EXECUTIVE SUMMARY

The Lymphoma & Myeloma Department is renowned internationally for the diagnosis, treatment, and research of diseases focused on lymphoma, myeloma, and blood disorders that affect the body’s blood and lymph systems. The Department is one of few cancer centers in the nation with a vast range of clinical trials and access to innovative therapies utilized to create customized treatment plans for each patient and committed to finding a cure for patients diagnosed with lymphoma or myeloma through cutting edge clinical and translational research and patient care.

Internal Audit performed a general assessment of the financial, administrative, and compliance controls within the Lymphoma & Myeloma Department. The scope of our review included activity between September 2020 and August 2021.

Audit Results

What We Found

Overall our review found that the Department has controls and processes in place for key personnel and financial management activities such as leave management, credentialing, revenue cycle/charge capture and monthly stat/expenditure sampling. We did, however, identify opportunities for improvement in the following areas:

<table>
<thead>
<tr>
<th>Area</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Financial Management</td>
<td>High</td>
</tr>
<tr>
<td>Effort Reporting</td>
<td>High</td>
</tr>
<tr>
<td>Procurement Cards</td>
<td>Medium</td>
</tr>
</tbody>
</table>

What We Recommend

We recommend that management should:

- Strengthen controls over financial management of clinical trials.
- Implement procedures to ensure actual effort is reported.
- Enhance procurement card reconciliation processes.

During the course of our review, we also identified an observation related to idle and excessive IT assets as well as the protection of IT assets that has been communicated to the Division of Cancer Medicine leadership under separate cover.

---

1 Source: Lymphoma & Myeloma website
Further details are outlined in subsequent sections of this report. Other less significant opportunities for improvement were communicated to management separately.

**Management Summary Response:**
Management agrees with the observations and recommendations and has developed action plans to be implemented on or before August 31, 2022.

**Appendix A** outlines the methodology for this project.

The courtesy and cooperation extended by the personnel in the Lymphoma & Myeloma Department are sincerely appreciated.

Sherri Magnus, CPA, CIA, CFE, CRMA, CHIAP  
Vice President & Chief Audit Officer  
March 28, 2022
Observation 1: Strengthen Controls over Clinical Trials Financial Management

Ranking: HIGH

The department needs to strengthen controls in place over the financial management of its clinical trials. Our review of five active clinical trials indicated issues related to billing errors, monitoring of sponsor payments, and accurate and timely invoicing of sponsors. Specifically, we noted the following:

Deficit Resulting from Drug Billing Error
In one instance, the department incurred a deficit of approximately $2.2M. This deficit occurred when Medicare requested reimbursement for study drug costs incorrectly billed, because the drug was being provided at no cost by the sponsor. The deficit was ultimately resolved.

Sponsor Payments not Received
Payments totaling $253,000 have not been received from a sponsor for accrued patient enrollments dating back to 2018. According to management, the study monitor changed. Delays occurred when the study team had challenges in identifying a new monitor. Management has resubmitted the invoice for review and approval.

Maximum Budgeted Enrollment Not Met
The department did not meet anticipated study enrollment for one trial. When the enrollment was not met, the maximum payment was not received, resulting in a missed opportunity of approximately $64,000 of agreed upon budgeted payment from the sponsor.

Institutional Policy states that department management should develop an appropriate internal controls structure for managing the department’s financial resources. Without adequate financial management of its clinical trials, there is an increased risk that the institution will bear the financial burden for the department’s trials.

Recommendation: Management should strengthen controls over the financial management of clinical trials, including timely and accurate billing to sponsors. Additionally, management should ensure that budgeted enrollment targets are met as agreed upon.

Management’s Action Plan:
The accounting team will ensure adherence to the invoicing schedule as outlined in the fully executive contract. To ensure compliance, the accounting team will include on the monthly PI summary report the invoicing recurrence as outlined in the fully executed contract to ensure invoicing remains on track and there is no delay in invoicing the sponsor. In addition, the accounting team will provide regular status updates of what was billed, not billed, outstanding to mitigate any future risk. Note: Future contact language will be included to mitigate disputed invoice resolution to ensure there is no delay in payment from the sponsor.

Executive Leadership Team Member: Dr. Welela Tereffe
Division/Department Executive: Dr. Christopher Flowers
Owner: Kimberly Corbett
Implementation Date: August 31, 2022
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 for federal grants reflects actual effort spent on projects.

**Management’s Action Plan:**
*Management will coordinate with the principal investigators to ensure that actual effort is captured and reported as required by federal regulations and institutional policy.*

Executive Leadership Team Member: Dr. Welela Tereffe  
Division/Department Executive: Dr. Christopher Flowers  
Owner: Kimberly Corbett  
Implementation Date: August 31, 2022

The procurement card reconciliation process is not adequate to ensure that transactions are appropriate, and the review and approval process occurs as required. For example:

- Recurring transactions (copier lease, journal subscription) were charged to two individuals’ procurement cards after they had transferred out of the department.
- Three transactions for membership dues totaling $1,400 were incorrectly charged to the department by a cardholder who is not an employee of the department.
- The Procard Monthly Reconciliation Logs did not have the required two levels of review and approval.
- One reconciliation was not reviewed by the Supervisor until six months after it was prepared.

Institutional Policy and the Procard User Guide states that reconciliations should be performed, reviewed and approved on a monthly basis. The Procard User Guide also states that when a
cardholder transfers or terminates employment, the cardholder’s supervisor should destroy the card and notify the Procard Administrator to deactivate the account. When procurement card transactions are not reconciled, reviewed and approved in a timely manner, errors and irregularities may occur and go undetected.

Recommendation: Management should establish controls to ensure that timely reconciliations are performed, with the required review and approvals. Also, management should establish a process to ensure that procards are deactivated when employees transfer or terminate employment.

Management’s Action Plan:
Management will implement two levels of review and approval for monthly statements to comply with Procard guidelines. Procard holders will be retrained on the Institution’s Procard User Guide to ensure compliance. When employees leave the department, management ensure that the procard is deactivated by including it was part of the exit process in coordination with the institutional ProCard Administrator.

Executive Leadership Team Member: Dr. Welela Tereffe
Division/Department Executive: Dr. Christopher Flowers
Owner: Kimberly Corbett
Implementation Date: August 31, 2022
The objective of this review was to provide a general assessment of the financial, administrative, and compliance controls within the Department. Testing periods varied based upon the area or process reviewed; however, all selected transactions occurred between September 2020 and August 2021, unless otherwise noted.

Our methodology included, but was not limited to, the following procedures:

- Interviewed key personnel and reviewed relevant organizational policies to understand financial and administrative processes within the Department.
- Examined timekeeping and leave records to determine if institutional leave management guidelines were followed.
- Tested procurement card transactions and reconciliations for compliance with institutional guidelines.
- Reviewed documentation to ensure required monthly certification of selected expenditures.
- Reviewed the results of the most recent physical inventory scanning and assessed processes and controls over assets.
- Reviewed IT assets reported as non-encrypted and validated current status.
- Reviewed charge capture processes including daily and monthly reconciliation.
- Reviewed grants and contract processes including effort reporting, grant expenditures, and related costs.
- Reviewed invoicing and payments related to clinical trials.

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.

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.”