



## STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR CONTROLLED ACCESS

CHAPTER: 2-Facility

SOP #: SF-2-3.16

SUPERSEDES SOP #: N/A

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### 1. REVISION

1.1. Significant changes incorporated in this version include:

- 1.1.1. Throughout SOP, all references to MS B-037 corrected to MS-B037, and MS B-036 corrected to MS-B036 for consistency with other SOPs.
- 1.1.2. Throughout SOP, all references to VPF management of key card programming, verification, and data extraction operations for event reporting replaced with directives for SSF management of key card programming, verification, and data extraction operations for event reporting. SSF began managing key card programming and verifications on SSF door Controllers on 03/11/2020.
- 1.1.3. Section references updated throughout SOP.
- 1.1.4. Revised the following directives after SSF Door Controllers transferred to the IU Security dnaFusion server on 3/11/2020:
  - 1.1.4.1. Door control defined in Step 3.1.4 and Section 3.1.5.
  - 1.1.4.2. Key card programming defined in Sections 3.1.6 and 3.1.7.
  - 1.1.4.3. Access levels streamlined to facilitate key card programming, verification, and quality control actions. Per Step 3.1.7, access levels are defined in the SSF Controlled Access Levels Chart, Appendix J.
  - 1.1.4.4. Directives for dnaFusion service interruptions added in Section 3.1.8.
  - 1.1.4.5. Assignment of controlled access expiration dates is not permitted in dnaFusion on the IU Security server. Therefore, all references to programming expiration dates replaced throughout SOP with directives to manage key card expiration dates internally on the non-SOP-driven CA spreadsheet and SSF calendar.
  - 1.1.4.6. Created Section 6.3.4 to define the process for rescinding access in dnaFusion.
  - 1.1.4.7. Facility access updates automatically on replaced key cards, therefore directives for management of the key card replacement process substantially revised in Sections 6.3.6 and 6.7.3.7.

- 1.1.4.8. Directives that key card actions must be completed by SSF personnel other than the personnel for whom access is to be authorized/rescinded/updated is specified in Sections 6.3.3.3.5, 6.3.4.1.1, 6.5.2.5.1.1, 6.7.3.6.7, and 6.7.3.7.5.
- 1.1.4.9. Table in Step 6.3.8.6 revised to correct erroneous rescind access step reference and reflect that directives for reflecting a name change do not include changing the personnel's name in dnaFusion, since SSF personnel do not have permissions to do so. Personnel name changes are reflected in dnaFusion once personnel replace their key card.
- 1.1.4.10. Event reporting access data export directives in Section 6.10. Directives added in Section 6.10 and throughout SOP that data extraction may be requested from IU Security if necessary.
- 1.1.5. Step 3.1.9 corrected to reflect that Support areas managed by key are controlled by IUPUI Police / IU Security according to IUPUI policies.
- 1.1.6. Removed references to Collaborating Biorepository Personnel (CBP) escorting other CBP from Sections 3.1.12, 4.4.2.1, and Appendix N.
- 1.1.7. Step 3.1.12 table revised to correct question to ask "Is the individual **permitted** (not entitled) to supervise the critical area access of other individuals?"
- 1.1.8. Section 4.4.2 revised to reduce CBP controlled access authorization privileges to only personnel working on their PI's freezer(s) or accessing their PI's freezer(s), to improve compliance.
- 1.1.9. Revised Section 4.5.5 to reflect consolidated/streamlined access levels and revisions to the Controlled Access Change form (Appendix B). Added directives for SSF key card programming and verification.
- 1.1.10. Step 4.5.5.4.1 directive corrected. SSF Director approval is not required for any non-critical access requests.
- 1.1.11. Added key card reader to Section 5, Materials list.
- 1.1.12. Added Section 6.1.2, As Needed Maintenance, to define the following:
  - 1.1.12.1. SSF contacts CFS to repair door mechanics problems
  - 1.1.12.2. SSF contacts IU Security to address issues with card readers or dnaFusion
  - 1.1.12.3. Any unresolvable controlled access issue is promptly escalated to Presidio or IU Security for troubleshooting and resolution.
  - 1.1.12.4. The SSF maintains one surplus key card reader for quick replacement of a failed reader
- 1.1.13. Added Steps 6.3.1.6, 6.3.2.4, 6.3.3.3.3.5 directive that an alternate SSF personnel verifies actions.
- 1.1.14. Erroneous step/section references removed in Steps 6.3.1.7.5, 6.7.2.1.1, and 6.12.1.5.1.
- 1.1.15. Added Step 6.3.1.7.6 directive for rescinding access should Collaborating Biorepository (CB) respond, to monthly inquiry indicating CBP have left Biobank.
- 1.1.16. Section 6.3.2.5 substantially revised to define Key Card Programming Verification procedure.
- 1.1.17. Step 6.3.3.3.4.1 revised to direct SSF personnel to rescind access as soon as possible.
- 1.1.18. Step 6.3.7.1 directive applies to all CBP, so specificity of permanent/temporary CBP was unnecessary and thus removed.
- 1.1.19. Clarified Step 6.3.7.2.4 to define that access extraction is completed by SSF personnel with "*at minimum*" read only dnaFusion access.
- 1.1.20. Clarified in Step 6.3.7.3 that in the event that completion of CBP training is delayed by several days, it is acceptable if electronic access is not immediately rescinded if

the performance of both rescinding and re-activating access cannot reasonably be accomplished in a short duration.

- 1.1.21. Added Step 6.3.8.6 to direct monthly inquiry with CBs utilizing SF-1-13 Appendices A & B to document freezer access, providing a copy of SF-1-13 Appendix A and asking if any personnel should be added or removed.
- 1.1.22. Sections 6.5.2, 6.6.2, and 6.6.10.1 revised to correct SOP titles to match titles on applicable effective versions of each SOP.
- 1.1.23. Removed extraneous directive that SF-1-13 is “applicable to GLP Collaborating Biorepositories utilizing optional SF-1-13 logs” from Steps 6.5.2.1.2 and 6.6.2.1.2, since the clarifying directive is not necessary for SSF personnel, who train on SF-1-13.
- 1.1.24. Directives for completion of Appendix B, Sections 6.5.2.3 and 6.6.2.3, substantially revised to reflect consolidated/streamlined access levels and to add authorization for non-critical LARC access, necessary for access to Annexes I and III.
- 1.1.25. Step 6.5.2.3.4.2 directive that authorizing MS-B037 and IB097/MS-B046 Cage access is not required if the applicable CB does not own freezers housed in either facility added to streamline access authorization, rescind, and verification process. If MS-B037 and IB097/MS-B046 Cage access will not be activated, check the box next to “MS LL 036 Annex III & 046 Cage N/A” on Appendix B.
- 1.1.26. The process for authorizing access in dnaFusion is defined in Section 6.5.2.5.
- 1.1.27. Added Step 6.5.2.5.1.1 directive that SSF personnel are not permitted to authorize their own key card access. Alternate personnel must complete those actions.
- 1.1.28. Step 6.5.2.5.1.3 directive to authorize access on SmartChip numbers only (likely 7-digits in length versus the 6-digit proximity (prox) number), since prox readers are permanently disabled.
- 1.1.29. Steps 6.5.3, 6.5.4, 6.6.3, and 6.6.4 revised to reflect new directives that in the event of a lost or forgotten key card, SSF personnel or a member of their biorepository are authorized to provide facility access.
- 1.1.30. Add Step 6.5.4.1 direct that if key card is replaced, access is reauthorized per Section 6.5.2 once replacement key card number is provided to SSF personnel.
- 1.1.31. Section 6.6.2.2 revised to remove SOP SF-3-16 from CBP training requirements after SSF Management determined that SF-3-16 is not required for CBP to safely access -80°C LN<sub>2</sub> freezers.
- 1.1.32. Added Step 6.6.4.1, directive erroneously omitted, that if key card is replaced, access is reauthorized per Section 6.6.2 once replacement key card number is provided to SSF personnel.
- 1.1.33. Removed Step 6.7.3.6 directive applying rescind access procedure to C135, C156, IB 097/MS-B046 Cage, and MS-B037, since the same Appendix B directives are applicable to all critical and non-critical doors with the exception of additional specificity added in Steps 6.7.3.6.3 – 6.7.3.6.4 as follows:
  - 1.1.33.1. Specified in Step 6.7.3.6.3 that SSF Director written notification (email acceptable) is required only for recension of critical access.
  - 1.1.33.2. Added Step 6.7.3.6.4 to direct that SSF Director notification is not required when rescinding only non-critical access.
- 1.1.34. Corrected sample access request Steps 6.8.1.2 and 6.8.2.2 directive that sample access authorization is verified against the PI’s storage agreement, SF-1-4 Appendix D, not the intake form.
- 1.1.35. Steps 6.10.2 and 6.10.3.1 directives corrected to indicate that SSF Personnel are notified of door alarm events, since door alarm events are emailed to [ictsissf@iupui.edu](mailto:ictsissf@iupui.edu), which notifies SSF personnel, including on-call personnel. The

- SSF email may or may not be redirected to the SSF Director, at the Director's discretion.
- 1.1.36. Steps 6.10.3.1 – 6.10.3.2 reconfigured to enhance readability and reworded to clarify directive regarding mandatory investigation of Point Active events and that investigation of Point Inactive events is not required.
  - 1.1.37. Step 6.10.4.3 and 6.11.1.2 directives for review of Appendix L added.
  - 1.1.38. Added Step 6.10.4.3.1 to note potential discrepancy between event timestamp from dnaFusion and the time documented on Appendix L.
  - 1.1.39. Added Step 6.11.1, directives that access authorization reports may be requested from IU Security personnel if necessary
  - 1.1.40. Specify in Section 6.11.1.1 that data extracted from dnaFusion or requested of IU Security must include all raw event data for all SSF critical doors for the applicable month.
  - 1.1.41. Section 6.11.3, Step 6.11.5, and Appendix G revised and Step 6.11.7 added to reflect directives for management of key card replacements discovered at monthly review.
  - 1.1.42. Step 6.11.4.2 revised to remove erroneous references to tables and examples removed from SOP in prior revision.
  - 1.1.43. Step 6.12.1.3 revised to clarify directives for obtaining access authorization report utilized for annual review.
  - 1.1.44. Steps 6.12.1.7.3.2 and 6.12.1.8.3.2 revised to direct that PI, Biorepository Manager, or SSF Management are copied, to accommodate PIs who'd prefer their Biorepository Manager be contacted regarding CBP controlled access matters.
  - 1.1.45. Extraneous reference to Section 6.12 removed from Steps 6.12.1.7.3.7, 6.12.1.8.3.7, and 6.12.1.10.2.
  - 1.1.46. Added Steps 6.12.1.7.4 and 6.12.1.8.4 directives specifying that access authorization dates are documented/tracked using the Controlled Access tracking spreadsheet.
  - 1.1.47. Steps 6.12.1.11 and 6.12.1.12 were erroneously copied from Section 6.11. Revised both steps to reflect directives for completion of Appendix H.
  - 1.1.48. Added Section 6.13, Annual CBP Recertification Training requirement, to be completed per SF-1-5. Best practice is to complete in conjunction with annual access review (Section 6.12).
  - 1.1.49. Section 7, References, revised as follows:
    - 1.1.49.1. Step 7.1 Contact Information directive moved from erroneous Step 6.13.1.1 location to Section 7.
    - 1.1.49.2. Reference to the dnaFusion User Manual added in Section 7.3.
    - 1.1.49.3. The location for requesting LARC non-critical access added in Step 7.4.
    - 1.1.49.4. Kratos contact removed, with their replacement's (Presidio) contact information added to Appendix C.
  - 1.1.50. Section 9 revised to add a new Appendix J & Appendix N.
  - 1.1.51. Added Section 10 and Appendix N to streamline Collaborating Biorepository personnel training.
  - 1.1.52. Appendix A revised substantially to define SSF control of SSF doors via dnaFusion on the IU Security server.
  - 1.1.53. Appendix B revised substantially as follows:
    - 1.1.53.1. Remove VPF management of key card programming
    - 1.1.53.2. Reflect revised access levels, improving feasibility of key card programming and documentation of actions
    - 1.1.53.3. Revise access transfer directives to define that personnel authorize access for new key card #(s) *or confirm access properly transferred to new key card.*

- 1.1.53.4. Add an N/A option for authorization of Annex I and Annex III access for those without freezers in Annexes I & III.
- 1.1.53.5. Include directive to authorize LARC access as applicable
- 1.1.53.6. Add directive clarifying that access expiration dates are not entered in dnaFusion and are tracked using the Shared Calendar and Controlled Access tracking spreadsheet.
- 1.1.54. Appendix C revised as follows:
  - 1.1.54.1. Replace VPF contact information with IU Physical Security contact information
  - 1.1.54.2. Add LARC authorization directives and contact information
  - 1.1.54.3. Add Presidio contact information. Presidio replaced Kratos for door hardware and controller issues resolution.
  - 1.1.54.4. Add CFS contact information
- 1.1.55. Appendix D revised to edit formatting to improve usability. Note added to bottom of form directing personnel to see SSF Personnel if uncertain of facility access directives and if unable to enter facility using your key card.
- 1.1.56. Appendix E revised to add spaces to document that the PI's storage agreement has been revised to reflect authorizing and rescinding personnel access.
- 1.1.57. Appendices E & F revised to correct IUSCC Tissue Bank acronym to IUSCC TB, since IUSCC is a department and as an acronym, doesn't reflect the Tissue Bank. Additionally revised to correct Orschell biobank name/acronym, since the biobank no longer stores any specimens under GLP designation.
- 1.1.58. Appendix G revised to add review of personnel discovered at monthly review to have replaced their key card.
- 1.1.59. Appendix H revised to add directive to attach documentation of actions representing access renewal.
- 1.1.60. Appendix I revised to correct section references, correct erroneous non-critical access approval directives, change footnotes from stars to numbers for improved usability, and add LARC access directives.
- 1.1.61. Appendix J, SSF Controlled Access Levels Chart, added to define controlled access SSF door Access Levels.
- 1.1.62. Appendix K revised to reflect that card reader C156-2, at the door from C158 to C156, is labeled C156-Lab-OUT in dnaFusion on the IUPUI Server.
- 1.1.63. Appendix N, Collaborating Biorepository Personnel Training, added to streamline Collaborating Biorepository personnel training.

## 2. PURPOSE

- 2.1. This Standard Operating Procedure (SOP) defines the procedures used to limit access to the Indiana CTSI Specimen Storage Facility (SSF). This procedure satisfies guidance set forth in ISBER as related to controlled access.

