# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO AUDIT & ADVISORY SERVICES

Biorepository and Tissue Biomarker Core Facility Review

Project #21-032

June 2021



#### **Audit & Advisory Services**

UCSF Box 0818 1855 Folsom Street San Francisco, CA 94143

tel: 415.476.3851 fax: 415.476.3326

www.ucsf.edu

June 15, 2021

## Dr. Benjamin Braun

Associate Professor in Residence Department of Pediatrics Associate Director for Shared Resources UCSF Helen Diller Family Comprehensive Center

#### SUBJECT: Biorepository and Tissue Biomarker ("B&T") - Core Facility Review

UCSF Audit and Advisory Services ("A&AS") completed a review to assess the adequacy of the internal controls and processes in place for governance and oversight over the financial management of the B&T Core. The review focused on roles and responsibilities for the governance and oversight of the B&T Core; billing for services; inventory management; financial controls; oversight and reporting; and budget development and recharge rate setting process.

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 March 2021. Management provided their final comments and responses to our observations in June 2021. 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 Board, 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

At the request of senior leadership, UCSF Audit & Advisory Services completed a review to assess the adequacy of the internal controls and processes in place for the governance and oversight over the financial management of the Biorepository and Tissue Biomarker Core ("B&T Core" or "the Core").

The B&T Core resides within the Helen Diller Family Comprehensive Cancer Center ("Cancer Center") and provides the following services:

- 1. Human biospecimen repository
- 2. Tissue biospecimen processing
- 3. Tissue biomarker technology

Currently, the governance structure over the B&T Core is shared between the Cancer Center and Biospecimen Resource Program (BIOS). The B&T Core is a self-supported recharge operation that is required to fully recover its costs. Recharge rates are developed through a recharge proposal process and approved by Budget and Resource Management (BRM). The B&T Core has been operating with a net deficit balance since at least 2014. As of FY 2020, the B&T Core accumulated deficit balance was \$1,022,474.

The B&T Core uses the Research Electronic Data Capture<sup>1</sup> (REDCap) database to track studies and its associated protocols. As part of this process, appointments are scheduled on the Clinical Research Coordinator (CRC) master calendar for specimen collection per protocol which is processed by the B&T Core. At the end of each month, an activity log, containing details of services performed, is generated from REDCap and uploaded to iLab<sup>2</sup> for billing.

Ineffective internal controls over the financial management of the B&T Core could result in loss of revenue, non-recovery of costs and non-compliance with federal cost accounting standards and University policies.

## II. AUDIT PURPOSE AND SCOPE

The purpose of the review was to assess the adequacy of the governance structure and determine whether appropriate internal controls are in place to ensure appropriate financial management of the B&T Core. The review focused on roles and responsibilities for the governance and oversight of the Core; billing for services; inventory management; financial controls, oversight and reporting; and budget development and recharge rate setting process.

The scope of the review was limited due to unavailability of storage inventory data and service request log for FY 2020. As such, validation of the completeness of billing for tissue storage and services performed could not be performed.

\_

<sup>&</sup>lt;sup>1</sup> REDCap is a secure and HIPAA-compliant web-based system for building and managing web-based research projects, such as surveys and databases. The REDCap system provides functionality and features to enable researchers to rapidly develop databases and online surveys.

<sup>&</sup>lt;sup>2</sup> iLab is a web-based scheduling, ordering and billing system.

Procedures performed as part of the review included interviews and walkthroughs with relevant personnel to identify internal controls and processes in place for the governance and oversight over the financial management, billing for services, inventory management, budget development and recharge rate setting. Validation testing included a sample of services performed to ensure accuracy and completeness of billing. For more detailed steps, please refer to Appendix A.

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 January 2021.

## III. SUMMARY

Based on work performed, B&T Core did not appear to have adequate internal controls or monitoring processes in place creating an environment conducive for fraud risks and errors/omissions occurring. Internal control deficiencies were noted in relation to ineffective segregation of duties; insufficient verification and reconciliation of revenues; lack of robust oversight and monitoring over financial activities and absence of documented procedures.

The review identified opportunities for improvement related to billing process, revenue reconciliation, inventory management, recharge rate setting, standard operating procedures and roles and responsibilities. The specific observations from this review are listed below as well as in Section IV.

