limited to the following:

- 6.10.1.1. SSF request for annual storage agreement renewal
- 6.10.1.2. SSF request for updated IRB approval
- 6.10.1.3. SSF request for provision of organizational racks, bins, etc. for freezers already housed in facility
- 6.10.1.4. SSF request for signature on agreement revised for storage increase/decrease
- 6.10.2. The SSF's Oversight Committee Chair may elect to initiate a discussion with other Oversight Committee members at the Chair's discretion.
- 6.10.3. Resultant actions to a lack of PI response may include but are not limited to the following:
 - 6.10.3.1. Increased storage fees based on the non-subsidized rate
 - 6.10.3.2. Escalation of issue to PI's department chair
 - 6.10.3.3. Cancellation of storage agreement

7. REFERENCES

- 7.1. ISBER Best Practices (current version)
- 7.2. Good Laboratory Practices 21 CFR 58 Subpart C: Facilities
- 7.3. Definition of Category A–Specimens -
<https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf>


8. DOCUMENTATION

- 8.1. Storage Agreements are retained in hard copy or electronically for a minimum of 7 years following removal of units per SOP SF-1-6 Controlled Document Management.
 - 8.1.1. Closed Storage Requests and Agreements, for which the freezer is still stored in the SSF, are retained a minimum of 3 years.
- 8.2. Master Logs are retained in hard copy for 2 years following request closure.
- 8.3. Hard copies of communications regarding referrals to the SSF's Oversight Committee are retained indefinitely.
- 8.4. 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: Template for SSF Storage Space Request (1 page)
 - Appendix B: Master Study Log (1 page)
 - Appendix C: Template for Provisional Approval for Future Use Notification (1 page)
 - Appendix D: Template for SSF Storage Agreement (3 pages)
 - Appendix E: Template for SSF Storage Assigned Locations for Liquid Nitrogen Room (1 page)
 - Appendix F: Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room (C135) (1 page)
 - Appendix G: Template for SSF Storage Assigned Locations for Rack Assignments for SSF -70°C Freezers (1 page)
 - Appendix H: Template for SSF Storage Assigned Locations for Box Assignments for SSF LN₂ or -80°C LN₂ Freezers (1 page)
 - Appendix I: Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room (IB 097/MS-B046 Cage) (1 page)
 - Appendix J: Freezer Intake Checklist (1 page)
 - Appendix K: Template for SSF Storage Assigned Locations for Rack Assignments for SSF -20°C Freezers and Drawer Assignments for SSF Ambient Storage Space (1 page)
 - Appendix L: Storage Space Request Management and Intake Flowchart / Administrative SSF Request Number Update Flowchart (2 pages)
 - Appendix M: Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room (MS-B037) (1 page)
 - Appendix N: SSF Director and PI Signatory Guidelines (2 pages)

Template for SSF Storage Space Request

 INDIANA CTSI Clinical and Translational Sciences Institute	STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility						
TO REQUEST <u>SSF CORE SERVICES</u> COMPLETE AND SUBMIT THIS FORM: Indiana CTSI Specimen Storage Facility - IUPUI R3 Building, Room C158 317-274-2213 OR 317-274-3569 – (For Questions, Contact ictsissf@iupui.edu)							
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Core Office Use</td> <td style="width: 50%;">Project</td> </tr> <tr> <td></td> <td>SSF # _____</td> </tr> <tr> <td></td> <td>Request Date _____</td> </tr> </table>	Core Office Use	Project		SSF # _____		Request Date _____
Core Office Use	Project						
	SSF # _____						
	Request Date _____						
1. REQUEST INFORMATION							
Principal Investigator	Primary Contact						
Division / Institution	Role on Study						
E-mail	E-mail						
Phone	Phone						
Study ID(s) (required) and IRB / IBC (if applicable):							
Study ID(s)							
IRB / IBC #(s)							
Institution							
2. SERVICES REQUESTED (check one or both storage services below)							
<input type="checkbox"/> Space for PI Owned Freezer: Anticipated dates of use: _____ <input type="checkbox"/> Funded Project <input type="checkbox"/> Proposal for Future Project							
Mechanical Unit Space	Liquid Nitrogen Space						
# of Upright units	# of LN ₂ units						
# of Chest units	Freezer Model(s)						
	# -80°C LN ₂ units						
	Freezer Model(s)						
<input type="checkbox"/> Space in SSF Freezer: Anticipated dates of use: _____ <input type="checkbox"/> Funded Project <input type="checkbox"/> Proposal for Future Project							
Mechanical Unit Space	Liquid Nitrogen Space						
Number of racks	# of 81 specimen boxes						
Number of half-racks	# of 25 specimen boxes						
Ambient Storage Space							
Number of drawers							
3. SPECIMEN INFORMATION							
De-identified: <input type="checkbox"/> Yes <input type="checkbox"/> No Biosafety Considerations: Human Blood, Body Fluid, or Tissue <input type="checkbox"/> Yes <input type="checkbox"/> No							
Infectious Agent Level: <input type="checkbox"/> CDC Category A <input type="checkbox"/> CDC Category B or lower							
Other Safety Considerations: <input type="checkbox"/> rDNA <input type="checkbox"/> Radioactive substances <input type="checkbox"/> GLP Study <input type="checkbox"/> N/A							
<input type="checkbox"/> Other Explain _____							
4. BILLING	<input type="checkbox"/> IUSM Account Number: _____ / _____ Authorized By: _____ <input type="checkbox"/> NON-IUSM Invoice Account Number: _____ Authorized By: _____						
5. REVISION SUMMARY							
<input type="checkbox"/> Storage Increase <input type="checkbox"/> Storage Decrease <input type="checkbox"/> Contact Information <input type="checkbox"/> Billing Account # <input type="checkbox"/> Study Identifier <input type="checkbox"/> IRB/IBC #(s) or Exempt status <input type="checkbox"/> Specimen Information <input type="checkbox"/> N/A							
6. SSF Summary (SSF Office Use Only)							
Samples stored in C156 require ISBER Compliance for room temperature <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A							
SSF Manager Comments _____							
SSF Director Approval: <input type="checkbox"/> Approve <input type="checkbox"/> Disapprove <input type="checkbox"/> N/A Initials _____ Date _____							
Comments _____							
PI Notified: Date: _____ Initials / Date: _____ New Request # (if applicable): _____							
Effective Date: _____ Initials/Date: _____ Obsolete Date: _____ Initials/Date: _____							