## 3. PRINCIPLE

- 3.1. Access to the Indiana CTSI Specimen Storage Facility (SSF) is restricted by electronic card readers and keys.
  - 3.1.1. Keys are used only in emergencies with usage documented as a deviation.
  - 3.1.2. Critical door keyholes are taped over to enhance detection of forced access attempts.
  - 3.1.3. Areas controlled electronically by cards include the following:
    - 3.1.3.1. Walther Hall Research Building (R3) Locations:
      - 3.1.3.1.1. DNA & Serum Bank (C135)
      - 3.1.3.1.2. Cell Repository (C156)
      - 3.1.3.1.3. DNA/Cell Processing Lab (C158 & C160)



- 3.1.3.1.4. Corridor (C199M) leading into the office suites and break room
- 3.1.3.2. Medical Research / Library Building (IB) and Medical Science Building (MS) Locations:
  - 3.1.3.2.1. SSF Annex I (IB 097/MS-B046 Cage)
  - 3.1.3.2.2. SSF Annex III (MS-B037), accessed via controlled access door MS-B036
  - 3.1.3.2.3. IB Mechanical Freezer Storage Room (IB 097)
  - 3.1.3.2.4. IB exterior doors
  - 3.1.3.2.5. R2/R3 IB tunnel
- 3.1.3.3. The critical SSF areas identified below are keyed separately from the building master and access to these areas is strictly limited to SSF Staff and CBP:
  - 3.1.3.3.1. DNA & Serum Bank (C135)
  - 3.1.3.3.2. Cell Repository (C156)
  - 3.1.3.3.3. SSF Annex I (IB 097/MS-B046 Cage)
  - 3.1.3.3.4. SSF Annex III (MS-B037)
- 3.1.4. SSF Doors are controlled and operated via IU Security Controller 1.123 (R3 doors defined in Step 3.1.3.1) and IU Security Controller 1.124 (IB/MS Freezer Room Doors IB 097/MS-B046 Cage and MS-B036).
- 3.1.5. SSF Doors on Controllers 1.123 and 1.124 are set to “Card Only” mode, programmed to open only with a programmed key card.
  - 3.1.5.1. IU Security personnel have the capability of modifying door hardware mode, however IU Security policy directs them to override “Card Only” mode only in the event of an emergency. Facility access by unauthorized personnel is documented as a deviation per this SOP.
  - 3.1.5.2. dnaFusion is programmed to notify [ictsissf@iupui.edu](mailto:ictsissf@iupui.edu) should SSF door hardware programming change to any mode other than “Card Only”.
  - 3.1.5.3. “Card Only” mode can be overridden with a key, and such access is documented as a deviation per this SOP.
- 3.1.6. Key card access to non-critical doors supporting SSF access to Annexes I & III is programmed by LARC on the LARC door Controller.
  - 3.1.6.1. Related doors are Medical Research / Library Building (IB) and Medical Science Building (MS) Locations:
    - 3.1.6.1.1. IB exterior doors
    - 3.1.6.1.2. R2/R3 IB tunnel
    - 3.1.6.1.3. IB 097
  - 3.1.6.2. Authorize / rescind access or transfer access on replacement key cards for doors listed in Step 3.1.6.1 using the non-SOP-driven LARC request form saved in the Controlled Access folder on the SSF Shared drive.
  - 3.1.6.3. Requests for doors listed in Step 3.1.6.1 are submitted on the LARC Sharepoint site.
- 3.1.7. Permissions are assigned to individuals on Controllers 1.123 and 1.124 by SSF personnel through access control software, dnaFusion, by access level. Access levels are defined in the SSF Controlled Access Levels Chart, Appendix J.
  - 3.1.7.1. SSF personnel obtain read/write or read-only dnaFusion access per directives in the Controlled Access System Description, Appendix A.

- 3.1.7.2. SSF personnel are not to rescind, authorize, or update their own access, assigning the task to alternate SSF personnel.
- 3.1.7.3. IU Security has the capability to program key card access, however IU Security policy directs them to authorize/rescind/transfer key card access only at SSF request.
  - 3.1.7.3.1. Steps throughout this SOP directing SSF personnel to rescind/authorize/transfer/verify key card access may be completed by IU Security Personnel, only at SSF request, and without incurring a deviation should SSF personnel be unable to complete defined tasks due to staffing or training.
  - 3.1.7.3.2. Completion of rescind/authorize/transfer key card access requests executed by IU Security personnel is documented on the Controlled Access Change Form, Appendix B.
  - 3.1.7.3.3. Documentation of verification completed by IU Security is received in writing (email acceptable), referenced on and attached to Appendix B.
- 3.1.8. dnaFusion Service Interruptions
  - 3.1.8.1. All SSF doors fail secure during service interruptions.
  - 3.1.8.2. Door controllers authorize and deny facility access as programmed during service interruptions.
  - 3.1.8.3. Door controllers track all door activity during service interruptions, however activity is not reported to dnaFusion until dnaFusion service is restored.
  - 3.1.8.4. Notification of door alarms occurring during a dnaFusion service interruption will not be received until dnaFusion returns to service. Such alarms will be investigated by SSF personnel per Section 6.10.4 upon receipt of alarm notification and documented as a deviation per SF-1-9 SOP for Deviation Management.
- 3.1.9. Support areas may be either within or outside of the key card controlled access area, and control of access to these rooms is not critical beyond that provided by electronic access control as related to the mission of the SSF; i.e., security and safety of SSF specimens unless otherwise defined in a separate SOP.
  - 3.1.9.1. Support areas managed by key are controlled by IUPUI Police / IU Security according to IUPUI policies.
- 3.1.10. Modifications to personnel names, positions, biobank affiliation, and departments are managed per SF-1-5 SOP for Personnel Training.
- 3.1.11. Deactivation of personnel is documented as described in SF-1-5, and reinstatement of previously deactivated personnel complies with SF-1-5.
- 3.1.12. Personnel accessing the SSF fall primarily into 4 groups defined in the following table:

	SSF Staff	Collaborating Biorepository Personnel (CBP)	Non-CBP Customers	Campus Facility Services personnel
			Untrained CBP	
			Visitors	
			(Excluding SSF Staff & CBP with forgotten/lost badges)	
What training is required?	All SOPs defined for role	Defined # of SOPs which are related to the critical areas being accessed	None required	No documented training
Is badge access granted?	Yes, if trained per this SOP	Yes, with PI permission for each critical access area + training for each area	No	No (emergency key access is managed by SSF deviation)
Is the individual permitted to have unaccompanied access to critical areas?	Yes, if trained per this SOP	Yes, if trained and per directives defined in this SOP	No	Only as required for managing emergencies
Is the individual permitted to supervise the critical area access of other individuals?	Yes, for anyone	Yes, but only for individuals directly related to their respective study and/or freezer(s)	No	Only as required for managing emergencies, with verbal safety instruction provided from SSF or CBP
Is the individual's access recorded on the visitor log?	No, unless unable to enter using badge per this SOP	No, unless unable to enter using badge per this SOP	Yes	Yes

#### 4. SCOPE

- 4.1. This SOP applies to all personnel that require access to the SSF areas as defined above.
- 4.2. A list of Collaborating Biorepositories (CB) is maintained in the SSF. A template for the CB list is provided in Appendix F.
- 4.3. **CBs** are granted access as follows:
  - 4.3.1. All personnel working with these CBs are granted autonomous access into the non-critical areas of the SSF per Section 4.5.
  - 4.3.2. All personnel working with these collaborating biorepositories who have (1) had access authorization requested by the PI or PI Designee and (2) completed training per Sections 6.5 and/or 6.6 are given autonomous access into the applicable critical areas of the SSF.
- 4.4. It is the responsibility of SSF Staff or CBP (as defined below) to assure that untrained personnel:
  - 4.4.1. Are provided with autonomous access into the non-critical areas of the facility (SSF Staff authorize access per Section 4.5 upon notification that personnel are included under the collaborating biorepository organization.)
  - 4.4.2. Are provided with continually monitored access into critical areas of the SSF by SSF Staff or CBP. SSF Staff may provide monitored access for all users, while
    - 4.4.2.1. Untrained personnel *who are involved in the corresponding biorepository's studies* (e.g., student employees, interns, personnel touring the biorepository facilities):



- 4.4.2.1.1. *Monitored access in this case is limited to units containing corresponding biorepository samples.*
- 4.4.2.2. Professional personnel executing preventative maintenance or repairs *for the corresponding biorepository's units or equipment.*
- 4.4.2.3. Personnel from Campus Facility Services *performing services for the corresponding biorepository.*
- 4.4.3. *Access by untrained, non-CBP is managed by SSF staff as follows:*
  - 4.4.3.1. When entering units dedicated solely to the PI's samples, SSF personnel visually monitor that access is limited to units for which access is authorized. This may be accomplished either by direct accompaniment or by monitoring via the viewing windows.
  - 4.4.3.2. When entering units storing samples for multiple PIs, monitoring must be accomplished by direct accompaniment to assure that only the authorized section(s) of the units are accessed.
- 4.4.4. Adhere to all SOPs.
- 4.5. **Access to Non-Critical Areas of the SSF:**
  - 4.5.1. This SOP is not applicable for managing access to the non-critical areas of the SSF, since these areas are not required to be operated as "controlled access" areas.
  - 4.5.2. Access to these areas may be managed by keys (and if so, are keyed with the building master key design) and/or may be managed by granting key card access at the discretion of SSF Management.
  - 4.5.3. Held door and forced door notifications for these areas are not received by SSF Personnel or investigated.
  - 4.5.4. For consistency, the following non-critical access process is recommended but not required.
  - 4.5.5. **Non-critical access is authorized, rescinded, and updated** using a Controlled Access Change Form (Appendix B) to:
    - 4.5.5.1. Rescind Access per Sections 6.3.2.1 and 6.3.4 upon notification from CBP.
    - 4.5.5.2. Update access for Replacement Key Cards per Section 6.3.6.
    - 4.5.5.3. To Authorize Access, upon notification from CBP supervisor (email acceptable), SSF Staff record on Appendix B:
      - 4.5.5.3.1. Employee Name
      - 4.5.5.3.2. Authorize Access for all Key Card #(s) in Section 2, item 1
      - 4.5.5.3.3. Access Key Card number(s)
      - 4.5.5.3.4. Appropriate rooms/levels in Section 3 Non-Critical Doors ONLY Section, recording N/A in the left-hand column for all other rooms/levels.
      - 4.5.5.3.5. Access Expiration Date per this SOP, or record N/A.
      - 4.5.5.3.6. N/A in response to the inquiry regarding whether badge was retained by IU, CB, or SSF personnel, if known, (Yes, No, N/A, Unknown)
    - 4.5.5.4. SSF Staff obtain SSF Management approval of action on Appendix B.
      - 4.5.5.4.1. *SSF Director* approval is not required.
      - 4.5.5.4.2. SSF Director and Management Approval, and CBP Approval or Directive guidelines are summarized in the Access Approval Requirements, Appendix I.

- 4.5.5.5. SSF personnel authorize access in dnaFusion per Section 6.5.2.5.
- 4.5.5.6. An alternate SSF personnel verifies actions per Section 6.3.2.5.

## 5. MATERIALS

- 5.1. Key card reader, obtained from Campus Facilities Services (CFS) and stored in the SSF Management Office

## 6. PROCEDURE (Refer to Appendix A for System Description)

### 6.1. **Maintenance**

#### 6.1.1. Annually

- 6.1.1.1. Confirm that Campus Facilities Services (CFS) personnel have scheduled and completed preventive maintenance (PM) for door mechanisms (clean, lubricate, repair as needed) for all critical access doors to R3-C135, C156, MS-B037, and IB 097/MS-B046 Cage.
  - 6.1.1.1.1. The stationary leaf of the double doors controlled by card reader C156-1 has a compartment for a lower flush bolt. The bolt has been removed to ensure the doors close automatically, and should not be replaced during the annual PM.
- 6.1.1.2. Confirm that CFS personnel have completed PM for magnetic locking mechanism on door R3-C135-3.
  - 6.1.1.2.1. Once work has been completed by CFS personnel, request and obtain email documentation of actions performed by CFS personnel.
  - 6.1.1.2.2. Alternately, SSF personnel authorizing the CFS visitor access and observing CFS personnel completing PM work per this SOP may document work as having been completed in the comments section of the Controlled Access System Annual Monitoring & PM Log (Appendix K).
- 6.1.1.3. If preventive maintenance cannot be completed as required, enter justification in comment section. Notify SSF Management.
- 6.1.1.4. File records, including CFS documentation if applicable, as described in Section 8.

#### 6.1.2. As Needed

- 6.1.2.1. Contact CFS for corrective action on problems with door mechanics.
  - 6.1.2.1.1. If door mechanics problems impair controlled access, post signage indicating that door should not be used, if possible, and document any access facility deviating from this SOP as a deviation per SF-1-9.
- 6.1.2.2. Contact IU Security for issues with key card readers or dnaFusion. If further assistance is required of Presidio, Presidio's involvement will occur at the direction of IU Security.
  - 6.1.2.2.1. If key card reader problems impair controlled access, post signage indicating that door should not be used, if possible, and document any facility access deviating from this SOP as a deviation per SF-1-9.
- 6.1.2.3. Any unresolvable controlled access issue is promptly escalated to IU Security or Presidio for troubleshooting and resolution.
- 6.1.2.4. The SSF maintains one surplus plug-and-play key card reader in the SSF Management Office for quick replacement of a failed key card reader.

- 6.1.2.4.1. Upon replacing a key card reader, order replacement from CFS.
- 6.1.2.4.2. If key card reader failure impairs controlled access, post signage indicating that door should not be used, if possible, and document any facility access deviating from this SOP as a deviation per SF-1-9.
- 6.2. **Access Change Authority:** SSF Director / Management approval requirements are defined throughout this SOP and summarized in Appendix I.
- 6.3. **CB Critical Area Access Request: Authorize/Rescind Access and Key Card Replacements for Authorized CBP** as follows:
  - 6.3.1. **Authorize Access:** PI for the CB requests to have access to SSF Critical areas authorized for designated personnel by completing Sections 1 and 2 of the Collaborating Biorepository Access Authorization Form (Appendix E), indicating whether personnel is a full-time employee (FTE), part-time employee, student, or temporary employee. Multiple boxes may be selected as applicable.
    - 6.3.1.1. SSF Personnel conduct training per Sections 6.5 and/or 6.6 of this SOP, as applicable.
    - 6.3.1.2. Record date training completed on Appendix E.
    - 6.3.1.3. **Annual Renewal Due Dates and Access Expiration** are assigned as follows:
      - 6.3.1.3.1. Full-time (FTE) personnel and Part-Time personnel *not also designated as a Student or Temporary employee* on Appendix E are referred to as “Permanent-CBP” throughout this SOP. Permanent-CBP are assigned an Annual Renewal due date for internal controlled access annual renewal purposes of December 31 of the current calendar year if training is completed prior to June 1; or December 31 of the following calendar year if training is completed after June 1.
        - 6.3.1.3.1.1. Annual Renewal due dates are managed internally by SSF on the non-SOP-driven Controlled Access management spreadsheet (CA spreadsheet) stored on the SSF Shared Drive Controlled Access folder.
        - 6.3.1.3.1.2. A controlled access expiration date is not applicable for Permanent-CBP.
          - 6.3.1.3.1.2.1. Select N/A in the access expiration section on Appendix B.
          - 6.3.1.3.1.2.2. Record N/A in the access expiration section of the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive. Access expiration is managed internally by SSF.
      - 6.3.1.3.2. Personnel designated as Student and/or Temporary on Appendix E (regardless of FTE and Part-Time designation) are referred to as “Temporary-CBP” throughout this SOP. Temporary-CBP are assigned Annual Renewal due dates and Access Expiration dates of one year from the date of training completion.
        - 6.3.1.3.2.1. Annual renewal due dates are managed per Step 6.3.1.3.1.1.