- 1. The controls over the billing processes are not sufficient to ensure complete and accurate billing for B&T Core services.
- 2. Incorrect and/or missed billing for biospecimen storage.
- 3. B&T Core's inventory management controls of bio-specimen tissues are not sufficient to ensure that inventory records are complete and accurate.
- 4. There are inadequate internal controls and monitoring processes in place resulting in an environment conducive to fraud risks.
- 5. Subsidy for Cancer Center members has not been consistently applied.
- Volume and expenditure forecasts calculations used in the FY2019-2020 Recharge Proposal were not consistently supported or validated based on prior figures.
- 7. Standard Operating Procedures (SOPs) for key financial processes have not been established or documented.
- 8. Roles and responsibilities over B&T Core's financial management and oversight processes are not clearly defined or documented.
- 9. An authorized deficit resolution business plan is not in place.

## IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS ("MCA")

No.	<u>Observation</u>	Risk/Effect		Recommendation	<u>MCA</u>
1.	The controls over the billing processes are not sufficient to ensure complete and accurate billing for B&T Core services.  Review of B&T Core's billing processes and validation of billing for a sample of specimens identified the following issues:  a) Service requests are not logged and tracked and therefore it is not possible to validate that all service requests were completed and billed.  Due to the above stated limitation, a sample of 15 services for the period July – November 2020 were selected from the clinical studies master calendar (maintained by Clinical Research Coordinators) and traced to the activity log in REDCap system and also to the iLab billing file to validate that the billing for services had occurred. We found that 8 of 15 (53%) blood/serum processed for clinical studies were not found in the iLab billing file indicating that billing had not occurred. Of these, 4 also could not be located in the REDCap activity log indicating that services performed were not entered in REDCap. Services performed per project protocol need to be input into REDCap as complete in order to get billed.  The B&T Core manager had relied on the Clinical Research Coordinator's Outlook master calendar to validate completeness of billing. Appointments are set up on the CRC calendar based on project protocols. However, as indicated above, this is not a reliable source.	Not having adequate process/internal controls to ensure services performed are billed increases the risk of unrealized revenue due to missed billing.  Not performing regular revenue reconciliation increases the risk of missed transactions not being detected timely and does not provide reasonable assurance on the completeness and accuracy of revenue.	•	Procedures to be developed to track via a log of all service requests received by the B&T Core. This service request log should be reconciled against the activity log in REDCap to ensure that all services performed have been entered.  Monthly revenue reconciliations should be performed to confirm that all specimen processed are billed. Evidence of the reconciliation should be retained.  Procedures to be developed for obtaining funding chart string from client departments	Action: 1. A template for work requests in the clinical studies master calendar will be implemented that provides adequate information for billing and reconciliation.  2. The clinical studies master calendar will be reconciled with the iLab billing file on a quarterly basis  3. Chart strings are now required at study opening.  4. Legacy studies will not be billed as this would be out of compliance with policies requiring timely billing by cores.  Target Date: January 31, 2022

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
	b) Reconciliation of services performed against		as soon as studies	
	charges is not routinely performed		are activated.	Responsible
	B&T Core does not have a process in place for reconciliation of services performed against billing July 2019, the former Chief Biobank Officer began performing monthly revenue analysis. The analysis compared actual billing against services performed analysis stopped in March 2020 and no on-going monitoring of revenue has been performed since.  c) The account chart string for recharging the process is not always provided timely by the department resulting in delayed billing and revenue recover 2020 to November 2020, we noted six projects with a speed type attached. Billing for internal customed cannot be done if the speed type is not obtained. The following table summarizes services provided quantities for these six projects:	g. In n sis ed. The then. ojects ent ery. July ithout ers	A reconciliation should be performed for the legacy studies to determine whether billing for prior period services has been completed.	Party: Associate Director for Shared Resources
	Service Name Quantity Additional Prep Step 29			
	Blood Processing 101			
	Extended Hours Processing 2			
	PBMC Processing 15			
	Shipping 76			
	Grand Total 223			
	d) Billing for legacy studies may not have been completed.			
	Discussion with the former B&T Core manager highlighted that several studies were not in REDC	Cap		