Year____/ **Page**____ of ____

[illegible]

* See Appendix A and/or D for summary of revisions. ** Appendix A and D revisions required.

¹ New request number assigned at SSF Management discretion every 3-5 years in order to consolidate active requests on Master Log per SF-1-4.

² New request number assigned when the number of storage increases / decreases exceeded the available "Date of Storage Revisions" spaces on Master Log for former request number per SF-1-4.

³ Appendix A created for storage increase or decrease.

Template for Provisional Approval for Future Use Notification

Indiana CTSI Specimen Storage Facility
980 West Walnut Street, R3 C158
Indianapolis, IN 46202

<date>

Dear <Investigator>:

We received your request for future use of the Indiana CTSI Specimen Storage Facility for your study <title>. You have requested <summary of request> with anticipated dates of use from <start> to <end>.

We are pleased to inform you that we anticipate being able to provide the requested service. The annual anticipated charge is <\$---- > based on current approved rates. You may wish to anticipate an annual 3% increase in rates.

Please let us know if additional information is required.

Best Regards,

SSF Management

SSF Director:

<Contact Information>

SSF Manager:

<Contact Information>

Template for SSF Storage Agreement
STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

SSF Request #	Prev. Req. # (if applicable)	Study Identifier:					
		IRB / IBC # (if applicable):					

1. Study Information Provided at Time of Request Requires Modification: ☐ No ☐ Yes (Define Below)

For Internal Use Only: Changes from last effective version

☐ Storage Increase ☐ Storage Decrease ☐ Revise Contact Information
☐ Revise Personnel Authorized for Sample Access
☐ ONLY Authorized (Non-PI, Primary, or Secondary) Collaborating Biobank Personnel revised per SF-2-3, Appendix E*
☐ Other _____

2. Contact Information:

	PI	Primary Contact (<input type="checkbox"/> Same as PI)	Secondary
Name			
Contact Phone Number			
e-mail			

Personnel Authorized for Sample Access (In Addition to PI, Primary, and Secondary; List Name Only)

--	--	--	--

3. Freezer Unit Information (N/A for space in SSF owned freezer units, all fields EXCEPT Location field)

Unit #	Manufacturer	Model	Serial Number	Power Req. & Configuration	Study Personnel Notification via Alarm System (Y / N)	Alarm Set Points if not Standard (Standard: Cold alarm, -90°C; Warm alarm, -60°C; Set point, -80°C)	Key Y / N	Warranty or Service Y / N	SSF Location Room/space (required field for all units)

4. BILLING: Changes in billing information provided in previous request ☐ No ☐ Yes (Define Below)

Institution (IU, IUSM, or External):		Account #	
--------------------------------------	--	-----------	--

5. Assurances

- I certify that I am not housing any CDC Category A specimens in the Indiana CTSI Specimen Storage Facility (SSF). Category A specimens are defined at <https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf>.
- I certify that I have reviewed and agreed to the policies of the SSF (attached)

PI Signature _____ Date _____

For internal use only: *Authorized (Non-PI, Primary, or Secondary) Collaborating Biobank Personnel updated per SF-2-3, Appendix E on _____. Initials/Date: _____ PI Signature on SF-1-4, Appendix D not required.

6. SSF Documentation for internal use only

Account Closure: SSF Request # Closure Reason _____

PI notified of closure by/date _____ New SSF request # (if applicable) _____ Initials/Date _____

Non-SOP-driven Shared Calendar Updated with SF-1-4 App D renewal due date: Initials/Date _____

Comments _____

SSF Commitments:

