Stem Cell Departmental Review

Audit No. MDA22-218

Executive Summary

The Department of Stem Cell Transplantation is one of the largest facilities in the world for stem cell transplants, performing more than 850 transplants and cell therapy infusions each year. The Department consists of approximately 330 full time employees, including 33 faculty members, and generated $81.5M in gross patient revenue during Fiscal Year (FY) 2022. The Department offers a range of services through their cell processing laboratory, including stem cell collection, manufacturing, infusion, and treatment of the patient. Additionally, the Department provides comprehensive stem cell transplant services including a matched unrelated donor program, which has earned the institution recognition as a specialized center for stem cell transplants by the National Marrow Donor Program.[1]

Audit Results

The Department has controls and processes in place for certain financial, grants and personnel management activities. We did, however, identify control gaps that require management's attention to mitigate the related risks. A summary of strengths and opportunities for improvement are outlined below:

AREA	Strengths	Opportunities
Financial and Asset Management	• STAT Sample transactions are reviewed and certified	• Protect and Safeguard IT assets • Submit missing/stolen asset forms timely
Grants Management	• Progress/financial reports are submitted timely • Expenditures appear allowable per the grant agreement	• Ensure effort reporting reflects actual effort spent
Charge Capture	• Laboratory Service and National Marrow Donor Program revenues are consistently and adequately reconciled	• Reconcile professional charges daily • Ensure charges occur for billable services
Clinical Trials		• Ensure timely billing for trials
Personnel Management	• Licenses/certifications are monitored	• Ensure timecards are approved as required • Ensure leave is accurately recorded

Further details are outlined in the Detailed Observations section. Less significant issues were communicated to management under a separate cover.

[1] Source: mdanderson.org

Management Summary Response:
Management agrees with the observations and recommendations and has developed action plans to be implemented on or before November 15, 2023.

Appendix A outlines the objective, scope and methodology for project.

The courtesy and cooperation extended by the personnel in Stem Cell Transplantation are sincerely appreciated.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA, CHIAP
Vice President & Chief Audit Officer
November 23, 2022

DETAILED OBSERVATIONS		
1. Ensure Protection over Information Technology (IT) Assets		**Ranking: HIGH**
At the time of our review, the Department had 33 computers and 34 mobile devices which did not have sufficient protective measures installed. For 9 of the 34 mobile devices, the users indicated that PHI was maintained on the device. The Information Resources Security Operations Manual requires the protection of all institutional computing devices that view or store confidential information. Without these device management protections, sensitive information could be accessible to unauthorized individuals.	Recommendation: Management should coordinate with the Information Technology department to ensure all institutional computing devices are sufficiently protected. Management should also coordinate with Institutional Compliance concerning actions needed related to any of the assets disclosed as having PHI.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 12/31/2022 We are putting a quarterly report review on the calendar to ensure all assets have required protective applications.
2. Report Missing and Stolen IT Assets as Required		**Ranking: HIGH**
The Asset Control Manual requires reporting of missing and stolen assets to maintain accurate inventory records. As of June 2022, the Department had not filed the required forms for 5 missing and 3 stolen IT assets, consisting of computers, iPhones and a tablet. For 1 of the 3 stolen IT assets the user indicated PHI was maintained on the device. When lost or stolen assets are not reported as required, the appropriate actions may not be taken to ensure timely mitigation of potential risks.	Recommendation: Management should coordinate with the Information Technology department to ensure all missing or stolen assets are appropriately reported. Management should also coordinate with Institutional Compliance concerning actions needed related to any of the assets disclosed as having PHI.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 12/31/2022 We are putting a quarterly report review on the calendar to ensure all assets are accounted for and attestation forms are completed.

DETAILED OBSERVATIONS		
3. Enhance Effort Reporting		**Ranking: HIGH**
In some instances, it appears effort is certified based on payroll distribution instead of actual effort spent on a project. According to federal guidelines and the Institution's Effort Certification policy, employees must certify the accuracy of effort spent on sponsored projects. While payroll distribution describes the sources of an employee's salary, effort certification describes the employee's actual effort on a project. Non-compliance with federal regulations relating to effort reporting on federal grants may result in penalties and fines and possible loss of future funding for the Institution.	Recommendation: Management should enhance controls to ensure that certified effort, especially for federal grants, reflects actual effort spent on projects.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 11/30/2023 We will meet with respective faculty every effort cycle to ensure accuracy of their effort on the respective projects.
4. Strengthen Revenue Reconciliation Controls		**Ranking: HIGH**
The Department's revenue reconciliation processes are not adequate to ensure that charges are accurately captured, posted timely, and that evidence of reconciliations is maintained. • While department management performs certain charge capture activities, such as reviewing open encounters and workqueues, daily reconciliations comparing services provided to charges dropped are not performed. • While management indicated that the monthly revenue reconciliation process (OneConnect to the general ledger) is being performed, no evidence is maintained. As a result, we were unable to review this reconciliation process for adequacy. Institutional Policy requires that charges be reconciled daily. Additionally, institutional guidance requires that	Recommendation: Management should strengthen revenue reconciliation processes.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 2/15/2023 We will implement a daily reconciliation process in addition to our current activities and we will retain documentation to support the process.

