UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT AND ADVISORY SERVICES

Biospecimen & Tissue Core Facility
Inventory Management
Project # 22-022

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University of California
San Francisco

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SUBJECT: Biospecimen & Tissue Core Facility – Inventory Management

As a planned audit for Fiscal Year 2022, Audit & Advisory Services ("A&AS") conducted a review to assess the adequacy of internal controls and processes for biospecimen inventory management and billing for biospecimen storage and handling fees.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the "IIA Standards").

Our review was completed and the preliminary draft report was provided to department management in June 2022. Management provided their final comments and responses to our observations in August 2022. The observations and corrective actions have been discussed and agreed upon with department management and it is management's responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Committee, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn
Chief Audit Officer
UCSF Audit and Advisory Services

EXECUTIVE SUMMARY

I. BACKGROUND

As a planned audit for Fiscal Year 2022, Audit & Advisory Services conducted a review to assess the adequacy of internal controls and processes for biospecimen inventory management and billing for biospecimen storage and handling fees.

The Biospecimen Services Program (BSP)[1] is a core facility within the Clinical & Translational Sciences Institute (CTSI). The BSP core provides a suite of biospecimen services to support clinical, translational, and basic life sciences research including custodianship of biospecimens, acquisition, processing, cold-chain logistics, storage, and retrievals. The BSP core currently manages over 10,000 biospecimens samples related to various research programs across the UCSF campus. Long-term biospecimens are stored at a freezer facility at the Mount Zion campus. BSP currently maintains a master inventory workbook in real-time to track samples but will transition to the MBioLIMS database system, a web-based regulatory compliant database to track samples through the collection, processing, storage, and distribution.

At the end of each month, the BSP Core manager uploads an activity log from UCSF Box of services performed to UCSF iLab[2] for billing.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess the adequacy of internal controls and processes for biospecimen inventory management and billing for biospecimen storage and handling fees. The scope of the review covered transactions and activities for January 2022 through March 2022.

Procedures performed as part of the review included reviews of University and local UCSF policies and procedures related to biospecimen inventory management and recharge billing; interviews and walkthroughs with relevant personnel to get an understanding of activities for the areas under examination; inventory count on a sample of freezers to validate the completeness and accuracy of biospecimen inventory records; validation testing of a sample of biospecimen storage and handling fees to determine that billing was complete, accurate, and timely; and reviewed the FY 2022 recharge proposal to determine costs were reasonable and appropriate.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in June 2022.

[1] Formerly called the Biospecimen Resource Program (BIOS)
[2] UCSF iLab Solutions is a web-based platform for scheduling, ordering, and billing system for core facilities and core customers.

III. SUMMARY

Based on work performed, biospecimen storage billed for January 2022 through March 2022 were posted to the general ledger the following business day and reconciled to the billing activity in iLab. In addition, the budgeted costs and assumptions in the FY 2022 recharge proposal appeared reasonable and appropriate.

Opportunities for improvement exist in the areas of strengthening inventory management controls, establishing a process to track and reconcile iLab staff technician time, and ensuring adequate separation of duties is in place for inventory management.

The specific observations from this review are listed below as well as in Section IV.

1. BSP core inventory records did not appear to be accurate and complete.

2. Discrepancies were identified in the billing of biospecimen inventory storage in iLab.

3. There are insufficient controls in place to track and reconcile iLab staff technician time hours.

4. There is inadequate separation of duties for inventory management.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (MCA)

No.	Observation	Risk/Effect	Recommendation	MCA
1.	***BSP core inventory records did not appear to be accurate and complete.*** An inventory count was performed for a sample of 100 boxes stored at the biospecimen freezer facility at Mount Zion. Out of the 100 boxes selected and counted, we were not able to locate 11 (11%) of the boxes shown on the master inventory file. Inaccurate inventory records may result in lab customers being charged for specimens no longer in storage.	• Customers could be charged for storage for missing inventory resulting in overbilling. • Depending on the missing specimens, valuable research materials may be lost that may negatively impact research.	• Hold billing for the missing boxes and investigate the discrepancy in the inventory records. If unable to locate the boxes, these should be removed from the master inventory file and lab owners should be notified of the missing inventory. • Departments should be refunded for any overbilled amounts.	**Actions:** (a) The boxes not identified during the on-site audit will be changed to "no" in the OK to bill tab, removing them from the billing script until they can be identified, and the locations can be updated on the Freezer Master List. **Target Completion Date:** August 31, 2022 (b) Inventory reconciliation will be performed and the Freezer Master List will be updated based on this reconciliation. **Target Completion Date:** December 31, 2022