- 1 The SSF maintains an oversight committee that reviews policies and advises the SSF.
- 2 The SSF maintains a set of Standard Operating Procedures that describes the policies and directs the staff of the SSF. The critical policy SOPs are reviewed by the SSF Oversight Committee. SOPs include the following policies and procedures pertinent to this agreement:
 - a The scope and charge of the SSF
 - b The management structure of the SSF
 - c Operating practices of the facility.
 - d Safety practices for the SSF staff and users
 - e Conditions maintained for each type of storage provided by the SSF and notifications if these conditions are exceeded.
 - f Maintenance and monitoring procedures for the SSF and the storage equipment within the SSF
 - g Notifications to investigators if conditions vary outside of the established parameters
 - h Training, controlled access, and alarm response practices developed to protect and insure confidentiality of materials stored in the SSF.
 - i Non-CTSI SSF staff entry practices including escorts for investigator personnel to access their specimens.
- 3 The SSF maintains the facility in compliance with current ISBER and GLP guidances relevant to facilities for storage.
- 4 Access is limited to CTSI SSF personnel and authorized study personnel who are escorted by CTSI SSF personnel for safety and security of the specimens.
- 5 If requested, the SSF will provide SOPs to the IUPUI IRB and other relevant IRBs and regulatory oversight groups.
- 6 The SSF functions as a recharge center and costs for services are determined by Indiana University.
- 7 This agreement limits SSF activity to facility maintenance, equipment oversight, study personnel escort, and emergency specimen transfer unless defined in a separate agreement.
- 8 SSF liability is limited to that associated with research activities at Indiana University.

Investigator Commitments:

- 1 The user is a PI with primary responsibility for the material to be stored in the facility.
- 2 The collection, storage and distribution of the stored material satisfy applicable regulatory agencies, e.g., IRB, IBC.
- 3 The PI agrees to pay user fees in a timely fashion.
- 4 If PI loses funds for biobanking activities, the PI agrees to remove specimens from storage within 30 days of notification.
- 5 PI agrees that all project-related personnel must provide the SSF with a request for access escort at least 2 working days in advance.
- 6 The PI provides and maintains current contact information for the study specimens.
- 7 Authorizes SSF personnel to move specimens to a back-up freezer in the event of primary unit failure.
 - a Provides clear directives for managing notification of relocation of cataloged samples.
 - b Agrees that, while the SSF will, in the event that transfer to a back-up unit is required, take all reasonable measures to place specimens into the back-up unit in a similar organizational pattern, no warranty of specimen location is made except for specimen protocols managed by CTSI Sample Management software.
- 8 PI owner of LN₂ freezer(s) agrees to allow SSF personnel to alter high level alarm point on an LN₂ freezer in the event of an overfill. PI will be notified the following business day, the freezer will continue to be monitored via the alarm system (low level alarm will not be affected) and high level alarm point will be restored when unit reaches acceptable level.

Investigator Commitments (Continued):

- 9 Agrees to accept charges for use of the SSF back-up freezer 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.)
- 10 The PI agrees to renew the SSF Storage Agreement annually to ensure continued regulatory approvals for samples stored in the SSF. This process is initiated by the SSF.
- 11 The PI agrees to certify annually during Storage Agreement renewal (point 10) that they are not housing any CDC Category A specimens in the SSF.
- 12 The PI agrees to inform SSF of all biohazard or other safety changes to the initial application safety statement and keep current all safety related designations for the specimens being stored. This includes biohazard level and all other safety considerations and practices.
- 13 The PI agrees to inform the SSF of studies which regulatory bodies have closed or placed on hold.
- 14 The PI agrees to contain samples in PI-provided racks, bins, or other storage receptacles to facilitate specimen relocation to a backup freezer in the event of an emergency.
- 15 The PI agrees to promptly inform the SSF of all personnel requiring de-activation of access authorization.
- 16 PIs storing freezers in the SSF agree to comply with the following freezer intake requirements:
 - a Freezers already in service and housing samples:
 - i Must be in good working order, with no known mechanical defects.
 - ii Must accommodate racks no larger than those with capacity to hold 16-25 two-inch boxes.
 - iii PI must have all samples contained in racks or bins to facilitate specimen relocation during freezer defrost.
 - b New (empty) freezers:
 - i Must accommodate racks no larger than those with capacity for 16-20 two-inch boxes –OR–
 - ii Unit may be acceptable if it can be reconfigured to comply with step 15.b.i by purchasing an additional shelf and shelf brackets. PI will purchase additional shelf and shelf brackets.
 - iii Any samples placed in freezer must be contained in PI-provided racks or bins to facilitate specimen relocation during freezer defrost.
- 17 If the SSF determines that the PI has failed to comply with these responsibilities:
 - a The SSF's Oversight Committee Chair will be notified, and discussion with other Oversight Committee members will be at Chair's discretion.
 - b Actions may include the following:
 - i Retraining, if applicable
 - ii Increased storage fees based on the non-subsidized rate
 - iii Escalation of issue to PI's department chair
 - iv Cancellation of storage agreement
 - v Oversight of specimens being transferred to the investigator's home Institution. Specimens may not be accessed except by authorization of the institutional representative.
- 18 If PI concerns regarding pricing, quality, operations, or policies of the SSF may be discussed with the SSF Director and/or the Chair of the SSF's Oversight Committee.

Template for SSF Storage Assigned Locations for Liquid Nitrogen Room

NORTH

C156

D1-
Available

D2-
Available

D3-
Available

D4-
Available

C1-
Available

C2-
Available

C3-
Available

C4-
Available

C5-
Available

B1 -
Available

B2 -
Available

B3 -
Available

B4 -
Available

B5 -
Available

A1-
Available

A2-
Available

A3-
Available

WEST

EAST

* MRU and -80°C LN₂ units must be denoted by adding an “M” (MRU) and a “V” (-80°C LN₂), as applicable.