6.3.1.3.2.2. Access expiration is designated on Appendix B and managed internally by SSF personnel on the non-SOP-driven CA spreadsheet and SSF calendar.

6.3.1.4. Record date authorization requested on Appendix E.

6.3.1.5. SSF personnel authorize access per Section 6.5.2 and/or 6.6.2 of this SOP.

6.3.1.6. An alternate SSF personnel verifies actions per Section 6.3.2.5.

6.3.1.7. **Manage Temporary-CBP Annual Renewal Due Dates and Access Expiration Dates** as follows:

6.3.1.7.1. Per Section 6.3.8, SSF personnel will provide CBs monthly a list of Temporary-CBP with Annual Renewal due dates in the next month. The CB will be required to provide a list of those requiring access extension and a requested extension date, or access will be allowed to expire.

6.3.1.7.2. Extension will be permitted only if the CBP are current on training per this SOP.

6.3.1.7.3. Extension may not exceed one year from date of request, however extensions may be granted indefinitely.

6.3.1.7.4. Annual controlled access review procedures, defined in Section 6.12, are applicable to Temporary-CBP personnel.

6.3.1.7.5. The requested access expiration date is extended to the requested date and managed internally per Step 6.3.1.3.1.1.

6.3.1.7.5.1. Both Annual Renewal and Access Expiration will be extended to the same date.

6.3.1.7.6. Should CB respond indicating that personnel are no longer with the CB, proceed per Section 6.3.2.

6.3.1.7.7. **Transition from Temporary-CBP to Permanent-CBP designation:**

6.3.1.7.7.1. Transition from Temporary-CBP to Permanent-CBP designation per this Section will be permitted only if the CBP are current on training per this SOP.

6.3.1.7.7.2. Upon receiving notification in writing (email acceptable) from CB indicating that personnel have been hired as Permanent-CBP, assign an Annual Renewal date for controlled access annual renewal purposes of December 31 of the current calendar year.

6.3.1.7.7.2.1. Annual Renewal due dates are managed per Step 6.3.1.3.1.1.

6.3.1.7.7.2.2. Record N/A in the access expiration section of the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive.

6.3.1.7.7.2.3. Access expiration managed internally by SSF per Steps 6.3.1.3.1.1 and 6.3.1.3.1.2.2.

6.3.1.7.8. **Temporary-CBP Access Expiration:**

6.3.1.7.8.1. If access is allowed to expire per CBP directive OR CBP non-response to Step 6.3.1.7.1 inquiry,

deactivate personnel training records per SOP SF-1-5.

6.3.1.7.8.1.1. Submission of an Appendix E rescind request is not required.

6.3.1.7.8.2. Re-institution of CBP expired access requires compliance with SF-1-5.

6.3.2. **Rescind Access per PI Request Process:** PI for the CB requests to have access to SSF Critical areas rescinded for designated personnel by completing Sections 1 and 3 of Appendix E.

6.3.2.1. Complete a Controlled Access Change Form (Appendix B) to include:

6.3.2.1.1. Employee name

6.3.2.1.2. To Rescind Access to All Rooms, select Rescind All Access (Section 2, item 3)

6.3.2.1.3. To Rescind Partial Access:

6.3.2.1.3.1. Select Update Access (Section 2, item 4)

6.3.2.1.3.2. Select all appropriate access levels in Section 3, recording N/A in the left-hand column for non-applicable rooms/levels.

6.3.2.1.4. "N/A" in the Access Key Card #(s) area of Section 2

6.3.2.1.5. Whether badge was retained by Indiana University, CBP, or SSF personnel at personnel exit, if known, (Yes, No, N/A, Unknown) (Section 2)

6.3.2.2. Obtain SSF *Management* approval of rescind authorization on Appendix B.

6.3.2.2.1. SSF *Director* approval is not required for rescind requests.

6.3.2.2.2. SSF/PI approval guidelines are summarized in Appendix I.

6.3.2.3. SSF personnel rescind access in dnaFusion per Section 6.3.4.

6.3.2.4. An alternate SSF personnel verifies actions per Section 6.3.2.5.

6.3.2.5. **Key Card Programming Verification**

6.3.2.5.1. Upon completion of action defined on Appendix B or notification of request completion, verify action as follows:

6.3.2.5.1.1. SSF personnel with read/write or read only dnaFusion access complete a dnaFusion Patron Search per the dnaFusion manual using name or key card number of personnel listed on Appendix B.

6.3.2.5.1.2. Verify actions defined on Appendix B for personnel defined on Appendix B, documenting initials and date on Appendix B in the "Reviewer Initials/Date" field upon completion.

6.3.2.5.1.3. Tracking of actions is managed internally by SSF on the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive.

6.3.2.5.1.4. An access report for the personnel listed on Appendix B may be printed from dnaFusion to confirm verification and attached to Appendix B, but is not required.

6.3.2.5.1.5. SSF personnel may request that IU Security personnel verify key card programming actions if

needed. Verification is documented on Appendix B by SSF personnel and documentation is attached to Appendix B.

### 6.3.3. **Rescinding Access for Cause Process**

- 6.3.3.1. In the event of:
  - 6.3.3.1.1. Failure of CBP to maintain applicable training
  - 6.3.3.1.2. Failure of CBP to comply with controlled access annual renewal per Section 6.12
  - 6.3.3.1.3. Violation of SSF safety procedures per SSF SOPs
  - 6.3.3.1.4. Violation of IUPUI policies
- 6.3.3.2. SSF Management notifies PI and SSF Director in writing (email acceptable) that access will be rescinded providing reason for action.
- 6.3.3.3. SSF Management Rescinds Access as follows:
  - 6.3.3.3.1. Completes an Appendix B per Section 6.3.2.1.
  - 6.3.3.3.2. SSF Director approval is not required, though notification is required per Step 6.3.3.2.
  - 6.3.3.3.3. SSF/PI approval guidelines are summarized in Appendix I.
  - 6.3.3.3.4. SSF personnel rescind access in dnaFusion per Section 6.3.4.
    - 6.3.3.3.4.1. In situations where there is a perceived risk to the facility based on hostile personnel departures (especially if key cards are retained by the employee) emergency rescind requests are entered in dnaFusion as soon as possible by SSF personnel.
  - 6.3.3.3.5. An alternate SSF personnel verifies actions per Section 6.3.2.5.
- 6.3.3.4. Access reinstatement may be granted and is handled on a case-by-case basis. Training requirements are assessed and documented per SF-1-5.

### 6.3.4. **Rescind Access in dnaFusion Process:**

- 6.3.4.1. SSF personnel with read/write dnaFusion access complete a dnaFusion Patron Search per the dnaFusion manual using name of personnel listed on Appendix B.
  - 6.3.4.1.1. SSF personnel are not permitted to rescind their own key card access. Alternate personnel must complete those actions.
- 6.3.4.2. Rescind access levels per Appendix B and the “Modify Access” section of the dnaFusion manual, documenting completion on Appendix B.
- 6.3.4.3. Tracking of actions is managed internally by SSF on the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive.
- 6.3.4.4. An alternate SSF personnel verifies actions per Section 6.3.2.5.
- 6.3.4.5. SSF personnel may request that IU Security personnel rescind key card programming if needed. Completion is documented on Appendix B by SSF personnel and documentation is attached to Appendix B. Actions are verified by SSF personnel per Section 6.3.2.5.

### 6.3.5. **Access may be Temporarily Rescinded, only as directed in Section 6.3.7.2.6.** Rescind access per Sections 6.3.2.1 and 6.3.4. Temporarily rescinded access is managed internally via the Controlled Access Tracking spreadsheet stored on the SSF Shared drive.

- 6.3.5.1. SSF/PI Approval guidelines are summarized in Appendix I.



### 6.3.6. Key Card Replacement Process:

- 6.3.6.1. Transfer of facility access to a new key card for personnel authorized for facility access typically occurs automatically in dnaFusion.
- 6.3.6.2. While the replaced key card is deactivated by IU Security when the replacement is issued, SSF facility access will remain active on the deactivated card until SSF personnel rescind access. Since the replaced card has been deactivated, it will not authorize SSF facility access.
- 6.3.6.3. The SSF will likely discover that personnel have replaced their key cards in the following manner:
  - 6.3.6.3.1. During the monthly inquiry with collaborating biorepositories per Section 6.3.8, the SSF requests notification that key cards have been replaced. New key card number(s) may be submitted to the SSF by CBP assigned the replacement card or other personnel of the applicable CB. Notification may be provided in writing (email acceptable) or verbally, with SSF personnel recording the new key number from the card itself.
  - 6.3.6.3.2. SSF personnel replacing their key card may notify SSF Management of the new key card number in writing (email acceptable) or verbally, with SSF personnel recording the new key number from the card itself.
  - 6.3.6.3.3. The SSF may learn of key card replacement at monthly review completed per Section 6.3.8 of this SOP and documented on the Access Report Monthly Review Checklist (Appendix G).
- 6.3.6.4. Discovering key card replacement for personnel trained for SSF Freezer Room Access at monthly renewal does not constitute a deviation from this SOP.
- 6.3.6.5. Upon discovery of key card replacement, complete an Appendix B to include:
  - 6.3.6.5.1. Employee name
  - 6.3.6.5.2. Card Replacement Section 2, item 2, Rescind All Access for the employee listed and Authorize Access for the new key card number(s) or confirm access properly transferred to new key card.
  - 6.3.6.5.3. New Access Key Card number(s)
  - 6.3.6.5.4. All appropriate access levels in Section 3, recording N/A in the left-hand column for non-applicable rooms/levels.
  - 6.3.6.5.5. Access Expiration Date per this SOP or record N/A.
  - 6.3.6.5.6. Whether replaced badge was retained by Indiana University, CBP, or SSF personnel, if known, (Yes, No, N/A, Unknown) (Section 2)
- 6.3.6.6. Obtain SSF *Management* approval of access transfer authorization on Appendix B. SSF *Director* approval is not required for access transfer requests. SSF/PI approval guidelines are summarized in Appendix I.
- 6.3.6.7. SSF personnel rescind access on all old key card numbers for personnel listed on Appendix B per Section 6.3.4 of this SOP and ensure access is authorized on key card(s) listed on Appendix B. Authorize access on new key card per Section 6.5.2 and/or 6.6.2 if needed.
- 6.3.6.8. An alternate SSF personnel verifies actions per Section 6.3.2.5.

- 6.3.6.9. SSF personnel may request that IU Security personnel ensure successful key card access transfer per Section 6.3.6.5 and Step 6.3.6.7 directives, if needed. Completion is documented on Appendix B by SSF personnel and documentation is attached to Appendix B. Actions are verified by SSF personnel per Section 6.3.2.5.

**6.3.7. Training Non-Compliance response is defined as follows:**

- 6.3.7.1. If CBP do not maintain training on SOP revisions per SF-1-5, refer to Sections 6.3.3 - 6.3.4.
- 6.3.7.2. Lack of response to training communication from Permanent-CBP out on leave (e.g. maternity leave) or Temporary-CBP will be managed per the following policy:
  - 6.3.7.2.1. Copy supervisor on training communication.
  - 6.3.7.2.2. Determine CBP expected return date.
    - 6.3.7.2.2.1. If both CB supervisor and CBP are non-responsive, rescind access per Sections 6.3.2.1 and 6.3.4.
    - 6.3.7.2.2.2. Determining expected return date from an Out-of-Office response including a return date is acceptable.
  - 6.3.7.2.3. If determined that CBP is currently working for CB and failed to comply with training directives, proceed per Sections 6.3.3 - 6.3.4.
  - 6.3.7.2.4. SSF personnel with at minimum read-only access to dnaFusion extract CBP access data report from dnaFusion to determine the last time CBP accessed an SSF MRU room and/or the LN<sub>2</sub> room, as applicable.
  - 6.3.7.2.5. Calculate the length of time expected to pass before CBP is expected to access the SSF, factoring the expected date of return and the date CBP most recently accessed the SSF.
  - 6.3.7.2.6. SSF action is dependent on length of absence from the SSF and defined as follows:
    - 6.3.7.2.6.1. NOTE: Actions defined in Steps 6.3.7.2.6.2 – 6.3.7.2.6.4 are applicable only to the room for which training is outstanding (e.g. If CBP is not current on SF-1-7 training, then access to both MRU and LN<sub>2</sub> rooms (as applicable) would be temporarily rescinded for that CBP. If SF-2-1 training is not current, only MRU room access would be temporarily rescinded).
    - 6.3.7.2.6.2. Absence of  $\leq 6$  months:
      - 6.3.7.2.6.2.1. Notify CBP, supervisor, and PI that access will be temporarily rescinded and proceed per Sections 6.3.2.1 and 6.3.4.
      - 6.3.7.2.6.2.2. CBP is expected to complete outstanding training upon their return.
      - 6.3.7.2.6.2.3. Upon completion of outstanding training, SSF personnel will reinstate

access per Section 6.5.2 and/or 6.6.2 and adhere to the Annual Renewal and Access Expiration dates assigned in Step 6.3.1.3.

6.3.7.2.6.3. Absence of 6-12 months:

- 6.3.7.2.6.3.1. Notify CBP, supervisor, and PI that access will be temporarily rescinded and proceed per Sections 6.3.2.1 and 6.3.4. Due to the length of absence, rescind LN<sub>2</sub> room access (if applicable) regardless of outstanding training per this section.
- 6.3.7.2.6.3.2. CBP is expected to complete outstanding training upon their return.
- 6.3.7.2.6.3.3. Upon return, CBP is expected to complete LN<sub>2</sub> Room Safety Retraining per Section 6.6.10.
- 6.3.7.2.6.3.4. Upon completion of outstanding training and LN<sub>2</sub> Room Safety Training, SSF personnel will reinstate access per Section 6.5.2 and/or 6.6.2 and adhere to the Annual Renewal and Access Expiration dates assigned in Step 6.3.1.3.

6.3.7.2.6.4. Absence of  $\geq 1$  year:

- 6.3.7.2.6.4.1. Notify CBP, supervisor, and PI that access will be rescinded due to the length of absence.
- 6.3.7.2.6.4.2. Rescind access per Sections 6.3.2.1 and 6.3.4.