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
	but were instead maintained in an Excel spreadsheet. While these studies have now been entered into REDCap (approx. 30 studies), the manager stated that a full review has not been completed to verify that billing of services for the prior periods for these studies had been done.  A copy of the Excel spreadsheet showing the legacy studies activity was requested but was not provided and therefore we could not substantiate the claim.  UCSF Campus Administrative Policy 300-11 "Accounts Receivable" requires that the receivable and associated revenue must be reflected accurately and timely on the University's financial records.			
2.	Incorrect and/or missed billing for biospecimen storage.  Validation of the completeness of tissue storage billing could not be performed due to the lack of complete inventory records. Additionally, with the departure of B&T Core manager, no-one in the B&T Core could provide information on how the tissue storage billing is being performed.  As a result, storage billed from iLab during the period July 1, 2020 to January 6, 2021 was reviewed to verify accuracy of billing. A total of 14 Principal Investigators (PIs) were billed for storage during this period and the following issues were noted:  1. One PI, an external customer, was not charged the correct rate. The PI was charged \$9.42 per box instead of the approved external rate of \$11.99, resulting in loss of revenue of \$2,282.16.	Not having adequate process/internal controls to ensure storage is billed increases the risk of unrealized revenue.	<ul> <li>Monthly reconciliation of storage billing should be performed</li> <li>Adequate processes to ensure completeness and accuracy of storage billing should be developed and implemented.</li> <li>Procedures for billing should be documented</li> </ul>	Action: 1. Storage boxes will be reinventoried and assigned Pl's and chart strings.  2. The new inventory will be updated in real time as boxes are added or removed.  3. The new inventory will be maintained in an Excel spreadsheet and will be used to calculate monthly bills. This has been

No.	<u>Observation</u>	Risk/Effect	Recommendation	<u>MCA</u>
No.	<ol> <li>Subsidy to Cancer Center members had not been applied (see Observation # 4 below).</li> <li>Waiver of storage charges for one PI has been in effect since August 2020, due to complaints of Tissue Core services, resulting in loss of revenue of approximately \$46,512. No end date for the waiver of charges has been set (the PI has approximately 2,280 boxes in storage per the last billing).</li> <li>Additionally, since November 2020 no billing for biospecimen storage has occurred. This was a decision made by management due to incomplete inventory recordkeeping.</li> </ol>		Recommendation	initiated in Feb 2021.  4. Standardized procedures for billing will be documented.  5. Inventory reconciliation will be performed on each freezer during routine maintenance. B&T Core expects to do this for each freezer over the course of every year.  Target Date: January 31, 2022  Responsible Party: Associate Director for Shared Resources
3.	B&T Core's inventory management controls of bio-	In the absence	Full inventory count of	Action:
	specimen tissues are not sufficient to ensure that inventory records are complete and accurate.	performing any inventory, the accuracy and	biospecimen tissues should be performed. Once the inventory	See MCA for observation #2; inventory
	Review of bio-specimen tissue storage billing processes identified that a full inventory of biospecimen tissues in	completeness of	has been completed, a reconciliation should	management is a prerequisite to

<u>No.</u>	<u>Observation</u>	Risk/Effect	<u>Recommendation</u>	<u>MCA</u>
	storage has not been performed. As such B&T Core does not know the complete quantity and owners of some of the tissues (particularly the historical tissues	storage billing cannot be verified.	be performed to determine unbilled storage charges.	accurate storage billing.
	that are stored), resulting in researchers not paying for the storage.  Per the FY 2019-2020 Recharge Rate proposal, storage and administration of tissues accounts for 47.6% of the projected revenue, therefore it is critical for B&T Core to ensure that record keeping and billing for biospecimen tissue storage is complete and accurate.	<ul> <li>Not having adequate process/internal controls over inventory management increases the risk of unrealized revenue due to missed billing.</li> </ul>		Target Date: January 31, 2022  Responsible Party: Associate Director for Shared Resources
4.	<ul> <li>There are inadequate internal controls and monitoring processes in place resulting in an environment conducive to fraud risks.</li> <li>During the review it was noted that adequate internal controls were not in place. The following internal control deficiencies were noted:         <ul> <li>There was a lack of effective segregation of duties - the B&amp;T Core Manager performed or had the ability to perform all the following functions: scheduling of services, charge entry, invoicing/billing, and charge reconciliation.</li> <li>Ineffective oversight and monitoring – reviews or monitoring of the financial activities performed by the B&amp;T Core Manager was not performed on a regular basis.</li> <li>Lack of documented procedures. The B&amp;T Core Manager separated from the University during the audit. No one was able to provide details of procedures performed and as a result A&amp;AS was not able to perform some of the audit steps.</li> </ul> </li> </ul>	Inadequate internal control increases the risk of fraudulent activities and errors and omissions not being detected.	<ul> <li>Management should ensure that proper segregation of duties over financial management are in place, specifically for charge entry, billing and reconciliation</li> <li>Management should ensure that proper internal controls over financial management are in place. Management should also monitor internal controls to ensure they are effective and</li> </ul>	Action: 1. With the hire of the new manager, proper segregation of duties will be in place for charge entry, billing and reconciliation. Procedures in process will ensure adequate internal controls.  2. The financial activities will be reviewed as part of the monthly financial review process by the Director of Finance and Operations.