Effective Date: _____
Obsolete Date: _____

Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room - C135

Ambient
Cabinet
Drawers
1-4

NORTH

Effective Date: _____
Obsolete Date: _____

WEST	F5-Available	E10-Available	E9-Available	D12-Available	D11-Available	C11-Available	B12-Available	11-Available	A10-Available	A9-Available	EAST
	F4-Available	E8-Available	E7-Available	D10-Available	D9-Available	C10-Available	C9-Available	B10-Available	B9-Available	A8-Available	A7-Available
	F3-Available	E6-Available	E5-Available	D8-Available	D7-Available	C8-Available	C7-Available	B8-Available	B7-Available	A6-Available	A5-Available
	F2-Available	E4-Available	E3-Available	D6-Available	D5-Available	C6-Available	C5-Available	B6-Available	B5-Available	A4-Available	A3-Available
	F1-Available	E2-Available	E1-Available	D4-Available	D3-Available	C4-Available	C3-Available	B4-Available	B3-Available	A2-Available	A1-Available
F	E		D		SOUTH	C	B		A		

Template for SSF Storage Assigned Locations for Rack Assignments for -70°C SSF Freezers

Indiana CTSI SSF -70°C
Freezers Users

Summary:
Freezer Unit Racks
Total:
Committed:
Available:

Effective Date: _____
Obsolete Date: _____

Record PI Name and Study Identifier (if Applicable)

Freezer #1 (Location: Room, Freezer ID (e.g. C135, A1))			
1-1	1-2	1-3	1-4
2-1	2-2	2-3	2-4
3-1	3-2	3-3	3-4
4-1	4-2	4-3	4-4

Freezer #3 (Location: Room, Freezer ID)			
1-1	1-2	1-3	1-4
2-1	2-2	2-3	2-4
3-1	3-2	3-3	3-4
4-1	4-2	4-3	4-4

Freezer #5 (Location: Room, Freezer ID)					
1-1	1-2	1-3	1-4	1-5	1-6
2-1	2-2	2-3	2-4	2-5	2-6
3-1	3-2	3-3	3-4	3-5	3-6
4-1	4-2	4-3	4-4	4-5	4-6
5-1	5-2	5-3	5-4	5-5	5-6

Freezer #2 (Location: Room, Freezer ID)			
1-1	1-2	1-3	1-4
2-1	2-2	2-3	2-4
3-1	3-2	3-3	3-4
4-1	4-2	4-3	4-4

Freezer #4 (Location: Room, Freezer ID)				
1-1	1-2	1-3	1-4	1-5
2-1	2-2	2-3	2-4	2-5
3-1	3-2	3-3	3-4	3-5
4-1	4-2	4-3	4-4	4-5

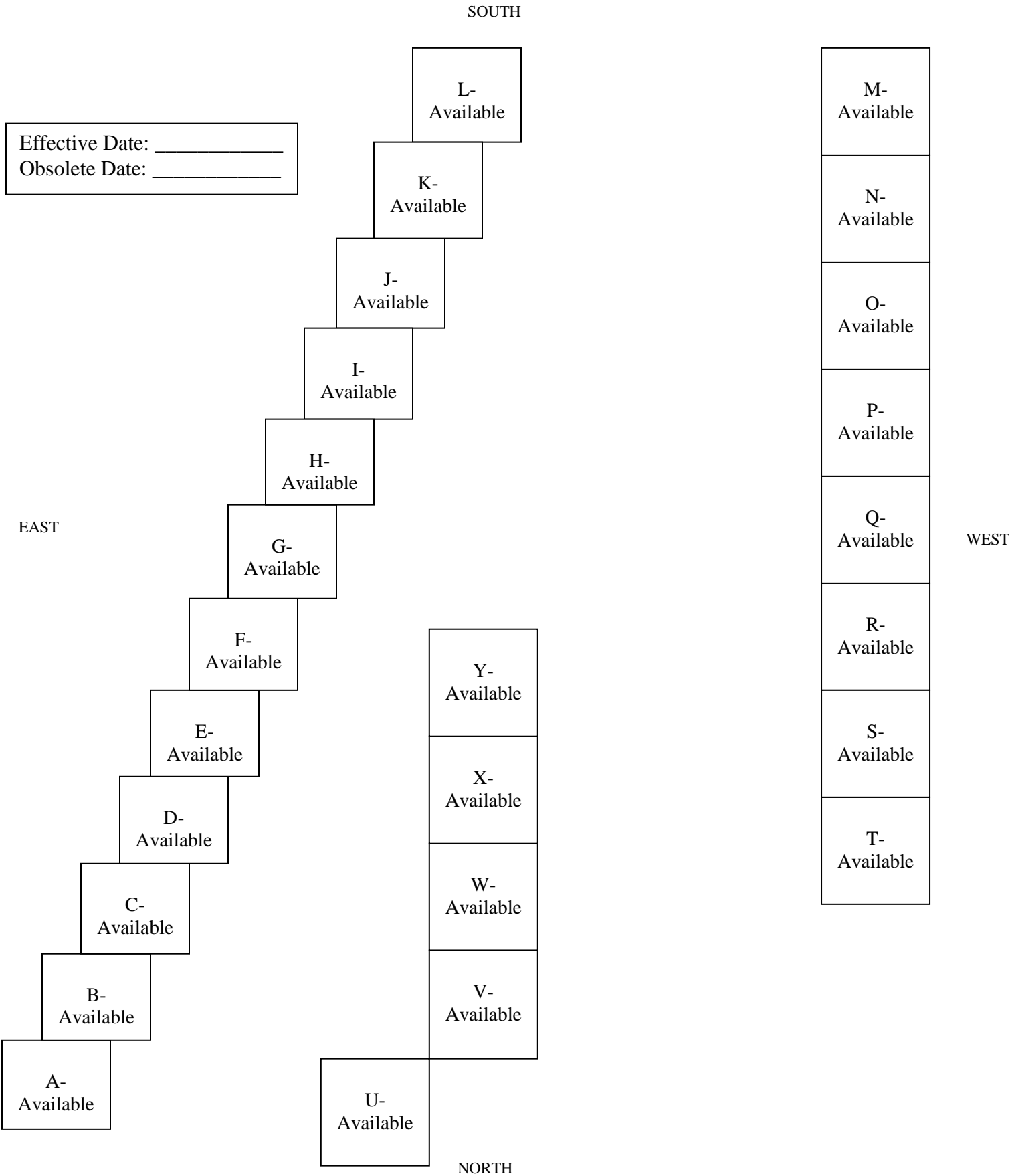
* References
provisional approval.