6.3.7.2.6.5. Retraining will be required in compliance with SF-1-5 before the CBP's access is re-instated.

- 6.3.7.3. **NOTE:** In the event that completion of CBP training is delayed by several days, it is acceptable if electronic access is not immediately rescinded if the performance of both rescinding and re-activating access cannot reasonably be accomplished in a short duration.
- 6.3.7.4. Access records are reviewed and the review documented to ensure that personnel without documented training did not access the facility. If personnel did access the facility, this is documented as a deviation.
- 6.3.7.5. Training non-compliance response for SSF personnel is defined in Section 6.7.

- 6.3.8. **Monthly Review:** SSF Management emails each CB monthly requesting that they reply with the following requested personnel updates, if not already provided. Actions required by CBP and SSF personnel in order to effect the following changes are defined throughout this SOP and in the table below:

- 6.3.8.1. New personnel requiring facility access
- 6.3.8.2. Personnel with name changes
- 6.3.8.3. Personnel with key card updates
- 6.3.8.4. Personnel no longer working for the CB, for whom facility access requires rescinding
- 6.3.8.5. *CBs with Temporary-CBP*, per Section 6.3.1, are provided with a list of personnel with access expiring in the next month per Section 6.3.1.7, with corresponding actions defined in Section 6.3.1.7.
- 6.3.8.6. *CBs utilizing SF-1-13 Appendices A & B to document freezer access*, are provided with a copy of SF-1-13 Appendix A and asked if any personnel should be added or removed.

Personnel Update	Collaborating Biorepository (CB) Action	SSF Action
New Personnel requiring SSF access	Complete Appendix E to request access, submitting signed form to SSF	Train personnel and request access authorization per Section 6.3.1.
CBP no longer working for Collaborating Biorepository	Complete Appendix E to rescind access, submitting signed form to SSF	Rescind access per Sections 6.3.2 and 6.3.4.
Replacement key card	Provide SSF with new key card number(s) for access update	Request transfer of access to new key card per Section 6.3.6.
Name change	Notify SSF in writing (email acceptable).	Update signature page, SF-1-5 Appendix A, per SOP SF-1-5.
		Follow Section 6.3.6 replacement key card directives if personnel replaces their key card.
Temporary-CBP Access Expiration	Provide a list of CBP requiring access extension and a requested extension date (not to exceed 1 year), or access will be allowed to expire.	Extend access or allow access to expire, depending on CB response.

- 6.3.8.7. Completion is documented on Access Report Monthly Review Checklist (Appendix G) with Initials and Date.

- 6.3.9. Appendix E Access Authorization Requests are filed in the SSF Operations Office with the personnel's SF-1-5 training documentation. Appendix E Rescind Requests are filed in the SSF Operations Office with the personnel's Appendix B (Controlled Access Change Forms) documents.

#### 6.4. Visitor Access Log

- 6.4.1. C156, C135, MS-B037, or IB 097/MS-B046 Cage
  - 6.4.1.1. Complete an entry on the visitor log (Appendix D) for anyone who does not use his/her own electronic access to enter.
    - 6.4.1.1.1. SSF personnel providing visitor facility badge access and/or escort must also verify the visitor's authorization to access their study's samples.

- 6.4.1.1.2. SSF personnel providing access and/or escort and verification as noted in Section 4.4 must print their name and sign their initials in the “Escort” column on the Visitor Log (Appendix D).
- 6.4.1.2. A single log entry for each day of access (when there are multiple times of access on the same date) per room is acceptable.
- 6.5. **Mechanical Refrigeration Unit Rooms (C135, C156, IB 097/MS-B046 Cage, and MS-B037)**
  - 6.5.1. SSF personnel who are signatories on the SOPs listed under Section 6.5.2.1 are considered trained by virtue of authoring or reviewing/approving the policies.
  - 6.5.2. For SSF or CBP who do not meet the requirements defined in Step 6.5.1, SSF Management:
    - 6.5.2.1. Assures that **SSF Personnel** have completed training on the following SOPs and that training is documented per Training Documentation SOP SF-1-5:
      - 6.5.2.1.1. SF-1-7 Personnel Safety
      - 6.5.2.1.2. SF-1-13 Housing Good Laboratory Practice (GLP) Collections
      - 6.5.2.1.3. SF-2-1 Mechanical Refrigeration Units Storage Room Operations
      - 6.5.2.1.4. SF-2-3 Controlled Access
      - 6.5.2.1.5. SF-3-1 Mechanical Refrigeration Units
    - 6.5.2.2. Assures that **CBP** have completed training on the following SOPs and that training is documented per Training Documentation SOP SF-1-5:
      - 6.5.2.2.1. SF-1-7 Personnel Safety
      - 6.5.2.2.2. SF-1-13 Housing Good Laboratory Practice (GLP) Collections (applicable to GLP Collaborating Biorepositories utilizing optional SF-1-13 logs)
      - 6.5.2.2.3. SF-2-1 Mechanical Refrigeration Units Storage Room Operations
      - 6.5.2.2.4. SF-2-3 Controlled Access
    - 6.5.2.3. Completes a Controlled Access Change Form (Appendix B) to include:
      - 6.5.2.3.1. Employee name
      - 6.5.2.3.2. Authorize Access for all Key Card #(s) in Section 2, item 1
      - 6.5.2.3.3. Access Key Card number(s)
      - 6.5.2.3.4. Access level “MRU Rooms ONLY” in Section 3, which includes the related non-critical access doors, for personnel completing training for ONLY Mechanical Refrigeration Unit Rooms.
        - 6.5.2.3.4.1. Access levels are defined in Appendix J.
        - 6.5.2.3.4.2. Authorizing MS-B037 and IB097/MS-B046 Cage access is not required if the applicable CB does not own freezers housed in either facility. If MS-B037 and IB097/MS-B046 Cage access will not be activated, check the box next to “MS LL 036 Annex III & 046 Cage N/A” on Appendix B.
      - 6.5.2.3.5. Access level “MRU & LN<sub>2</sub> Room Access” in Section 3, which includes the related non-critical access doors, for personnel also completing Liquid Nitrogen Freezer Room Training per Section 6.6. Refer to Step 6.5.2.3.4.2 regarding authorizing MS-B037 and

IB097/MS-B046 Cage access for personnel without freezers in those facilities.

- 6.5.2.3.6. Access level “LARC Non-Critical Access” in Section 3 if personnel’s CB has freezers housed in Annex I or III. LARC non-critical access is granted per Section 3.1.6.
- 6.5.2.3.7. Record N/A in the left-hand column for non-applicable rooms/levels.
- 6.5.2.3.8. Access Expiration Date per this SOP, or record N/A
- 6.5.2.3.9. N/A in response to the inquiry regarding whether badge was retained by Indiana University, CBP, or SSF personnel

6.5.2.4. Obtains SSF Director approval of access authorization on Appendix B. SSF/PI approval guidelines are summarized in Appendix I.

**6.5.2.5. Authorize Access in dnaFusion Process:**

- 6.5.2.5.1. SSF personnel with read/write dnaFusion access complete a dnaFusion Patron Search per the dnaFusion manual using name or key card number of personnel listed on Appendix B.
  - 6.5.2.5.1.1. SSF personnel are not permitted to authorize their own key card access. Alternate personnel must complete those actions.
  - 6.5.2.5.1.2. Searching by name requires verification of key card number before authorizing access in order to ensure access is granted to appropriate personnel.
  - 6.5.2.5.1.3. Authorize access on SmartChip numbers only (likely 7-digits in length versus the 6-digit proximity (prox) number), since prox readers are permanently disabled.
- 6.5.2.5.2. Authorize access levels per Appendix B and the “Modify Access” section of the dnaFusion manual, documenting completion on Appendix B.
- 6.5.2.5.3. Tracking of actions is managed internally by SSF on the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive.
- 6.5.2.5.4. An alternate SSF personnel verifies actions per Section 6.3.2.5.
- 6.5.2.5.5. SSF personnel may request that IU Security personnel authorize key card access if needed and per Appendix B key card programming directives. Completion is documented on Appendix B by SSF personnel and documentation is attached to Appendix B. Actions are verified by SSF personnel per Section 6.3.2.5.

6.5.3. In the event of a forgotten card, the affected person may be allowed access by SSF personnel or a member of their biorepository and be given all of the privileges of entry that access by his/her own card would have conferred. This event is recorded on the Visitor Access Log (Appendix D).

6.5.4. In the event of a lost card, the access for that card is revoked by SSF personnel per Sections 6.3.2.1 and 6.3.4. The affected person may be allowed access by SSF personnel or a member of their biorepository and be given all of the privileges of entry that access by his/her own card would have conferred and entry is recorded at least once daily on Appendix D for each room accessed.



- 6.5.4.1. If key card is replaced, access is reauthorized per Section 6.5.2 once replacement key card number is provided to SSF personnel.
- 6.5.5. Access is valid as long as the card holder remains an SSF Staff member and is current on training for requisite SOPs. Refer to Section 6.3 for CB Staff.
- 6.5.6. Authorized access is not applicable to untrained personnel, and entry, oversight and instruction is provided by SSF Staff or CBP per SOP SF-2-1 Mechanical Freezer Storage Room Operations.
- 6.5.7. Key for emergency access is retained in the key lockbox in the SSF Management office and by the SSF Director, and use must be documented as a deviation per SOP SF-1-9. If forced access is deemed necessary:
  - 6.5.7.1. Break glass window.
  - 6.5.7.2. Force entry into room.
  - 6.5.7.3. SSF personnel record the forced entry and manage per SOP SF-1-9.
  - 6.5.7.4. Forced entry records are managed per Section 6.10 of this SOP.
- 6.5.8. CB staff who are trained per above and granted authorization are limited to the following functions:
  - 6.5.8.1. Personal access in the event of a building emergency.
  - 6.5.8.2. Providing instruction to additional untrained personnel applicable to the emergency situation regarding safety and security practices per the applicable SOP (SOP SF-2-1 Mechanical Freezer Storage Room Operations).
  - 6.5.8.3. Additional personnel entering must have an entry completed in the Visitor Access Log (Appendix D) per Section 6.4.
- 6.6. **Liquid Nitrogen Freezer Room (C156)**
  - 6.6.1. SSF personnel who are signatories on the SOPs listed under Section 6.6.2.1 are considered trained by virtue of authoring or reviewing/approving the policies.
  - 6.6.2. For SSF or CBP who do not meet the requirements defined in Step 6.6.1, SSF Management:
    - 6.6.2.1. Assures that **SSF personnel** have completed training on the following SOPs and that training is documented per Training Documentation SOP SF-1-5:
      - 6.6.2.1.1. SF-1-7 Personnel Safety
      - 6.6.2.1.2. SF-1-13 Housing Good Laboratory Practice (GLP) Collections
      - 6.6.2.1.3. SF-2-2 LN<sub>2</sub> System and LN<sub>2</sub> Freezer Room Operations
      - 6.6.2.1.4. SF-2-3 Controlled Access
      - 6.6.2.1.5. SF-3-2 LN<sub>2</sub> Freezers
      - 6.6.2.1.6. SF-3-9 Emergency Escape Breathing Apparatus
      - 6.6.2.1.7. SF-3-15 Dräger Pac 5500 Personal O<sub>2</sub> Monitor
      - 6.6.2.1.8. SF-3-16 -80°C LN<sub>2</sub> Freezers (applicable to Collaborating Biorepositories owning -80°C LN<sub>2</sub> Freezer Units)
    - 6.6.2.2. Assures that **CBP** have completed training on the following SOPs and that training is documented per Training Documentation SOP SF-1-5:
      - 6.6.2.2.1. SF-1-7 Personnel Safety
      - 6.6.2.2.2. SF-1-13 Housing Good Laboratory Practice (GLP) Collections (applicable to GLP Collaborating Biorepositories utilizing optional SF-1-13 logs)

- 6.6.2.2.3. SF-2-2 LN<sub>2</sub> System and LN<sub>2</sub> Freezer Room Operations
- 6.6.2.2.4. SF-2-3 Controlled Access
- 6.6.2.2.5. SF-3-9 Emergency Escape Breathing Apparatus
- 6.6.2.2.6. SF-3-15 Dräger Pac 5500 Personal O<sub>2</sub> Monitor

6.6.2.3. Completes an Appendix B to include:

- 6.6.2.3.1. Employee name
- 6.6.2.3.2. Authorize Access for all Key Card #(s) in Section 2, item 1
- 6.6.2.3.3. Access Key Card number(s)
- 6.6.2.3.4. Access level “LN<sub>2</sub> Room ONLY” in Section 3, which includes the related non-critical access doors, for personnel completing training for ONLY the Liquid Nitrogen Freezer Room.
  - 6.6.2.3.4.1. Access levels are defined in Appendix J.
- 6.6.2.3.5. Access level “All MRU & LN<sub>2</sub> Room Access” in Section 3, which includes the related non-critical access doors, for personnel also completing Mechanical Refrigeration Unit Room Training per Section 6.5.
- 6.6.2.3.6. Access level “LARC Non-Critical Access” in Section 3 if personnel’s CB has freezers housed in Annex I or III. LARC non-critical access is granted per Section 3.1.6.
- 6.6.2.3.7. Record N/A in the left-hand column for non-applicable rooms/levels
- 6.6.2.3.8. Access Expiration Date per this SOP, or record N/A
- 6.6.2.3.9. N/A in response to the inquiry regarding whether badge was retained by Indiana University, CBP, or SSF personnel

6.6.2.4. Obtains SSF Director approval of access authorization on Appendix B. SSF/PI approval guidelines are summarized in Appendix I.

6.6.2.5. Authorize Access in dnaFusion per Section 6.5.2.5.

- 6.6.3. In the event of a forgotten card, the affected person may be allowed access by SSF personnel or a member of their biorepository and be given all of the privileges of entry that access by his/her own card would have conferred.
- 6.6.4. In the event of a lost card, the access for that card is revoked per Sections 6.3.2.1 and 6.3.4. The affected person may be allowed access by SSF personnel or a member of their biorepository and be given all of the privileges of entry that access by his/her own card would have conferred and entry is recorded at least once daily on the Visitor Access Log (Appendix D).
  - 6.6.4.1. If key card is replaced, access is reauthorized per Section 6.6.2 once replacement key card number is provided to SSF personnel.
- 6.6.5. Access is valid as long as the card holder remains an SSF Staff member and is current on training for requisite SOPs. Refer to Section 6.3 for Collaborating Staff.
- 6.6.6. Authorized access is not applicable to untrained personnel and entry oversight and instruction is as provided by SSF Staff or CBP per SOP SF-2-2 LN<sub>2</sub> System and LN<sub>2</sub> Freezer Room Operations.
- 6.6.7. Key for emergency access is retained in the key lockbox in the SSF Management office and by the SSF Director, and use must be documented as a deviation per SOP SF-1-9.
- 6.6.8. If forced access is deemed necessary:
  - 6.6.8.1. Break glass window.