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monthly reconciliations be performed between OneConnect and the general ledger, and that these be evidenced by supporting documentation. When daily revenue reconciliations are not performed, charges may not be captured for all services rendered, as evidenced in **Observation #6**. Additionally, when monthly reconciliations are not documented, management may not have assurance that these are being performed as required.		
5. Ensure Timely Billing for Clinical Trials		**Ranking: HIGH**
Prior to our audit, the Department and Clinical Research identified a billing error for a specific clinical trial. This error resulted in approximately $3M of unbillable costs. Based upon discussions with Clinical Research, Department Management, as well as other involved departments, the resolution of these costs is being addressed. With that understanding, we reviewed this trial in order to identify the potential root causes for the error's occurrence. From interviews conducted, it appears the error resulted from lack of timely billing and insufficient communication. When billing is not timely, the Institution may bear the cost of trials that should be covered by the sponsor.	Recommendation: Management should implement controls to ensure billing for clinical trials is timely.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 2/15/2023 As a result of the example provided, we have instituted bi-weekly meeting to ensur all invoicing and clinical trial billing reconciliation is performed timely.
6. Strengthen Charge Capture Processes		**Ranking: MEDIUM**
The Department is not consistently capturing charges for office and telehealth visits. Additionally, documentation for telehealth visits is not always complete (call duration) to allow for billing. Our review indicated the following:	Recommendation: Management should strengthen charge capture processes and controls to ensure that charges occur for billable services provided, and that documentation	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky

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• 18 telehealth visits without charges were identified. 16 of these telehealth encounters did not include the duration of the call within the medical record documentation. • 38 of 77 encounters reviewed were identified as billable services without associated charges. Charges were subsequently dropped after these were brought to management's attention. When services are provided but not charged, loss of revenues occur. Additionally, without complete documentation in the medical record, there is an increased risk that billable encounters may not be sufficiently supported.	is adequate to support billable telehealth visits.	Due Date: 2/15/2023 We will educate providers to ensure that they are aware of required documentation for telehealth encounters. We will also perform daily charge capture reconciliations as indicated in Observation #4. Finally, we will include the charge capture reconciliation documentation with our monthly financial documents.
7. Enhance Annual Capitalized Asset Inventory Process		**Ranking: MEDIUM**
For FY21, 3 areas within the Department did not complete their annual inventory scan and certification. Per the Institution's Asset Management Manual, all divisions and departments are required to complete an annual inventory of their capitalized and controlled assets. When the annual inventory is not completed as required, to ensure capitalized and controlled assets are accounted for each year, there is an increased risk that theft or losses may occur and not be detected in a timely manner.	Recommendation: Management should ensure that the annual asset inventories are completed each year.	Management's Action Plan: Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 11/15/2023 As part of our asset management process we will ensure that all assets are scanned, and the attestation is signed. We have already started discussions with the Division asset team due to the many conflicting spreadsheets received by the

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		department, ie. One says scanning is complete and the next says scanning is not complete resulting in confusion particularly in a setting where there are a large number of assets (clinical and research laboratories).
8. Ensure Leave is Accurately Recorded		**Ranking: MEDIUM**
The department is not capturing all leave within Kronos. Our review identified the following: • One employee did not have Paid Time Off (PTO) entered into Kronos for three days of leave taken • For one employee, 20 hours of PTO were incorrectly entered into Kronos on a single day instead of being separately entered as 10 hours on two consecutive days. Per institutional policy, both timekeepers and managers are responsible for reviewing all data sources to ensure timecards are accurately coded. When leave is not recorded accurately, accruals could be over/under stated.	<u>Recommendation:</u> Management should enhance controls to ensure leave is accurately recorded in Kronos. Additionally, Management should consult with Human Resources to determine if leave balances for the identified individuals needs to be revised to accurately reflect leave taken.	<u>Management's Action Plan:</u> Responsible Executive: Dr. Welela Tereffe Division/Department Executive: Dr. Elizabeth Shpall Owner: Suzanne Dworsky Due Date: 2/15/2023 We will perform a reconciliation between Kronos and Webschedule monthly as part of our financial review.

Appendix A

Objective, Scope and Methodology:
The objective of the review is to provide a general assessment of the financial, administrative, and compliance controls within the Department. Our review of the Department covered personnel/Leave management, financial management, asset management, revenue cycle and grants and contracts processes in place for the period of September 1, 2021 thru June 30, 2022 and any related periods. Our procedures included the following:

- Interviewed key personnel and reviewed relevant organizational policies
- Examined personnel management processes for credentialing, timekeeping and extramural leave to determine if institutional leave management guidelines were followed.
- Reviewed the protection of IT assets.
- Reviewed the results of the most recent annual physical inventory scanning and assessed processes and controls over capitalized and controlled assets
- Tested procurement card transactions and reconciliations for compliance with institutional guidelines.
- Reviewed documentation to ensure required monthly certification of selected expenditures
- Examined review processes in place over purchased services
- Reviewed grant administration processes related to effort reporting and certification; allowable expenditures; cost allocation; subrecipient monitoring; timely progress reports; and use of material transfer agreements.
- Reviewed charge capture processes including workqueues, open encounters, and reconciliations.
- Reviewed clinical trial invoicing and payments.
- Examined Velos/Stafa and the Stem Cell Match Unrelated Donor Program software user access.

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*. The internal audit function at MD Anderson Cancer Center is independent per the *Generally Accepted Government Auditing Standards (GAGAS)* requirements for internal auditors.

Audit Team: Megan Dotson (Lead), Rachel Bourns, Anthony Buancore, Melissa Prompuntagorn, Leslie McDaniel, Randy Ray

Number of Priority Findings to be monitored by UT System: *None*
A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"