Template for SSF Storage Assigned Locations for Box Assignments for SSF LN₂ or -80°C LN₂ Freezers

Freezer										
Rack 1	Rack 2	Rack 3	Rack 4	Rack 5	Rack 6	Rack 7	Rack 8	Rack 9	Rack 10	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
Rack 11	Rack 12	Rack 13	Rack 14	Rack 15	Rack 16	Rack 17	Rack 18	Rack 19	Rack 20	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
Rack 21	Rack 22	Rack 23	Rack 24							
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										

Effective Date: _____
 Obsolete Date: _____

Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room
(IB 097/MS-B046 Cage)



SSF Freezer Intake Checklist (Suggested Tool)

FREEZER INFORMATION					
Location / Location ID and S/N: (Ex: C135-D9, S/N: 801139-342)		Labels printed Accuracy of Label S/N Verified	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A (Unit returned from repair)		
PI Name:	<input type="checkbox"/> N/A (SSF-Owned Unit)				
Receipt Date:		Returned to Service Date:			
Reason:	<input type="checkbox"/> New Unit <input type="checkbox"/> Returned from Repair <input type="checkbox"/> Replacement Freezer <input type="checkbox"/> Freezer Relocation				
Previous Location (Room & Location Ex. C135-D9)		<input type="checkbox"/> N/A (New Unit or Unit returned to previous location)	Non-SOP-defined SSF Shared Calendar Due Dates Updated/Added:	Quarterly <input type="checkbox"/>	Annual <input type="checkbox"/>
Initials / Date:					
FORMS / MAINTENANCE UPDATE (Initial & Date When Completed)					
New, Replacement, and Relocated Units					
SF-1-4 Appendices A & D <input type="checkbox"/> N/A (Unit Returned to Prior Location After Repair OR SSF-Owned Unit)					
SF-1-4 Appendix D (Storage Agreement):	Sent to PI:		Received from PI:		Room Maps <input type="checkbox"/> N/A (LN ₂) (SF-1-4, App. E-F, I, K, M)
SF-1-4 Appendix A (Storage Request):	Created:		Director Approved:		
Postings – LN ₂ Units	LN ₂ Accept. Crit. (SF-3-2, App. C)		-80°C LN ₂ Acceptance Criteria (SF-3-16, App. C)		N/A (MRU Unit) <input type="checkbox"/>
Set points entered / verified (per SF-1-4, Appendix D, SF-3-2, Appendix C, or SF-3-16, App. C):					
MECHANICAL UNITS (MRU) (New, Returned from Repair, Replacement, or Relocated) <input type="checkbox"/> N/A (LN ₂ Freezer)					
SF-3-1 Appendix C (Daily Monitoring Log):	Posted on Freezer:		SF-3-1 Appendix D (Quarterly Maintenance):	Posted on Freezer:	
SF-3-1 Appendix B (Annual/Biannual):	Completed: N/A (Not due/New/Replacement) <input type="checkbox"/>		Missed/Intake Maintenance Completed:	Quarterly <input type="checkbox"/> Annual <input type="checkbox"/> Bi-Annual <input type="checkbox"/>	<input type="checkbox"/> Not due <input type="checkbox"/> N/A <input type="checkbox"/> Not due <input type="checkbox"/> N/A <input type="checkbox"/> Not due <input type="checkbox"/> N/A
SF-3-1 Forms for Replaced Unit Archived:	Completed:	<input type="checkbox"/> N/A	Explain all Missed/Intake Maintenance N/A Selections:		
LIQUID NITROGEN or -80°C LN ₂ UNITS (New, Returned from Repair, Replacement, or Relocated) <input type="checkbox"/> N/A (MRU)					
SF-3-2 or SF-3-16 Appendix A (Daily Monitoring Log):	Posted on Freezer:		SF-3-2 or SF-3-16 Appendix B (Semi-Annual / Annual Log):	Posted on Freezer:	
Probe Placement Evaluation:	Probe A: Probe B:	Completed <input type="checkbox"/> N/A <input type="checkbox"/> Completed <input type="checkbox"/> N/A <input type="checkbox"/>	Explain all N/A selections:		
Missed Maintenance Evaluation:	Semi-Annual <input type="checkbox"/> Annual <input type="checkbox"/>		Missed/Intake Maintenance Completed:	Semi-Annual <input type="checkbox"/> Annual <input type="checkbox"/> Defrost Eval. <input type="checkbox"/> Quarterly <input type="checkbox"/>	<input type="checkbox"/> Not Due <input type="checkbox"/> N/A <input type="checkbox"/> Not Due <input type="checkbox"/> N/A <input type="checkbox"/> Not Due <input type="checkbox"/> N/A <input type="checkbox"/> Not Due <input type="checkbox"/> N/A
SF-3-2 Forms for Replaced Unit Archived:	Completed:	<input type="checkbox"/> N/A	Explain all Missed / Intake Maintenance N/A selections:		
Out of Specification Instance Closeout Completed:			Initials/Date: <input type="checkbox"/> N/A		
Comments					
Reviewer Initials / Date:					