- 6.6.8.2. Force entry into room.
- 6.6.8.3. SSF personnel record the forced entry and manage per SOP SF-1-9.
- 6.6.8.4. Forced entry records are managed per Section 6.10 of this SOP.
- 6.6.9. CB staff who are trained per above and granted authorization are limited to the following functions:
  - 6.6.9.1. Personal access in the event of a building emergency.
  - 6.6.9.2. Providing instruction to additional untrained personnel applicable to the emergency situation regarding safety and security practices per the applicable SOP (SOP SF-2-2 LN<sub>2</sub> System and LN<sub>2</sub> Freezer Room Operations).
  - 6.6.9.3. Additional personnel entering must have an entry completed in Appendix D per Section 6.4.
- 6.6.10. **LN<sub>2</sub> Room Safety Retraining After Defined Absence:**
  - 6.6.10.1. Safety Retraining, as directed for CBP per Step 6.3.7.2.6, includes the following SOPs and procedures:
    - 6.6.10.1.1. SF-1-7 Personnel Safety
    - 6.6.10.1.2. SF-2-2 LN<sub>2</sub> System and LN<sub>2</sub> Freezer Room Operations – Alarm Response Procedures
    - 6.6.10.1.3. SF-3-9 Emergency Escape Breathing Apparatus
    - 6.6.10.1.4. SF-3-15 Dräger Pac 5500 Personal O<sub>2</sub> Monitor
  - 6.6.10.2. Retraining is documented via the SSF Training Plan (SF-1-5 Appendix B), SSF Read and Understand Training Form (SF-1-5, Appendix C), SSF Technical Training Form (as applicable, SF-1-5, Appendix D), and SSF Seminar Training Form (SF-1-5, Appendix E) per SF-1-5, SOP for Personnel Training.
- 6.7. Procedure for **Authorizing and Rescinding Access and Managing Key Card Replacements for SSF Staff.** (CBP Access policies are defined in Section 6.3.)
  - 6.7.1. **Authorize Access:** Complete training per Sections 6.5 and/or 6.6 of this SOP, as applicable.
  - 6.7.2. **Annual Renewal Due Dates and Access Expiration** are assigned as follows:
    - 6.7.2.1. Annual Renewal due date for internal controlled access annual renewal purposes of December 31 of the current calendar year if training is completed prior to June 1; or December 31 of the following calendar year if training is completed after June 1.
      - 6.7.2.1.1. Annual Renewal due dates are managed internally by SSF on the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive.
      - 6.7.2.1.2. Controlled access expiration dates are not assigned to SSF personnel.
        - 6.7.2.1.2.1. Select N/A in the access expiration section on Appendix B.
        - 6.7.2.1.2.2. Record N/A in the access expiration section of the non-SOP-driven CA spreadsheet stored on the SSF Shared Drive. Access expiration managed internally by SSF.
  - 6.7.3. **Rescinding Access** - In the event of:
    - 6.7.3.1. Employee termination,
    - 6.7.3.2. Failure of employee to maintain applicable training,

- 6.7.3.3. Failure of employee to comply with SSF safety procedures per SSF SOP procedures,
- 6.7.3.4. Failure of employee to comply with controlled access annual renewal procedures per Section 6.12, or
- 6.7.3.5. Employee violation of IUPUI policies,
- 6.7.3.6. SSF Management Rescinds Access as follows:
  - 6.7.3.6.1. Completes an Appendix B per Section 6.3.2.1.
  - 6.7.3.6.2. SSF Director approval not required
  - 6.7.3.6.3. SSF Director written notification (email acceptable) required for rescension of critical access.
  - 6.7.3.6.4. SSF Director notification not required when rescinding only non-critical access.
  - 6.7.3.6.5. SSF/PI approval guidelines are summarized in Appendix I.
  - 6.7.3.6.6. SSF personnel completes Appendix B.
  - 6.7.3.6.7. SSF personnel other than the personnel for whom access is to be rescinded, rescinds access per Section 6.3.4.
  - 6.7.3.6.8. An alternate SSF personnel verifies completion of rescind actions per Section 6.3.2.5.
- 6.7.3.7. **Key Card Replacement:** Transfer of facility access to a new key card for personnel authorized for facility access occurs automatically in dnaFusion.
  - 6.7.3.7.1. While the replaced key card is deactivated by IU Security when the replacement is issued, SSF facility access will remain active on the deactivated card until SSF personnel rescind access. Since the replaced card has been deactivated, it will not authorize SSF facility access.
  - 6.7.3.7.2. Complete an Appendix B per Section 6.3.6.5.
  - 6.7.3.7.3. Obtain SSF Management approval of access transfer authorization on Appendix B. SSF Director approval is not required for access transfer requests.
  - 6.7.3.7.4. SSF/PI approval guidelines are summarized in Appendix I.
  - 6.7.3.7.5. SSF personnel other than the personnel for whom access is to be transferred, transfers key card access to replacement card and verifies completion per Steps 6.3.6.7-6.3.6.9.

## 6.8. **Responding to requests for access by personnel without authorized access**

### 6.8.1. Pre-Scheduled Access

- 6.8.1.1. Request is received and reviewed by SSF personnel to determine:
  - 6.8.1.1.1. Room(s) and freezer(s) to be accessed
  - 6.8.1.1.2. Date and time access is requested
  - 6.8.1.1.3. Individual requesting access
  - 6.8.1.1.4. Anticipated duration in the accessed area
- 6.8.1.2. SSF personnel verify the request against the Storage Agreement (SF-1-4, Appendix D) for the specified freezer(s) to ensure that the requestor is an approved user.
  - 6.8.1.2.1. SSF personnel evaluate the request and notify the requestor of the approval or denial.
  - 6.8.1.2.2. If the request is denied, an explanation is provided to the requestor.

- 6.8.1.3. Post the time frame and relevant information on the shared calendar.
- 6.8.1.4. Meet the requestor at the scheduled time and location to permit access.
- 6.8.1.5. Complete visitor access log per Section 6.4.
- 6.8.1.6. Monitor that the requestor accesses only the areas that s/he has authorization to access.

6.8.2. Non-Scheduled Access

- 6.8.2.1. Requestor requests access.
- 6.8.2.2. SSF personnel verify the request against the Storage Agreement (SF-1-4, Appendix D) for the specified freezer(s) to ensure that the requestor is an approved user.
- 6.8.2.3. If the access request is denied, explain the reason for denial.
- 6.8.2.4. If access is approved, permit access to the requestor if SSF personnel are available to provide the required monitored access.
- 6.8.2.5. Complete visitor access log per Section 6.4.
- 6.8.2.6. Monitor that the requestor accesses only the areas that s/he has authorization to access.
- 6.8.2.7. If SSF personnel are unable to accommodate the non-scheduled request, instruct the requestor to initiate a request as described in Step 6.8.1.

- 6.8.3. Access for personnel in CB groups who do not have access authorization may be provided by SSF staff or by staff from a CB.

6.9. **Door Control**

- 6.9.1. At all times, doors allow free egress.
- 6.9.2. In case of a system failure, electronic locks in R3 and Annex sections of the SSF enter a “fail secure” mode.
- 6.9.3. Doors to critical access areas are not to be propped open.
- 6.9.4. All SSF & CBP, trained per this SOP, entering a critical facility must scan their key card for access.
  - 6.9.4.1. When multiple personnel enter together (i.e.: when the door has been opened initially by one person and held open for the rest of the party), each individual with key card access must scan their badge before entering the facility.
  - 6.9.4.2. Personnel are prohibited from using a key card assigned to other trained personnel to enter SSF critical areas.
  - 6.9.4.3. Violations may result in access recension.
  - 6.9.4.4. Refer to Steps 6.5.3 and 6.5.4 (mechanical rooms) or 6.6.3 and 6.6.4 (liquid nitrogen freezer room) if providing access to SSF & CBP, trained per this SOP, who’ve forgotten or lost their key card.

6.10. **Event Reporting**

- 6.10.1. Reports for access authorization and records of entry are available in electronic format when extracted from dnaFusion by personnel with read/write or read-only dnaFusion access or requested from IU Security. The reports are printed as needed and/or reviewed electronically.
- 6.10.2. Forced Door/Door Held alarm events (all doors except MS-B037 Emergency Exit Only Doors MS-B037-1 and MS-B037-2) are e-mailed to SSF Personnel via [ictsissf@iupui.edu](mailto:ictsissf@iupui.edu) at the time of occurrence.
- 6.10.3. Point Active events (door opened) and Point Inactive events (door closed) occur only when “Emergency Exit Only” Doors MS-B037-1 and MS-B037-2 are opened/closed.

6.10.3.1. Point Active notifications are e-mailed to SSF Personnel via [ictsissf@iupui.edu](mailto:ictsissf@iupui.edu) at the time of occurrence. All Point Active notifications are investigated per Section 6.10.4.

6.10.3.2. Point Inactive notifications are received via [ictsissf@iupui.edu](mailto:ictsissf@iupui.edu) SSF email for informational purposes only. Investigation of Point Inactive notifications is not required.

**6.10.4. Occurrences and Investigation of Door Held/Forced Door and Point Active events** are investigated as soon as possible to ensure that no breaches to the facility have occurred and as follows:

6.10.4.1. Door Alarm Events Occurring During SSF Business Hours:

6.10.4.1.1. Visit door generating alarm as soon as possible, investigating occurrence per the Door Held/Forced Door/Point Active Event Log (Appendix L).

6.10.4.1.2. The alarm event occurrence and subsequent investigation must be documented on Appendix L.

6.10.4.1.3. Any findings of the event investigation must be documented on the same business day, either by email to SSF personnel or documenting on Appendix L.

6.10.4.1.4. Initiate deviation process per SOP SF-1-9, if applicable.

6.10.4.2. Door Alarm Events Occurring Outside SSF Business Hours:

6.10.4.2.1. Investigation of notifications occurring outside SSF business hours must start as soon as possible, but initiation may not exceed 2 hours post-notification.

6.10.4.2.2. Contact CBP known to be accessing the facility per the non-SOP driven CTSI Phone Number List, if applicable.

6.10.4.2.3. Determine if CBP generated alarm on door in question.

6.10.4.2.4. *If CBP generated alarm*, email findings to SSF personnel.

6.10.4.2.5. Document the alarm event occurrence and any findings of the event investigation on Appendix L the next business day.

6.10.4.2.6. *If CBP DID NOT generate alarm, cause could not be determined, or CBP are not known to be accessing the facility*, call IUPUI Public Safety Dispatch Center to investigate.

6.10.4.2.7. Email findings to SSF personnel.

6.10.4.2.8. The alarm event occurrence and subsequent investigation must be documented on Appendix L.

6.10.4.2.9. Any findings of the event investigation must be documented on the next business day, either by email to SSF personnel or documenting on Appendix L.

6.10.4.2.10. Initiate deviation process per SOP SF-1-9, if applicable.

6.10.4.3. Appendix L review requires reconciling email notifications of alarm events, alarm events reported during Appendix G review (refer to Section 6.11.3), and alarm events investigated and documented on Appendix L.

6.10.4.3.1. Due to a lag between dnaFusion logging alarm events and sending notifications via email, the time documented on App L may differ from the dnaFusion timestamp. (E.g., dnaFusion will log 10:28:53 AM while 10:29 AM is documented on App L)

6.10.4.4. Appendix L is attached to Appendix G monthly.



- 6.10.4.5. See Door Event Investigation Plan (Appendix M) for steps involved in investigating door held/forced or point active events.
- 6.10.4.6. Door Held, Forced Door, and Point Active events that are found to include unauthorized access are deviations of this SOP and are documented per SOP SF-1-9.
- 6.10.4.7. Any known unauthorized access event is investigated as soon as possible as a possible system failure and documented as a deviation of this SOP per SF-1-9.

#### **6.11. Reviewing Access Records – Monthly**

- 6.11.1. Minimally every month, SSF Management reviews the access authorization report (for C-135, C-156, IB 097/MS-B046 Cage, and MS-B037) and reviews that access authorization is appropriate (reports received following access change requests are also used to satisfy this requirement). Reports may be reviewed electronically or in printed format.
  - 6.11.1.1. The access authorization report is extracted from dnaFusion by SSF personnel or may be requested from IU Security personnel if necessary.
    - 6.11.1.1.1. Data extracted from dnaFusion or requested from IU Security must include all raw event data for all SSF critical doors for the applicable month.
  - 6.11.1.2. If Appendix L has not yet been reviewed and approved, reconcile door alarm investigation per Step 6.10.4.3 at this time.
  - 6.11.1.3. The date data is downloaded or received is recorded on Appendix G in the “Raw Data Download / Receipt Date” field.
  - 6.11.1.4. The raw data is saved on the SSF Shared Drive Controlled Access folder with a title such as July 2018 Controlled Access Raw Data.
- 6.11.2. Record the following dates on Appendix G:
  - 6.11.2.1. Date / Time Range of the reporting
  - 6.11.2.2. Raw Data Download / Receipt Date per Step 6.11.1.3.
  - 6.11.2.3. Data Manipulation Date per Step 6.11.3.
  - 6.11.2.4. Review is initiated after data is manipulated per Step 6.11.3, and the Review Initiated Date is recorded on Appendix G.
- 6.11.3. Raw data is manipulated / sorted to enhance review of the following access/events per Appendix G:
  - 6.11.3.1. Access was granted only to personnel who were authorized to access the location during the time period covered.
  - 6.11.3.2. Access was not denied to any personnel who were authorized to access the location during the time period covered.
  - 6.11.3.3. Key Card Numbers are appropriate for respective personnel for the time period covered.
  - 6.11.3.4. Replaced key cards
  - 6.11.3.5. Forced entry events
  - 6.11.3.6. Point active events
  - 6.11.3.7. Door held events
- 6.11.4. Manipulated Data
  - 6.11.4.1. The manipulated data is saved in the SSF Shared Drive Controlled Access folder with a title such as July 2018 Controlled Access All Doors Manipulated Data.