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
	<ul> <li>Inadequate billing process and revenue reconciliation</li> <li>Inadequate inventory management controls and processes.</li> <li>The combination of these control deficiencies creates an environment that is conducive for fraudulent activities.</li> </ul>			Target Date: January 31, 2022  Responsible Party: Associate Director for Shared Resources
5.	Subsidy for Cancer Center members has not been consistently applied.  Review of storage charges for the period July 1,2020 – January 6, 2021 found seven PI's, who are Cancer Center members, that were charged full rate instead of the subsidized rate.  Cancer Center members receive a subsidy funded through the National Cancer Institute (NCI) grant. The methodology for the application of the subsidy has been to off-set against 50% of the storage charges. No reconciliation has been performed to determine outstanding refunds owed to cancer center members.  CAP 250-11 "Sales & Service Center(s) Recharges, External Sales & Service of Education Related Activities, & Common Cost Allocations": sales and service center activities are required to charge all users consistently and equitably with the same approved rates and for external users, applicable F&A.	Inconsistent subsidy application increases the risk of non-compliance with University policies.	A reconciliation should be performed to determine refunds owed to cancer center members. As part of this process, identify any federally sponsored projects that was over-charged and appropriate adjustments to the grants should be made.	Action:  Difficulty in proper allocation of NCI-funded support has been addressed by migrating from MyCores to iLab core management software.  The mechanism for utilizing NCI-funded support has been impacted by the COVID-19 pandemic for all HDFCCC cores. It has been reapplied to direct salary expenses rather than copayments.

<u>No.</u>	<u>Observation</u>	Risk/Effect	Recommendation	<u>MCA</u>
				Subsidy to cancer center members will resume once the new recharge proposal is created and approved. As part of this process, the Tissue Core will implement a monthly validation of the list of members in iLabs.  Target Date: September, 2021  Responsible Party: Associate Director for Shared Resources
6.	<ul> <li>Volume and expenditure forecasts calculations used in the FY2019-2020 Recharge Proposal were not consistently supported or validated based on prior figures.</li> <li>a. The FY 2019-2020 Recharge Rate Proposal calculation projected that annual expenditures would equal approximately \$697,755. However, the actual expense for FY 2020 was \$990,770. The expenses were underestimated by \$293,015, impacting the recharge recovery.</li> <li>b. Review of the volume projections used in the FY 2019-2020 Recharge Rate Proposal noted that</li> </ul>	Inaccurate projections of volume and expenses can result in incorrect recharge rate and increases risks of costs not being fully recovered.	<ul> <li>Management should perform trend analysis to ensure that projected expenditures and volume projections are reasonable</li> <li>Management to establish requirements to ensure volume</li> </ul>	Action: A new recharge proposal will be created that accurately reflects costs and revises projected volume estimates. These will be based on analyses of current operations (beginning Jan. 2021).

Project #21-032

<u>lo.</u>		<u>Obser</u>	<u>vation</u>		Risk/Effect	Recommendation	MCA
	there was instance support these has not been biospecimen support these projections co.  We performed and determine the real projections. It was categories where increase without suppojection, please	ufficient supprojections a full invenstorage, the uld not be analysis be sonablenes noted that volume prosufficient be	oporting documents. For example accuracy of validated.  ased on FY2 as of the volutions shows the supposes to supposes.	ole, since there of for inventory  O billing to several wed significant the		projections are supported by adequate documentation.	Target Date: August 31, 2021  Responsible Party: Associate Director for Shared Resources
	Item Description	Actual Qty Billed per MYCore	Qty per FY 2019-2020 Recharge Proposal	Under/(Ov er) Projection			
	Archive Blocks, collection	34	400	(366)			
	Surgical Collection	270	1,250	(981)			
	Aliquoting, sample	135	450	(315)			
	DNA/RNA Extraction, sample	7	1,100	(1,093)			
	Serum or Plasma Processing, sample	2,513	4,100	(1,587)			
	Additionally, there monitor projected identify reasons for	service vo	lumes agains	st actuals and			