Template for SSF Storage Assigned Locations for Rack Assignments for -20°C SSF Freezers and
Drawer Assignments for SSF Ambient Storage Space

Indiana CTSI SSF -20°C
Freezer Users

Summary:
Freezer Unit Racks
Total:
Committed:
Available:

Indiana CTSI SSF Ambient
Storage Users

Summary:
Ambient Storage Drawers
Total:
Committed:
Available:

Record PI Name and Study Name (if applicable)
*References Provisional Approval

Freezer #6 -20°C (Location: Room, Freezer ID)					
1-1	1-2	1-3	1-4	1-5	1-6
2-1	2-2	2-3	2-4	2-5	2-6
3-1	3-2	3-3	3-4	3-5	3-6
4-1	4-2	4-3	4-4	4-5	4-6

Ambient Cabinet #1
(Location: Room)

1

2

3

4

5

Ambient Cabinet #2
(Location: Room)

1

2

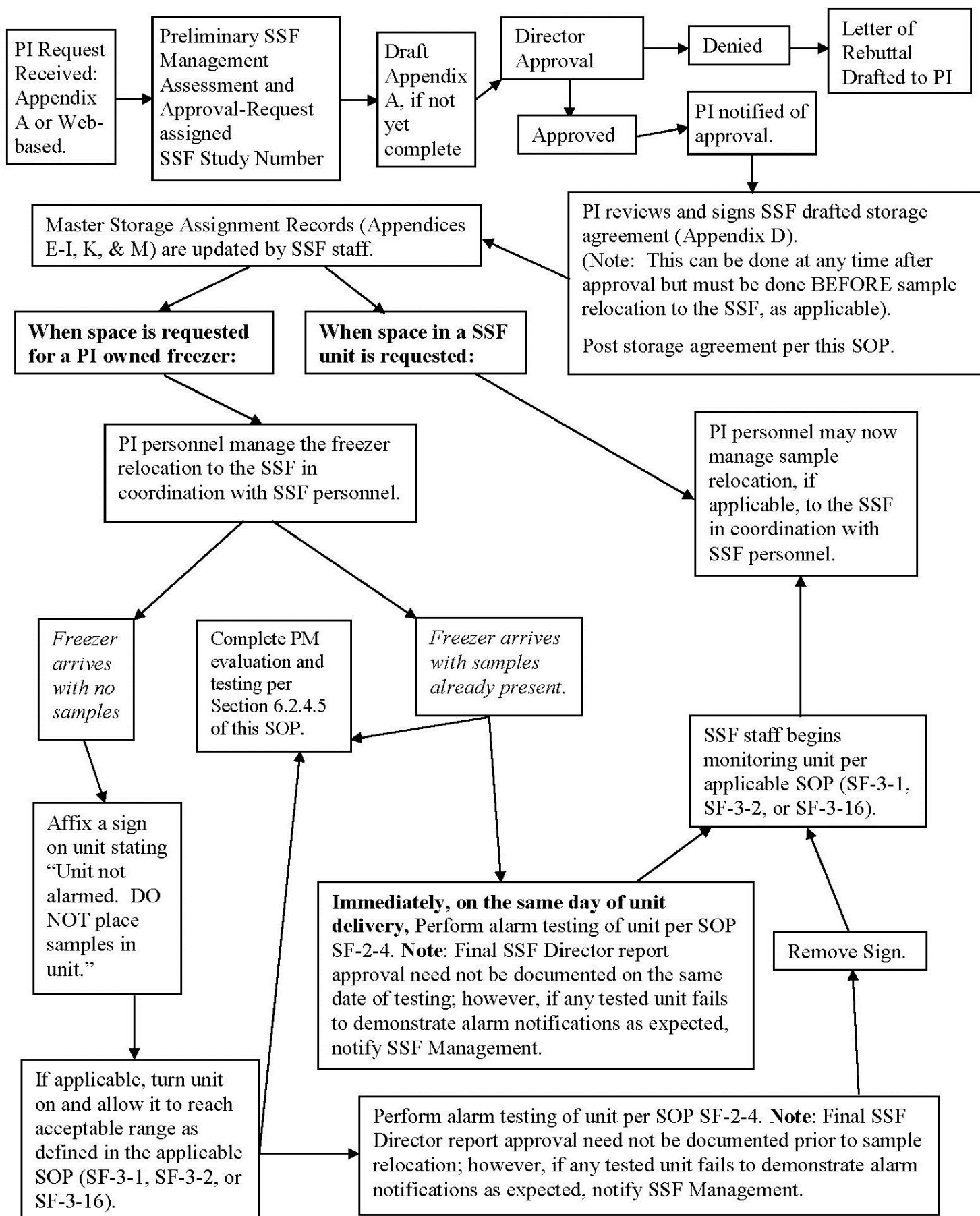
3

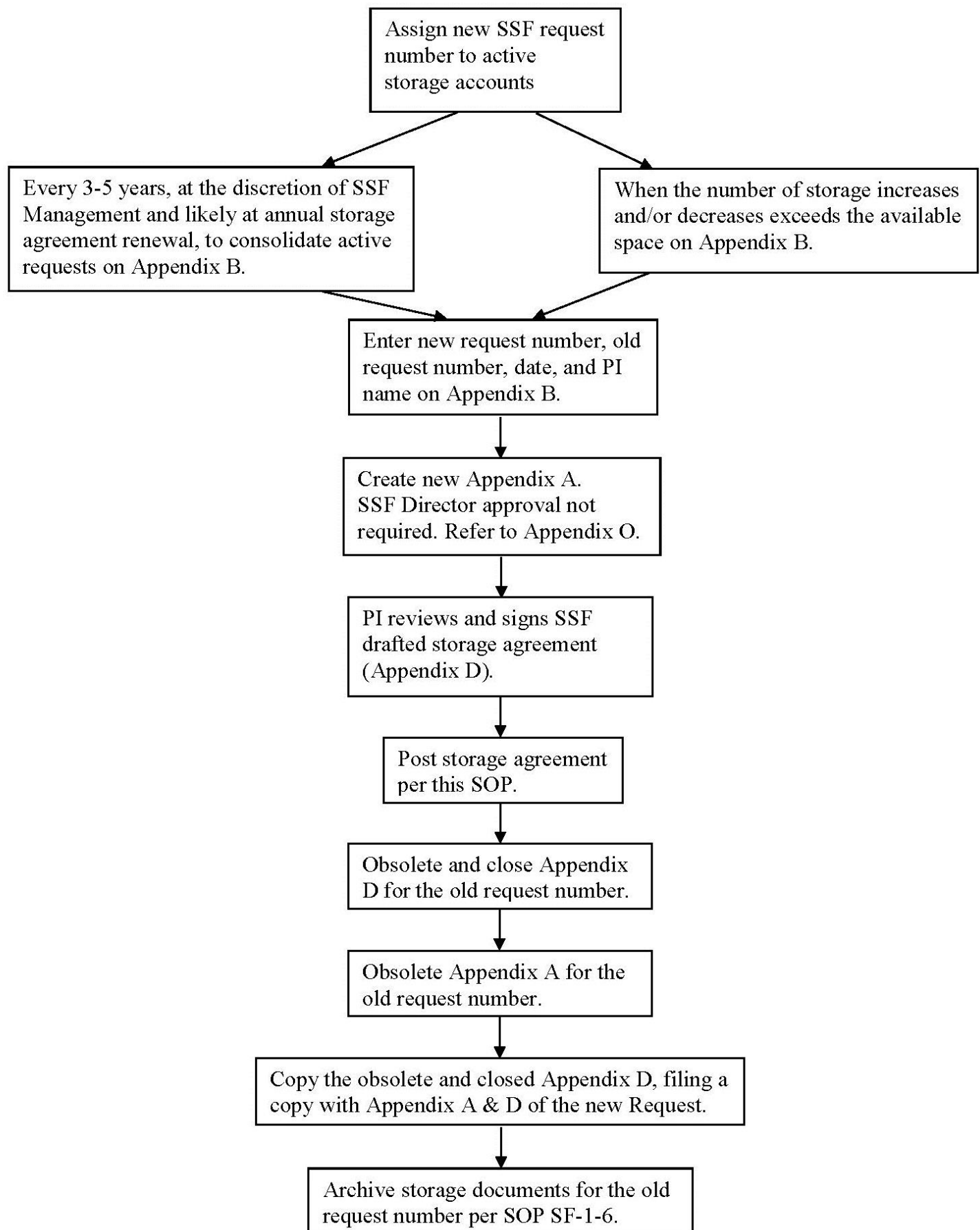
4

5

Effective Date: _____
Obsolete Date: _____

Storage Space Request Management and Intake Flowchart



Administrative SSF Request Number Update Flowchart

Template for SSF Storage Assigned Locations for Mechanical Refrigeration Room
Annex III – MS-B037

Effective Date: _____

Obsolete Date: _____

WEST

D1 -
Avail.

D2 -
Avail.

D3 -
Avail.

E9 -
Avail.

SOUTH

A1 -
Avail.

A2 -
Avail.

A3 -
Avail.

B1 -
Avail.

B2 -
Avail.

B3 -
Avail.

B4 -
Avail.

C1 -
Avail.

C2 -
Avail.

C3 -
Avail.

C4 -
Avail.

Column

B5 -
Avail.

B6 -
Avail.

E4 -
Avail.

E3 -
Avail.

E2 -
Avail.

E1 -
Avail.

E8 -
Avail.

E7 -
Avail.

E6 -
Avail.

E5 -
Avail.

NORTH

F3 -
Avail.

F2 -
Avail.

F1 -
Avail.

F6 -
Avail.

F5 -
Avail.

F4 -
Avail.

G7 -
Avail.

G6 -
Avail.

G5 -
Avail.

G4 -
Avail.