- 6.11.4.2. In preparation for Controlled Access Annual Review, per Section 6.12, the manipulated data is sorted for “Name”, and all personnel access data for all rooms referred to in Step 6.11.1 is copied to an annual review file with a title such as “All Rooms – October 2018 – September 2019” saved in the SSF Shared Drive Controlled Access folder.
- 6.11.5. Review manipulated data per Appendix G Steps 1.1 – 1.4. Record initials and date on Appendix G upon completion.
- 6.11.6. A monthly review of Forced Entries, Held Door, and Point Active events for critical access areas is performed via a log obtained from the Controlled Access System (dnaFusion) and documented in Appendix G.
  - 6.11.6.1. Compile into one report from the manipulated data file, using Microsoft Excel’s Filter or Sort feature.
  - 6.11.6.2. The report is titled, printed, and attached to Appendix G.
  - 6.11.6.3. Evaluate data per Appendix G, Steps 2-4, and initial and date on Appendix G upon completion.
  - 6.11.6.4. Forced entry records that correspond to known forced entries are managed as a deviation per SOP SF-1-9.
  - 6.11.6.5. Any event corresponding to known unauthorized access is managed as a deviation per SOP SF-1-9.
- 6.11.7. Access for any replacement key cards discovered during the monthly review is updated per Section 6.3.6.5. Initial and date on Appendix G upon completion.
- 6.11.8. Complete the remaining sections of Appendix G.
- 6.11.9. Attach the Events report reviewed in Step 6.11.5 and Appendix L.
- 6.11.10. Initial and Date completion in the “Reviewer Initials / Date” field.
- 6.11.11. Submit to SSF Management for review.
- 6.11.12. Discrepancies are reported to the SSF Director and managed per SOP SF-1-9.
- 6.12. Reviewing Access Records – Annually**
  - 6.12.1. Annually in October of each year the SSF will review access records for the critical access doors (C-135 1, 2 and 3, IB 097/MS-B046 Cage, MS-B036 and C-156 1 and 2), and results are documented on Appendix H.
    - 6.12.1.1. NOTE: Review is initiated as early as possible in October, regardless of prior year completion date.
    - 6.12.1.2. NOTE: Room MS-B037 is accessed via one critical access door, MS-B036. Doors MS-B037-1 and MS-B037-2 are emergency exit access only and will alarm per Section 6.10.3 when opened.
    - 6.12.1.3. The access authorization report may be found in the SSF Shared Drive Controlled Access folder per Step 6.11.4.2, must be created per Step 6.11.4.2, or may be obtained from IU Security personnel if necessary. The report should contain, at minimum, all personnel access for all doors listed in Step 6.12.1 for November of the previous year through September of the current year.
    - 6.12.1.4. Review training records to confirm that all personnel authorized to access critical access doors are current on applicable training referenced in Steps 6.5.2.2 (mechanical refrigeration rooms) and 6.6.2.2 (liquid nitrogen freezer room).
      - 6.12.1.4.1. Those not current on training must complete retraining or their critical access will be rescinded per Sections 6.3.3 - 6.3.4.

- 6.12.1.5. Access Authorization Report Review:
  - 6.12.1.5.1. Access the access authorization file described in Step 6.12.1.3.
  - 6.12.1.5.2. Confirm that all doors listed in Step 6.12.1 are represented.
  - 6.12.1.5.3. Confirm that the time frame November of the previous year through September of the current year is represented.
  - 6.12.1.5.4. Save a copy of the file in the SSF Shared Drive Controlled Access\Annual folder.
  - 6.12.1.5.5. Document date of completion on Appendix H in the “File Verified Date” field.
  - 6.12.1.5.6. Document Date/Time Range of the reporting on Appendix H.
- 6.12.1.6. Data Manipulation:
  - 6.12.1.6.1. Using the file saved in the Controlled Access\Annual folder, manipulate data in order to confirm that each personnel has accessed doors per their access level and Sections 6.12.1.7 and 6.12.1.8.
  - 6.12.1.6.2. Document date of completion on Appendix H in the Data Manipulation Date field.
- 6.12.1.7. Access for C-135, IB 097/MS-B046 Cage, MS-B037
  - 6.12.1.7.1. Personnel who have accessed minimally 1 door into C-135, IB 097/MS-B046 Cage, or MS-B037 since October of the previous year and are current on their training per Section 6.5 of this SOP are considered qualified for continued access into C-135, IB 097/MS-B046 Cage, and MS-B037 through December of the following calendar year.
  - 6.12.1.7.2. For personnel who have NOT accessed minimally 1 door into C-135, IB 097/MS-B046 Cage, or MS-B037 since October of the previous year, check training records to determine when the initial training to obtain access (per Section 6.5 this SOP) was performed. If the initial required training was performed after October of the previous year, personnel are considered qualified for continued access into C-135, IB 097/MS-B046 Cage, and MS-B037 through December of the following calendar year, provided that any additional training requirements are met.
  - 6.12.1.7.3. For personnel who have not accessed or have not been trained as above, contact the applicable CB Representative or SSF Management and arrange for the employee to either access C-135, IB 097/MS-B046 Cage, or MS-B037 using the appropriate process OR complete retraining. Once successfully completed, authorize for access through December of the following calendar year.
    - 6.12.1.7.3.1. Personnel will have at least 3 weeks to comply and will be notified of the annual renewal requirement at least 3 times.
    - 6.12.1.7.3.2. Time limit for compliance and results of non-compliance will be provided at notification, with applicable PI, Biorepository Manager or other

- personnel designated by the PI, or SSF Management copied.
- 6.12.1.7.3.3. CBP failing to comply will have facility access rescinded per Sections 6.3.3 - 6.3.4. See related Section 6.12.1.9.
- 6.12.1.7.3.4. SSF personnel failing to comply will have facility access rescinded per Section 6.7.
- 6.12.1.7.3.5. PI written notification of CBP access recension required (email acceptable).
- 6.12.1.7.3.6. SSF Director notification of SSF personnel access recension required (email acceptable).
- 6.12.1.7.3.7. Appendix E not required when access rescind results from annual controlled access review of records.
- 6.12.1.7.4. Access authorization dates are documented / tracked using the Controlled Access tracking spreadsheet.
- 6.12.1.8. Access for C-156
  - 6.12.1.8.1. Personnel who have accessed minimally 1 door into C-156 and are current on their training per Section 6.6 of this SOP are considered qualified for continued access into C-156 through December of the following calendar year.
  - 6.12.1.8.2. For personnel who have NOT accessed minimally 1 door into C-156 since October of the previous year, check training records to determine when the initial training to obtain access (per Section 6.6 this SOP) was performed. If the initial required training was performed after October of the previous year, personnel are considered qualified for continued access into C-156 through December of the following calendar year, provided that any additional training requirements are met.
  - 6.12.1.8.3. For personnel who have not accessed or have not been trained as above, contact the applicable CB Representative or SSF Management and arrange for the employee to either access C-156 using the appropriate process or complete retraining and, once successfully completed, authorize for access through December of the following calendar year.
    - 6.12.1.8.3.1. Personnel will have at least 3 weeks to comply and will be notified of the annual renewal requirement at least 3 times.
    - 6.12.1.8.3.2. Time limit for compliance and results of non-compliance will be provided at notification, with applicable PI, Biorepository Manager or other personnel designated by the PI, or SSF Management copied.
    - 6.12.1.8.3.3. CBP failing to comply will have facility access rescinded per Sections 6.3.3 - 6.3.4. See related Section 6.12.1.9.
    - 6.12.1.8.3.4. SSF personnel failing to comply will have facility access rescinded per Section 6.7.

- 6.12.1.8.3.5. PI written notification of access rescension required (email acceptable).
- 6.12.1.8.3.6. SSF Director notification of SSF personnel access rescension required (email acceptable).
- 6.12.1.8.3.7. Appendix E not required when access rescind results from annual controlled access review of records.

6.12.1.8.4. Access authorization dates are documented / tracked using the Controlled Access tracking spreadsheet.

6.12.1.9. Manage notification from CB Representative that Temporary-CBP is not currently working with the CB OR Permanent-CBP is on leave per the following policy:

6.12.1.9.1. Personnel unavailable to comply per 6.12.1.7 - 6.12.1.8, as applicable, will have access rescinded per Sections 6.3.3 - 6.3.4 for safety concerns. Retraining will be required, per Sections 6.5 and/or 6.6 should personnel require access upon returning.

6.12.1.10. Should CBP no longer require access to critical areas, they may choose to forgo retraining and allow access to be rescinded (Proceed per Section 6.3.2).

6.12.1.10.1. PI written notification and approval required (email acceptable).

6.12.1.10.2. Appendix E not required when request to rescind access results from annual controlled access review of records.

6.12.1.11. Complete the remaining sections of Appendix H.

6.12.1.12. Attach documentation of actions representing access renewal to Appendix H.

6.12.1.13. Initial and Date completion in the "Reviewer Initials / Date" field.

6.12.1.14. Submit to SSF Management for review.

### 6.13. Annual CBP Recertification Training Requirement

6.13.1. Annually CBP Recertification Training is conducted per SOP SF-1-5.

6.13.2. Best practice would be conducting retraining in October, in conjunction with Annual Access Review per Section 6.12.

6.13.3. CBP failing to comply will have facility access rescinded per Sections 6.3.3 – 6.3.4.

6.13.4. Training is documented per SF-1-5.

## 7. REFERENCES

7.1. **Contact Information:** Refer to Appendix C for contacts referenced in this SOP.

7.2. ISBER Best Practices (current version)

7.3. Indiana University DNA Fusion User Manual (current version)

7.3.1. Hard copy saved in the Controlled Access binder

7.3.2. Digital version stored in the Controlled Access folder on the SSF Shared drive

7.4. LARC Sharepoint site <https://indiana.sharepoint.com/sites/IUSM-LARC/Security/SiteAssets/Security%20Access%20Request%20Form.aspx>

## 8. DOCUMENTATION

8.1. Documents are retained in the SSF Operations office per the SOP for Controlled Document Management (SF-1-6).

8.2. Deviations are managed per SOP for Deviation Management (SF-1-9).

## 9. APPENDICES

9.1. The current version of the following appendices should be used to implement this SOP:

- Appendix A: Controlled Access System Description (1 Page)
- Appendix B: Controlled Access Change Form (1 Page)
- Appendix C: Controlled Access Contact Information (1 Page)
- Appendix D: Controlled Access Visitor Log (1 Page)
- Appendix E: Collaborating Biorepository Staff Request Form (1 Page)
- Appendix F: Collaborating Biorepository List (Template) (1 Page)
- Appendix G: Access Report Monthly Review Checklist (1 Page)
- Appendix H: Access Report Annual Review Checklist (1 Page)
- Appendix I: Access Approval Requirements (1 Page)
- Appendix J: SSF Controlled Access Levels Chart (1 Page)
- Appendix K: Controlled Access System Annual Monitoring & PM Log (1 Page)
- Appendix L: Door Held / Forced Door / Point Active Event Log (1 Page)
- Appendix M: Door Event Investigation Plan (1 Page)
- Appendix N: Collaborating Biorepository Personnel Training (3 Pages)

## 10. COLLABORATING BIOREPOSITORY PERSONNEL (CBP) TRAINING

- 10.1. CBP comply with Read and Understand training on SOP SF-2-3, SOP for Controlled Access Operations, by continuing to and reading **Collaborating Biorepository Personnel Training, Appendix N, of this SOP.**
- 10.2. CBP comply with directives defined in Appendix N.

**Controlled Access System Description**

1. Access is controlled via electronic card readers connected to magnetically locked doors. The system is managed by remote access control software, dnaFusion, operated by the SSF. dnaFusion is housed on IU Security's server.
  - 1.1. The SSF Director, SSF Facility Manager, and SSF QA Specialist (at minimum) are authorized for read/write access to key card programming and event viewing on SSF door Controllers 1.123 (R3) and 1.124 (MS).
  - 1.2. SSF technicians are authorized for read only access to key card programming and event viewing on Controllers 1.123 and 1.124.
  - 1.3. dnaFusion read/write and read only access are authorized by the SSF Director and implemented by IU Security.
  - 1.4. dnaFusion training is managed by SSF personnel or IU Security.
2. The access control management software maintains user lists and transaction reports to provide historical record of entries for each card holder at each card reader.
3. Access privileges for the SSF areas are assigned and/or modified by SSF Management directive.

## SSF CONTROLLED ACCESS CHANGE FORM

<b>Section 1</b>			
Employee Name			
<b>Section 2</b>		<b>Requested</b>	<b>Completed</b>
Action	1. Authorize Access for all Key Card #(s)	<input type="checkbox"/>	<input type="checkbox"/>
	2. Card Replacement:		
	a. <i>Rescind <b>All Access</b> under current active card numbers</i>	<input type="checkbox"/>	<input type="checkbox"/>
	b. <i>Authorize Access for new Key Card #(s) or confirm access properly transferred to new key card</i>	<input type="checkbox"/>	<input type="checkbox"/>
	3. Rescind <i>All Access</i> *	<input type="checkbox"/>	<input type="checkbox"/>
	4. Update Access		
	a. <i>Rescind <b>All Access</b> under current active card numbers</i> b. <i>Authorize Access for new Key Card #(s)</i>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Access Key Card #(s)		<input type="checkbox"/> N/A (Rescind Access)	
Key Card Retained by IU, CB, or SSF personnel at Exit?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Unknown	
<b>Section 3</b>		<b>Requested</b>	<b>Completed</b>
<b>MRU &amp; LN<sub>2</sub> Room Access</b> <input type="checkbox"/> N/A	Walther Hall – All SSF R3 Doors	<input type="checkbox"/>	<input type="checkbox"/>
	MS LL 036 Annex III & 046 Cage	<input type="checkbox"/>	<input type="checkbox"/>
	MS LL 036 Annex III & 046 Cage   N/A <input type="checkbox"/>		
<b>MRU Rooms ONLY</b> <input type="checkbox"/> N/A	Walther Hall Room C135 Access	<input type="checkbox"/>	<input type="checkbox"/>
	MS LL 036 Annex III & 046 Cage	<input type="checkbox"/>	<input type="checkbox"/>
	MS LL 036 Annex III & 046 Cage   N/A <input type="checkbox"/>		
<b>LN<sub>2</sub> Room ONLY</b> <input type="checkbox"/> N/A	Walther Hall Room C156 Access	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Critical Doors ONLY</b> <input type="checkbox"/> N/A	Walther Hall – Non-Critical Doors	<input type="checkbox"/>	<input type="checkbox"/>
	-OR- Corridor C199M ONLY	<input type="checkbox"/>	<input type="checkbox"/>
<b>LARC Non-Critical Access</b> <input type="checkbox"/> N/A	IB097, IB Exterior Doors, R2/R3 Tunnel	<input type="checkbox"/>	<input type="checkbox"/>
Expiration Date, if applicable <input type="checkbox"/> N/A	___ / ___ / ____	<input type="checkbox"/>	<input type="checkbox"/> **
Approved Initials/Date:			
Completed Initials/Date:			
<b>Comments:</b>			
Reviewer Initials/Date:			

\* Rescind *all access for all key cards* for personnel listed. SSF personnel input name only; no key card numbers

\*\*Expiration date is not entered in dnaFusion. Track using Shared Calendar and Controlled Access spreadsheet.