N	Observation	Risk/Effect	Recommendation	MCA
	CAP 250-11 "Sales & Service Center(s) Recharges, External Sales & Service of Education Related Activities, & Common Cost Allocations": Rate methodologies and rates must be accompanied by sufficient justification, detail and documentation so reviewers can easily follow the rationale and calculations supporting proposed rate structures.			
7.	<ul> <li>Standard Operating Procedures (SOPs) for key financial processes have not been established or documented.</li> <li>During the review, it was noted that documented SOPs for key financial processes such as billing, inventory management, and reconciliation have not been developed. A&amp;AS met with the B&amp;T Core Manager several times in order to obtain an understanding of SOPs for key financial processes, some of which were complex.</li> <li>The B&amp;T Core Manager subsequently separated from the University during the audit and as a result A&amp;AS was limited in its validation of B&amp;T Core's processes and procedures. For example, A&amp;AS tried to obtain procedures on how billing is done for biospecimen storage from other personnel, however, no one knew how the storage billing was performed.</li> </ul>	The lack of documented SOPs increases the risk of inconsistent or erroneous practices for capturing financial transactions as well as impacting continuity of business operations.	Management should document SOPs for key business operations and financial management processes.	Actions: We will document SOPs for billing, inventory management, and reconciliation. This task will be assigned to the new manager when they are hired (anticipated Summer 2021).  Target Date: January 31, 2022  Responsible Party: Associate Director for Shared Resources

No.	<u>Observation</u>	Risk/Effect	Recommendation	MCA
8.	Roles and responsibilities over B&T Core's financial management and oversight processes are not clearly defined or documented.  Currently, the governance structure over the B&T Core is shared between the Cancer Center and Biospecimen Resource Program (BIOS). Based on interviews with key personnel it was noted that the Cancer Center is financially responsible for the B&T Core while the BIOS manages the operations and billing for services, resulting in a misalignment between decision-making authority and financial management.  Roles and responsibilities are not clearly defined to ensure effective oversight and monitoring of activities, including processes such as financial review and approval, monitoring of expense and billing. The lack of clarity on the roles and responsibilities has impacted timely decision-making; lack of accountability for financial deficits and delayed development of a strategy for deficit resolution.	Lack of clarity on the oversight and monitoring of the B&T core activities can contribute to ineffective decision-making and financial management.	Management should clearly define roles and responsibilities for the Cancer Center and BIOS regarding operational and financial oversight and monitoring to ensure that accountability is appropriately established and aligned.	Actions: The governance has been consolidated within HDFCCC. Roles and responsibilities of leadership have been defined clearly.  Action Completed
9.	An authorized deficit resolution business plan is not in place.  B&T Core has been operating with a net deficit balance since at least 2014. As of FY 2020, the B&T Core accumulated deficit balance was at \$1,022,474. While the B&T Core recharge rate plan has a five-year amortization of the deficit balance, it does not have an authorized deficit resolution business plan in place. A draft business plan was prepared in July 2019, but it has not yet been finalized resulting in mitigation plans not being implemented to address the structural deficit and to ensure the long-term financial viability of the B&T Core.	In the absence of an authorized business resolution plan there is no strategic plan and accountability for improving the financial stability of the core and the risk of continued operations in deficit is increased.	A deficit resolution business plan should be fully developed and mitigation actions should be undertaken to resolve the deficit.	Action: The new recharge proposal will incorporate deficit reduction through user fees, with approval from the budget office. We will also explore options for deficit reduction through institutional investment to

No.	<u>Observation</u>	Risk/Effect	<u>Recommendation</u>	<u>MCA</u>
	Dan Oannan Administrativa Dalian 050 40 "Dafisit			reduce the impact
	Per Campus Administrative Policy 250-12 "Deficit Monitoring and Resolution:" "Deficits may be carried"			on user fees.
	forward to the next fiscal year for non-sponsored project			Target Date:
	funds only if an authorized deficit resolution business plan is in place and the unit is in compliance with the			August 31, 2021
	plan".			Responsible
				Party:
				Associate Director
				for Shared
				Resources

## APPENDIX A

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

- Reviewed relevant UC and local UCSF campus policies and procedures.
- Interviewed personnel and performed walkthroughs to get an understanding of activities under examination.
- Performed a 5-year analysis of the revenues and expenses.
- Determined if the recharge rates used by the B&T Core was approved by BRM.
- Determined if appropriate separation of duties was in place.
- Selected a sample of services performed from the CRC master calendar and verified whether billing was done consistently and accurately.
- Determined whether volume projections used in the FY2019-2020 recharge rate proposal were supported by adequate documentation.
- Determined if volume projections used in FY2019-2020 recharge rate proposal was reasonable by comparing it to actual FY 2020 volumes obtained from the B&T Core billing data.
- Verified whether Cancer Center members received subsidy for storage billed.
- Reviewed storage billed and verified whether billing was done consistently and accurately.
- Selected a sample of services performed from the CRC master calendar and verified whether REDCap was updated.