No.	Observation	Risk/Effect	Recommendation	MCA
				Responsible Party: Director, UCSF Biospecimen Services
2.	***Discrepancies were identified in the billing of biospecimen inventory storage in iLab.*** UCSF iLab Solutions is a web-based platform for scheduling, ordering, and billing system for core facilities and core customers. Of the sample of 25 inventory billing selected for review, we identified the following: a) For 7 transactions, the quantity billed in iLab differed from the quantity ending balance of the inventory snapshot files resulting in a potential difference of $1,958 under billed for January 2022- March 2022. At the end of each month, the BSP master inventory file is saved as a snapshot file to reflect the inventory month-end balances for billing purposes. The master inventory snapshot file is copied onto an iLab template and uploaded to iLab for billing. In January 2022, the master inventory snapshot file was not refreshed before the template file was uploaded to iLab causing the quantity billing discrepancies. b) Additionally, two biospecimen inventory management & storage fees were not billed timely. The number of business days between completion and billing date in iLab was 47 days.	Not having adequate process/internal controls over inventory tracking and management increases the risk of missed revenue opportunities due to inaccurate billing.	• BSP should review the quantity billed against the inventory master file and correct the identified discrepancies. • BSP should refresh the master inventory file before saving a copy of the month-end snapshot file to ensure inventory balances are correct and ensure billing is completed in a timely manner.	**Action:** The Freezer Master List will be refreshed prior to downloading the monthly billing snapshots to ensure accurate box counts. **Target Completion Date:** August 31, 2022 **Responsible Party:** Director, UCSF Biospecimen Services

No.	Observation	Risk/Effect	Recommendation	MCA
	Per UCSF Campus Administrative Policy 250-11, *"Sales & Services Center(s) Recharges, External Sales & Services of Education Related Activities & Common Costs"* recharge journals to internal users and/or billings to external users must be processed on a monthly basis, at a minimum.			
3.	***There are insufficient controls in place to track and reconcile iLab technician time to the lab billing for services performed.*** The lab technician's time to pull samples from inventory and perform non-standardized biobank services are billed on an hourly basis in iLab. Each lab staff technician maintains individual logs to track time hours. However, the tracking logs were not always saved and contained insufficient detail (i.e. service request date, service type, and completion date) which limits the ability to properly track and reconcile the hours billed in iLab.	Lack of sufficient detail on tracking logs limits the ability to validate the accuracy and completeness of time billed for services performed.	BSP should develop tracking procedures and include sufficient details to ensure the hours tracked are appropriate and accurately billed in iLab.	**Action:** A uniform tracking log has been developed to more thoroughly document staff time including the iLab request number. **Target Completion Date:** August 31, 2022 **Responsible Party:** Director, UCSF Biospecimen Services
4.	***There is inadequate separation of duties for inventory management.*** There are 24 employees who have access rights to edit the Master Inventory file in Microsoft SharePoint. Of the 24: • 3 employees are custodians of the BSP inventory. There must be adequate separation of duties amongst those who have access to the	Having sufficient separation of duties reduces the risk of inappropriate manipulation of records and provides additional checks to identify errors or fraud.	• BSP should ensure that adequate separation of duties is in place for the record-keeping and physical custody of the	**Action:** User access level rights have been updated to only include pertinent individuals. This includes the BSP program manager, the financial director, and the

No.	Observation	Risk/Effect	Recommendation	MCA
	physical inventory and maintain inventory records. • 3 employees are staff administrators in CTSI who do not perform BSP inventory management functions and do not need access to the inventory master file. Not ensuring employees have appropriate access increases the risk of unauthorized and/or unintentional edits to the file. • 9 employees (including the owner of the Master Inventory file) are from departments outside of CTSI resulting in the potential risk of unauthorized access to the file. Per UCSF Campus Administrative Policy 350-12 "*Internal Controls",* No one person should have complete control over more than one key function or activity (e.g., authorizing, approving, certifying, disbursing, receiving, or reconciling). For custodial and security arrangements, the responsibility for physical security/custody of University assets are separated from recordkeeping/accounting for those assets.		biospecimen inventory. • User access level rights should be reviewed against the master inventory file and identify individuals who do not require edit access rights. Also remove individuals who no longer require access and/or restrict access rights to the viewer level.	BSP staff who update inventory records. **Target Completion Date:** August 31, 2022 **Responsible Party:** Director, UCSF Biospecimen Services

APPENDIX A

To conduct our review the following procedures were performed for the areas in scope:

- Reviewed University and local UCSF policies and procedures related to biospecimen inventory management and recharge billing activity.
- Conducted walkthroughs and interviews with relevant personnel to understand and assess processes and identify any control gaps.
- Performed inventory count on a sample of freezers to validate the completeness, and accuracy of biospecimen inventory records and verified the assignment of the specimen.
- Performed analysis of potential loss of revenue to unidentified lab owners.
- Reviewed a sample of biospecimen storage and handling fees to determine that billing was complete, accurate, and timely.
- For the selected samples, reviewed the general ledger transactions to determine that transactions reconciled to iLab billing activity.
- Determined whether there was appropriate separation of duties between reviewing and completing service requests in iLab, uploading monthly billing event files in iLab, and approving billing events in iLab.
- Reviewed the FY 22 recharge proposal to determine if budgeted costs and assumptions appear reasonable and appropriate.