## Controlled Access Contact Information

### Campus Facilities Services (CFS)

Work request submission - <https://cfs.iupui.edu/forms/work-request.html>

Dispatch – 317-278-1900

### IU Physical Security and Access

Public Safety and Institutional Assurance

Indiana University

[physsec@iu.edu](mailto:physsec@iu.edu)

Physical Security Analysts - 317-274-1335, 317-274-1342

### IUPUI Protective Services:

IUPUI Public Safety Dispatch Center

(317) 274-7911

### LARC Doors Access:

Medical Research / Library Building (IB) and Medical Science Building (MS) Locations:

- IB exterior doors
- R2/R3 IB tunnel
- IB 097

LARC Sharepoint site:

<https://indiana.sharepoint.com/sites/IUSM->

[LARC/Security/SiteAssets/Security%20Access%20Request%20Form.aspx](https://indiana.sharepoint.com/sites/IUSM-LARC/Security/SiteAssets/Security%20Access%20Request%20Form.aspx)

[larc@iupui.edu](mailto:larc@iupui.edu)

(317) 274-8649

### Presidio


- Door Hardware / Controller Issues unresolvable by IU Security and CFS Locksmiths

12272 Hancock Street

Carmel, IN 46032

(317) 581-1900

[www.presidio.com](http://www.presidio.com)

 <b>Indiana Clinical and Translational Sciences Institute</b>		<b>Visitor Log</b>	Month/Yr _____	Room # _____	
		<b>Indiana CTSI Specimen Storage Facility</b>		Page ____ of ____	
Date	Escort* Print Name and Sign Initials	Visiting Personnel Name (First and Last Name)	Visitor Affiliation	Forgotten Card (F) Lost Card (L) Broken Card (B) N/A	Purpose of Visit
1	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
2	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
3	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
4	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
5	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
6	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
7	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
8	Name (print) _____ Initials (sign) _____			<input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/> B <input type="checkbox"/> N/A	<input type="checkbox"/> Access samples <input type="checkbox"/> Other (describe) _____
Comments:					
Reviewed By (Initials / Date):					

\*Escort is acknowledging that they are providing the visiting personnel facility escort and have verified the visitor's authorization to access specific study samples.

\*\*See SSF Personnel if uncertain of facility access directives and if unable to enter facility using your key card.



## STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility

**COLLABORATING BIOREPOSITORY STAFF ACCESS TO CONTROLLED AREAS - REQUEST OR RESCIND**  
 Indiana CTSI Specimen Storage Facility - IUPUI R3 Building - 317-274-2213 OR 317-274-3569 -- ([ictsissf@iupui.edu](mailto:ictsissf@iupui.edu))  
 FOR QUESTIONS, CONTACT Jenna York, SSF Facility Manager ([jlyork@iu.edu](mailto:jlyork@iu.edu) and 317-274-2213)

### 1. AUTHORIZED BY

Date of Request:	
Request Access for entry to:	<input type="checkbox"/> C135, IB 097/MS-B046 Cage, and MS-B037 (-80 storage rooms) <input type="checkbox"/> C156 (LN <sub>2</sub> storage room) <input type="checkbox"/> ALL
Principal Investigator's Name: print	
Principle Investigator's Signature:	
Collaborating Biorepository:	<input type="checkbox"/> KOMEN <input type="checkbox"/> IUSCC TB <input type="checkbox"/> IUGB <input type="checkbox"/> NGVB <input type="checkbox"/> VPF <input type="checkbox"/> Orschell GSCL <input type="checkbox"/> KIC <input type="checkbox"/> CGTM <input type="checkbox"/> Other ( <i>List in Comments Section</i> )

### 2. GRANT ACCESS TO MECHANICAL AND/OR LN<sub>2</sub> FREEZER ROOMS TO FOLLOWING PERSONNEL


<u>Staff Name</u>	<u>Employment Status (may select multiple)</u>	<u>TO BE COMPLETED BY SSF PERSONNEL</u>			
		<u>Completed Training</u>	<u>Recorded By/Date</u>	<u>Authorization Requested</u>	<u>Recorded By/Date</u>
	<input type="checkbox"/> FTE <input type="checkbox"/> Part-Time <input type="checkbox"/> Student / Temporary	<input type="checkbox"/>		<input type="checkbox"/>	
	<input type="checkbox"/> FTE <input type="checkbox"/> Part-Time <input type="checkbox"/> Student / Temporary	<input type="checkbox"/>		<input type="checkbox"/>	
	<input type="checkbox"/> FTE <input type="checkbox"/> Part-Time <input type="checkbox"/> Student / Temporary	<input type="checkbox"/>		<input type="checkbox"/>	
	<input type="checkbox"/> FTE <input type="checkbox"/> Part-Time <input type="checkbox"/> Student / Temporary	<input type="checkbox"/>		<input type="checkbox"/>	
	<input type="checkbox"/> FTE <input type="checkbox"/> Part-Time <input type="checkbox"/> Student / Temporary	<input type="checkbox"/>		<input type="checkbox"/>	
TO BE COMPLETED BY SSF PERSONNEL:		Storage Agreement Revised: <input type="checkbox"/>	Initial/Date:		

### 3. RESCIND ACCESS TO MECHANICAL AND/OR LN<sub>2</sub> FREEZER ROOMS FOR THE FOLLOWING PERSONNEL

<u>Staff Name</u>	<u>TO BE COMPLETED BY SSF PERSONNEL</u>		<u>Staff Name</u>	<u>TO BE COMPLETED BY SSF PERSONNEL</u>	
	<u>Rescind Authorization Requested</u>	<u>Date/By</u>	<u>Rescind Authorization Requested</u>	<u>Date/By</u>	
	<input type="checkbox"/>			<input type="checkbox"/>	
	<input type="checkbox"/>			<input type="checkbox"/>	
	<input type="checkbox"/>		Storage Agreement Revised:	Completed <input type="checkbox"/>	

Comments:

**List of Collaborating Biorepositories (Template)**

Effective Date:				
Obsolete Date:				
 <div style="text-align: right;">Collaborating Biorepositories</div>				
	Biorepository Name	Contact	Phone	Alternate
1	IU Simon Cancer Center Tissue Procurement and Heme Bank (IUSCC TB)			
2	IU Genetics Biorepository (IUGB)			
3	National Gene Vector Biorepository (NGVB)			
4	Komen Tissue Bank (KTB)			
5	Orschell GSCL Laboratory (GSCL)			
6	Krannert Institute of Cardiology (KIC)			
7	Cell and Gene Therapy Manufacturing Group (CGTM)			
8	Vector Production Facility (VPF)			
9				
10				



Clinical and Translational  
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## SSF ACCESS REPORT MONTHLY REVIEW CHECKLIST

Date / Time Range:	Raw Data Download / Receipt Date:
Data Manipulation Date:	Review Initiation Date:
Location Descriptor(s):	Reviewer:
<p>1. An electronic copy of the SSF Controlled Access Report for the above time period has been reviewed for the following items:</p> <p>1.1. Access was granted <u>only</u> to personnel who were authorized to access the location during the time period covered. (No unauthorized access) Initials/Date _____</p> <p>1.2. Access was not denied to any personnel who were authorized to access the location during the time period covered. (Applicable to all personnel for whom Point 1.4 does not apply.) Initials/Date _____</p> <p>1.3. Key Card Numbers are appropriate for respective personnel for the time period covered. Initials/Date _____</p> <p>1.4. Replacement key cards: Appendix B created, access rescind on old key card completed, &amp; access granted on new key card completed/confirmed for any replacement key cards discovered at monthly review. Initials/Date _____</p> <p>2. Forced entry Report is reviewed and found to have been managed as described in Section 6.10 of this SOP. Initials/Date _____</p> <p>3. Point active events are reviewed and found to have been managed as described in Section 6.10 of this SOP. Initials/Date _____</p> <p>4. Door held events are reviewed and found to have been managed as described in Section 6.10 of this SOP. Initials/Date _____</p> <p>5. Collaborating Biorepositories have been contacted requesting updates for personnel access changes per Section 6.3.8. Initials/Date _____</p>	
Name personnel and actions taken for any discrepancies noted in Points 1.1-1.3 and personnel discovered in Point 1.4.	
Name: _____	Action: _____
Name: _____	Action: _____
Name: _____	Action: _____
<p><input type="checkbox"/> All reviewed items were found to be acceptable</p> <p><input type="checkbox"/> A list of attached items* were investigated and ultimately determined to be acceptable</p> <p><input type="checkbox"/> A list of attached items* were determined to be discrepant. (Enter date of SSF Director notification and Deviation # below)</p> <p>Date of Notification: _____ Deviation #: _____</p>	
Reviewer Initials / Date:	Management Review – Initials / Date:

\* It is acceptable for attachments to include events filtered from dnaFusion raw door access data, provided the attachments are identified as such.



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## SSF ACCESS REPORT ANNUAL REVIEW CHECKLIST

Date / Time Range:	Data File Verified Date:
Data Manipulation Date:	Renewal Initiated Date:
Location Descriptor(s):	Reviewer:
<p>List the names of all SSF and Collaborating Biorepository personnel who have not accessed the facility since October of the previous year and indicate action taken as either:</p> <ol style="list-style-type: none"> <li>1. Renewed (personnel have accessed the SSF within the previous year or have performed the requisite training required)**</li> <li>2. Rescinded (per Sections 6.12.1.7.3, 6.12.1.8.3, and 6.12.1.10.)</li> <li>3. Retrained (with appropriate documentation and per Sections 6.12.1.7.3 and/or 6.12.1.8.3.)</li> </ol>	
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
Name:	Action:
<input type="checkbox"/> All reviewed items were found to be acceptable <input type="checkbox"/> A list of attached items* were investigated and ultimately determined to be acceptable <input type="checkbox"/> A list of attached items* were determined to be discrepant. (Enter date of SSF Director notification and Deviation # below) Date of Notification: _____ Deviation #: _____	
Reviewer Initials / Date:	Management Review – Initials / Date:

\* It is acceptable for attachments to include events filtered from dnaFusion raw door access data, provided the attachments are identified as such.

\*\* Attach documentation of actions representing access renewal.

## Access Approval Requirements

Category	Change	Section Reference	Personnel Affected		Approval Required		
			Collaborating Biorepository Personnel (CBP)	SSF Personnel	SSF Director	SSF Management	CBP Directive / Approval
Critical Access	Authorize Access	6.3.1 6.5.2 6.6.2	X		X		X <sup>1</sup>
		6.5.2 6.6.2 6.7.1		X	X		
Rescind Access	Per PI Request	6.3.2	X	N/A		X	X <sup>1</sup>
	For Cause	6.3.3	X		X <sup>2</sup>	X	X <sup>2</sup>
	For SSF Personnel	6.7.3		X	X <sup>2</sup>	X	
	Temporary Rescind	6.3.5	X	N/A		X	X <sup>2</sup>
Key Card Replacement	Key Card Replacement	6.3.6	X			X	X <sup>2</sup>
		6.7.3.7		X		X	
Non-Critical Access	Authorize/Update	4.5.5	X	X		X	X <sup>3</sup>
	Rescind		X	X		X	X <sup>3</sup>
LARC Non-Critical Access	Authorize/Update	3.1.6	X	X		X	N/A <sup>4</sup>
	Rescind		X	X		X	N/A <sup>4</sup>
<sup>1</sup> SF-2-3 Appendix E required							
<sup>2</sup> Approval is not required, but <i>notification is required</i> .							
<sup>3</sup> Email acceptable							
<sup>4</sup> Access authorized / updated / rescinded by SSF personnel upon receipt of request to authorize / update / rescind Annex I and Annex III access.							

## SSF Controlled Access Levels Chart

Door Controller	Level	Door(s)	dnaFusion Device Address
1.123	Walther Hall – All SSF R3 Doors	C135-1 DNA & Serum Bank	1.123.D1
		C135-2 DNA & Serum Bank	1.123.D2
		C135-3 DNA & Serum Bank	1.123.D9
		C156-1 Cell Repository	1.123.D3
		C156-Lab	1.123.D7
		C156-Lab-OUT (previously C156-2)	1.123.D8
		C158 Receiving & Coding	1.123.D4
		C160 Cell Lab Entry	1.123.D5
		C199M Offices/Breakroom	1.123.D6
1.123	Walther Hall – Non-Critical Doors	C158 Receiving & Coding	1.123.D4
		C160 Cell Lab Entry	1.123.D5
		C199M Offices/Breakroom	1.123.D6
1.123	Walther Hall Room C135 Access	C135-1 DNA & Serum Bank	1.123.D1
		C135-2 DNA & Serum Bank	1.123.D2
		C135-3 DNA & Serum Bank	1.123.D9
		C158 Receiving & Coding	1.123.D4
		C160 Cell Lab Entry	1.123.D5
		C199M Offices/Breakroom	1.123.D6
1.123	Walther Hall Room C156 Access	C156-1 Cell Repository	1.123.D3
		C156-Lab	1.123.D7
		C156-Lab-OUT (previously C156-2)	1.123.D8
		C158 Receiving & Coding	1.123.D4
		C160 Cell Lab Entry	1.123.D5
		C199M Offices/Breakroom	1.123.D6
1.123	Walther Hall [IN015] 3 CTSI C199M	C199M Offices/Breakroom	1.123.D6
1.124	MS LL 036 Annex III & 046 Cage	MS 036 Annex III Only	1.124.D1
		MS LL 046 Freezer Cage Only	1.124.D2