G3 -
Avail.

G2 -
Avail.

G1 -
Avail.

EAST

SSF Director and PI Signatory Guidelines

- **Wet Ink Signature (WS):** Signature documented with an indelible pen in blue or black ink
- **Digital Signature (DS):** Signature captured digitally and uniquely assigned to the signatory by means of a login/password or via log/in password to an IU-managed, web-based program
- **Electronic Signature (ES):** Signature conveyed via e-mail provision of document (signatory and e-mail address are linked to the same individual)
- **Typewritten Signature (TS):** Name typewritten (**Note:** this is unacceptable unless accompanied by Electronic Signature as defined above)

Event Description	SF-1-4 Step Reference	SOP + Appendix reference	PI signature required (Y/N/NA)	If yes, list acceptable types	SSF Director signature required (Y/N/NA)	If yes, list acceptable types
New Storage Agreement <ul style="list-style-type: none"> new protocols new Request # new PI 	6.1.6 and 6.2.6	SF-1-4 App. A	N/A		Y	WS, DS, ES, TS
		App. A Web Submission	N/A		Y	WS, DS, ES, TS
	6.4.6.6	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Storage Increase / Decrease <ul style="list-style-type: none"> existing protocols no new Request # assigned excluding account closure 	6.2.7.3	SF-1-4 App. A	N/A		N	
	6.4.6.7.1.3	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Transfer of Ownership of some, but not all units	6.2.7.3 & 6.2.8.3	SF-1-4 App. A	N**		Y	
	6.4.6.7.1.4	SF-1-4 App. D	***		N/A	
Transfer of Ownership of all units	6.2.7.8 & 6.2.8.3	SF-1-4 App. A	N**		Y	
	6.4.6.7.1.5	SF-1-4 App. D	***		N/A	
Closure (removal of <i>all</i> PI units/samples)	6.2.7.8	SF-1-4 App. A	N**		N	
	6.4.6.7.1.6	SF-1-4 App. D	N**		N/A	
Sample location change: Room	6.2.7.6	SF-1-4 App. A	N		N	
	6.4.6.7.1.9.1.1	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Sample location change: Outlet/Alarm point in same room	6.2.7.6	SF-1-4 App. A	N		N	
	6.4.6.7.1.9.1	SF-1-4 App. D	N		N/A	
Annual Storage Agreement Renewal	6.4.6.9.9	SF-1-4 App. A	N/A		N/A	
	6.4.6.9	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Replacement Request # – Administrative Change at Annual Renewal (no Storage increase or decrease)	6.2.9	SF-1-4 App. A	N/A	WS, DS, ES, TS	N	
	6.2.9	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	

* PI-signed SF-2-3 Appendix E required

** Written directive from PI/PI-personnel per designated section is required.

*** Per designated section, signature required from PI assuming ownership of samples. Written directive required from PI transferring ownership.

- Wet Ink Signature (WS): Signature documented with an indelible pen in blue or black ink
- Digital Signature (DS): Signature captured digitally and uniquely assigned to the signatory by means of a login/password or via log/in password to an IU-managed, web-based program
- Electronic Signature (ES): Signature conveyed via e-mail provision of document (signatory and e-mail address are linked to the same individual)
- Typewritten Signature (TS): Name typewritten (**Note**: this is unacceptable unless accompanied by Electronic Signature as defined above)

Event Description	SF-1-4 Step Reference	SOP + Appendix reference	PI signature required (Y/N/NA)	If yes, list acceptable types	SSF Director signature required (Y/N/NA)	If yes, list acceptable types
Replacement Request # at Storage Increase / Decrease	6.2.7.3	SF-1-4 App. A	N/A		N	
	6.2.9	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Change in PI	6.6.1.2	SF-1-4 App. A	N/A		Y	WS, DS, ES, TS
	6.6.1.2	SF-1-4 App. D	Y	WS, DS, ES, TS	NA	
Change in Primary personnel	6.2.7.1	SF-1-4 App. A	N		N	
	6.4.6.7.1.1	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Change in PI-authorized personnel	N/A	SF-1-4 App. A	N/A		N/A	
	6.4.6.7.1.1	SF-1-4 App. D	Y	WS, DS, ES, TS	N/A	
Change in <i>Collaborating Biobank</i> PI-authorized personnel (Excluding PI, Primary, and Secondary Contacts)	N/A	SF-1-4 App. A	N/A		N/A	
	6.4.6.7.1.2	SF-1-4 App. D	N*		N/A	
Billing account number revision	6.2.7.2	SF-1-4 App. A	N**		N	
	6.4.6.7.1.7	SF-1-4 App. D	N**		N/A	
Study Identifier and/or IRB / IBC or Exempt status	6.2.7.4	SF-1-4 App. A	N**		N	
	6.4.6.7.1.8	SF-1-4 App. D	N**		N/A	
Specimen Information Revision	6.2.7.5	SF-1-4 App. A	N**		N	
	N/A	SF-1-4 App. D	N/A		N/A	
Administrative error correction	6.2.7.6	SF-1-4 App. A	N		N	
	6.4.6.7.1.9.2	SF-1-4 App. D	N		N/A	

* PI-signed SF-2-3 Appendix E required

** Written directive from PI/PI-personnel per designated section is required.

*** Per designated section, signature required from PI assuming ownership of samples. Written directive required from PI transferring ownership.