Year: \_\_\_\_\_

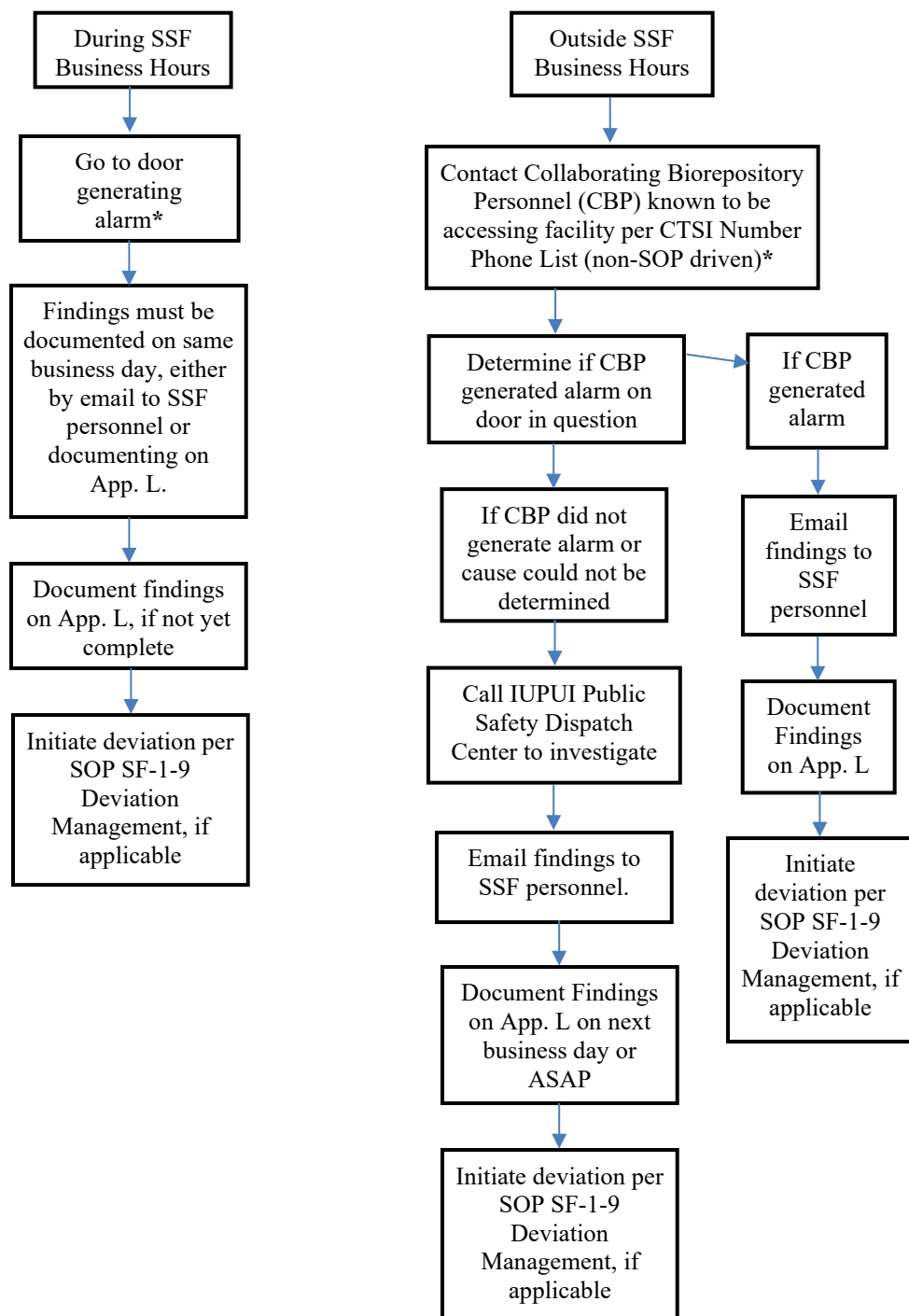
<b>CONTROLLED ACCESS SYSTEM ANNUAL PREVENTIVE MAINTENANCE LOG</b>				
<b>ANNUAL PM DOOR</b>	<b>COMPLETION</b> <i>Document Result (✓): Note: Expected Result = Yes</i>	<b>SSF Personnel</b>		<b>Name of CFS Technician Performing Work</b>
		<b>Initials</b>	<b>Date</b>	
<b>Clean, lubricate, repair as needed</b>				
<b>C135-1 (NE Door)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>C135-2 (NW Door)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>C135-3 (Door from C199M Hallway)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>Inspect magnetic locking mechanism for tightness – magnet affixed at top of door C135-3</b>				
<b>C135-3 (Door from C199M Hallway)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>Clean, lubricate, repair as needed</b>				
<b>C156-1 (Double doors from hallway)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>C156-Lab/C156-Lab-OUT (Door from C158 to C156)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>Clean, lubricate, repair as needed</b>				
<b>MS-B036 (MS-B037 entry door)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>IB 097/MS-B046 Cage</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable*			
<b>Clean, lubricate, repair as needed</b>				
<b>Documentation of CFS performance attached</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable**			
<b>Comments / Corrective Actions</b>				
<b>Reviewed By / Date:</b>				

\* SSF personnel must document rationale if Annual PM was not completed or not applicable.

\*\*Alternately, SSF personnel observing CFS PM may document work completed in the comments section per Step 6.1.1.

Door Held / Forced Door / Point Active Event Log						Month/Year _____	Page ____ of ____
Date / Time	Door*	Event Type	Door Found Closed / Secure	Door & Keyhole Undamaged	Event Cause (Check all that apply)	Tech. Initials/ Date	Investigation Results / Comments
1		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
2		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
3		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
4		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
5		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
6		<input type="checkbox"/> Forced <input type="checkbox"/> Held <input type="checkbox"/> Point Active	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Yes <input type="checkbox"/> No**	<input type="checkbox"/> Event Caused by SSF Trained Personnel <input type="checkbox"/> Maintenance / Freezer Move <input type="checkbox"/> Other (See Investigation section)		<input type="checkbox"/> No unauthorized personnel inside secure facility <input type="checkbox"/> Other _____ <input type="checkbox"/> Comment _____
Reviewed By / Date:					*Each door is labeled on the bottom of the controlled access key card panel. **Record observations and assigned deviation number (if applicable) in the Investigation Results / Comments Section.		

## Door Event Investigation Plan



**\* Initiation of the investigation occurs as soon as possible, but initiation may not exceed 2 hours post-notification.**

## COLLABORATING BIOREPOSITORY PERSONNEL (CBP) TRAINING

### 1. PURPOSE

- 1.1. Standard Operating Procedure (SOP) SF-2-3, Controlled Access Operations defines the procedures used to limit access to the Indiana CTSI Specimen Storage Facility (SSF) and satisfies guidance set forth in ISBER as related to controlled access.

### 2. PRINCIPLE

- 2.1. Access to the SSF is restricted by electronic card readers and keys.
  - 2.1.1. Keys are used only in emergencies, and critical door keyholes are taped over to enhance detection of forced access attempts.
  - 2.1.2. Areas controlled electronically by key cards include the following:
    - 2.1.2.1. Non-Critical Walther Hall Research Building (R3) Doors:
      - 2.1.2.1.1. DNA/Cell Processing Lab (C158 & C160)
      - 2.1.2.1.2. Corridor (R3-C199M) leading into the office suites and break room
    - 2.1.2.2. Non-Critical Medical Research / Library Building (IB) and Medical Science Building (MS) Locations (LARC Access):
      - 2.1.2.2.1. IB Mechanical Freezer Storage Room (IB 097)
      - 2.1.2.2.2. IB exterior doors
      - 2.1.2.2.3. R2/R3 IB tunnel
    - 2.1.2.3. Critical Access Freezer Rooms:
      - 2.1.2.3.1. DNA & Serum Bank (R3-C135)
      - 2.1.2.3.2. Cell Repository (R3-C156)
      - 2.1.2.3.3. SSF Annex I (IB 097/MS-B046 Cage)
      - 2.1.2.3.4. SSF Annex III (MS-B037)

### 3. SCOPE

- 3.1. This SOP applies to all personnel that require access to SSF areas defined above.
- 3.2. A list of *Collaborating Biorepositories (CB(s))* is maintained in the SSF. (Refer to and review Appendix F in this SOP.)
- 3.3. CBs are granted access as follows:
  - 3.3.1. All personnel working with these CBs are granted autonomous access into the non-critical areas of the SSF upon request.
  - 3.3.2. All personnel working with these CBs who have:
    - (1) had access authorization requested by the PI or PI Designee and
    - (2) completed training per this SOP
 are given autonomous access into the applicable critical areas of the SSF.
- 3.4. It is the responsibility of *Collaborating Biorepository personnel (CBP)* to assure that **untrained personnel:**
  - 3.4.1. Are provided with **continually monitored access** into critical areas of the SSF **as needed for your CB operations**
  - 3.4.2. SSF Staff may provide monitored access for all users,
  - 3.4.3. while **CBP are only permitted to provide monitored access to the following:**
    - 3.4.3.1. Personnel unable to enter SSF facilities with their key card **who are involved in your CB's studies** (e.g., student employees, interns, personnel touring the biorepository facilities):
      - 3.4.3.1.1. *Monitored access in this case is limited to **units containing your CB's samples.***
    - 3.4.3.2. Professional personnel executing preventative maintenance or repairs **for your CB's units or equipment.**
    - 3.4.3.3. Personnel from Campus Facility Services (CFS) *performing services for your CB.*
    - 3.4.3.4. **CBP are not authorized to provide CFS personnel facility access for any other purposes (i.e. facility maintenance).**
  - 3.4.4. *Access by all personnel unrelated to your CB is managed by SSF staff*
  - 3.4.5. Adhere to all SOPs.
- 3.5. CB Access to SSF Critical Areas
  - 3.5.1. Authorize Access: PI for the CB, Biorepository Manager, or other personnel designated by the PI requests to have access to SSF Critical areas authorized for designated personnel by completing the

Collaborating Biorepository Access Authorization Form (Appendix E), indicating whether personnel is a full-time employee (FTE), part-time employee, student, or temporary employee. Multiple boxes may be selected as applicable. Refer to and review Appendix E in this SOP.

3.5.1.1. SSF Personnel or Super Trainer conducts Mechanical Refrigeration Unit (MRU) Freezer Room Training and/or Liquid Nitrogen (LN<sub>2</sub>) Freezer Room training, as applicable, per this SOP.

3.5.1.2. Temporary Personnel Access Expiration:

3.5.1.2.1. Personnel designated as Student and/or Temporary on Appendix E are designated “Temporary-CBP” and assigned Access Expiration dates of one year from the date of training completion.

3.5.1.2.2. Extension of Access Expiration date will be permitted only if the CBP are current on training per this SOP and may not exceed one year from date of request, however extensions may be granted indefinitely.

3.5.2. Rescind Access per PI Request: PI for the CB requests to have access to SSF Critical areas rescinded for designated personnel by completing and submitting Appendix E.

3.5.3. **Rescinding Access for Cause**

3.5.3.1. In the event of:

3.5.3.1.1. Failure to maintain applicable training (Training occurs at SSF direction, likely by email)

3.5.3.1.2. Failure to comply with controlled access annual renewal (Occurs at SSF direction, likely by email)

3.5.3.1.3. Violation of SSF safety procedures per SSF SOPs

3.5.3.1.4. Violation of IUPUI policies

3.5.3.2. SSF Management notifies PI, Biorepository Manager, or other personnel designated by the PI that access will be rescinded providing reason for action, and SSF facility access is rescinded.

3.5.3.3. Access reinstatement requires retraining per SSF SOPs.

3.6. **Notification of Personnel Who’ve Left the CB / Key Card Replacement / Name Change:** SSF Management emails each CB monthly, providing the Collaborating Biorepository Access Authorization Form (Appendix E) and requesting that they reply with the following requested personnel updates, if not already provided.

3.6.1. New personnel requiring facility access

3.6.2. Personnel with name changes

3.6.3. Personnel with new key cards

3.6.4. Personnel no longer working for the CB, for whom facility access requires rescinding

3.6.5. CBs with Temporary-CBP are provided a list of personnel with access expiring in the next month and asked if access for those personnel should be extended

3.7. **Visitor Access Log**

3.7.1. All Freezer Rooms - C156, C135, MS-B037, or IB 097/MS-B046 Cage

3.7.1.1. Complete an entry on the Visitor Log (Appendix D) for anyone who does not use his/her own electronic access to enter. Refer to and review Appendix D in this SOP.

3.7.1.1.1. Personnel providing access and escort must print their name and sign their initials in the “Escort” column on the Visitor Log and record name and affiliation (your Biobank, repair company, etc.) of the visitor.

3.7.1.2. A single log entry for each day of access (when there are multiple times of access on the same date) *per freezer room* is acceptable.

3.7.1.3. See SSF personnel if you’re unable to enter the facility using your own key card (i.e. your keycard is broken.)

3.8. **Door Control**

3.8.1. At all times, doors allow free egress.

3.8.2. In case of a system failure, electronic locks in the SSF enter a “fail secure” mode, locking all doors.

3.8.3. Doors to critical access areas are not to be propped open.

3.8.4. All personnel entering a critical facility must scan their key card for access.

- 3.8.4.1. Personnel unable to enter a freezer room using their key card require, at minimum, an entry on the Visitor Log per Section 3.7 and Steps 3.8.5-3.8.6 of this Appendix.
- 3.8.4.2. When multiple personnel enter together (i.e.: when the door has been opened initially by one person and held open for the rest of the party), each individual with key card access must scan their badge before entering the facility.
- 3.8.4.3. Personnel are prohibited from using a key card assigned to other trained personnel.
- 3.8.4.4. Violations may result in access rescension.
- 3.8.5. In the event of a **forgotten card**, the affected person may be allowed access *by SSF personnel or another trained CBP from your biobank with freezer room access via their own key card* and be given all of the privileges of entry that access by his/her own card would have conferred. This event is recorded on the Visitor Log for each room accessed.
- 3.8.6. In the event of a **lost or broken card**, notify SSF personnel and your manager immediately. The affected person may be allowed access *by SSF personnel or another trained CBP from your biobank with freezer room access via their own key card* and be given all of the privileges of entry that access by his/her own card would have conferred. This event is recorded on the Visitor Log for each room accessed.
  - 3.8.6.1. Access is reauthorized once replacement key card number is provided to SSF personnel.
- 3.8.7. CB staff who are trained per this SOP and granted freezer room access are limited to the following functions in an Emergency:
  - 3.8.7.1. Personal access in the event of a building emergency.
  - 3.8.7.2. Break glass window and force entry into room only if deemed necessary.
  - 3.8.7.3. Providing instruction to untrained personnel applicable to the emergency situation regarding safety and security practices per the applicable SOP (SOP SF-2-1 Mechanical Freezer Storage Room Operations or SOP SF-2-2 Liquid Nitrogen System and Freezer Room Operations).
  - 3.8.7.4. Document entry of additional personnel by completing a Visitor Log entry.
- 3.8.8. All door alarms (Door Held, Door Forced, use of Exit-Only doors in MS-B037) are investigated by SSF personnel immediately.
- 3.9. **Annual Freezer Room Access Review**
  - 3.9.1. Annually in October, the SSF reviews access records for MRU and LN<sub>2</sub> Rooms, confirming that all personnel authorized for freezer room access have entered an MRU room and/or the LN<sub>2</sub> room at least once in the past year and are current on their SSF training. Those meeting both qualifications are considered qualified for continued access into freezer rooms for the following calendar year.
    - 3.9.1.1. Personnel who have NOT accessed minimally 1 door into an MRU room and/or the LN<sub>2</sub> room in the past year, will be contacted to access the applicable freezer room and discuss any concerns regarding safety and SSF procedures. Once successfully completed, access will be authorized through December of the following calendar year.
      - 3.9.1.1.1. Personnel have at least 3 weeks to comply.
      - 3.9.1.1.2. CBP failing to comply will have facility access rescinded.
- 3.10. **Annual Recertification Training Requirement**
  - 3.10.1. Annually, typically in October, the SSF will send CBP a summary of all critical directives applicable to CBP from all SOPs required to maintain access to SSF Mechanical Refrigeration Unit Rooms and/or the Liquid Nitrogen Freezer Room.
    - 3.10.1.1. Recertification training is likely conducted via email.
    - 3.10.1.2. Personnel must read and understand directives, and reply to the SSF indicating completion of training.
    - 3.10.1.3. Personnel have at least 3 weeks to comply.
    - 3.10.1.4. CBP failing to comply will have facility access rescinded.
- 3.11. **Additional Appendices Requiring Review**
  - 3.11.1. Appendix D: Visitor Log (posted at the main entry for each freezer room)
  - 3.11.2. Appendix E: Collaborating Biorepository Access Authorization Form
  - 3.11.3. Appendix F: Collaborating Biorepositories List