UT Southwestern
Medical Center

Research Participant Payment Card Audit

Internal Audit Report 20:55

April 1, 2020

Executive Summary

Background

The UT Southwestern Medical Center (Medical Center) clinical research program supports the mission to "promote health and a healthy society that enables achievement of full human potential." Payments to research participants are defined in the study agreement between the Medical Center and the study sponsor and can vary based on the complexity of the study requirements and length of the study participant's expected commitment. In the 13 months from September 2018 through early October 2019, 26,000 transactions were processed in the system totaling $1.4M. From September 2018 through December 2019, there were approximately 750 card replacement transactions where research participant issued cards were closed and a new card was issued at the cardholder's request.

Study agreements are reviewed and approved by the Institutional Review Board (IRB). The IRB has the responsibility to review proposed research in order to ensure that the rights of research participants are protected and that risk of harm is minimized. The Sponsored Programs Administration's (SPA) Industry Clinical Trials Contracts (CTA) group, reviews and negotiates the terms of industry contracts between the Medical Center and for-profit companies, when a clinical research study will be conducted with monetary support from an associated entity.

The Greenphire Clincard System is used to administer payments to clinical research participants once the study contract, the participation payment schedule and the patient informed consent have been approved. The system, which was implemented in 2015 through a UT System contract, was implemented in 2015, is currently managed by the SPA Clinical Trial Accounting and Analysis team. Velos, is the primary system used for information on clinical research studies and the research subjects enrolled in the studies. When patients consent to participate in a study, they are registered with the study in Velos and then set up in the Clincard system for participant payments as defined in the sponsor agreements.

Scope and Objectives

The Office of Internal Audit has completed its Research Participant Payment Card Audit. This is a risk based audit added to the fiscal year 2020 Audit Plan based on risk assessment. The audit scope period included activities of the Greenphire Clincard System from September 2018 to December 2019. Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, data analytics and substantive testing of selected transactions.

We conducted our examination according to guidelines set forth by the *Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.*

Fieldwork was initiated, performed, and completed during January through March 2020 and consisted of evaluation of effectiveness and efficiency of the following primary program objectives:

- Adequate program oversight and financial management controls are in place,
- Payments are accurate and complete and processed in accordance with approved research protocols and budgets,
- Monitoring activities to identify payment transactions and card activities that require additional follow up with research study teams,
- Appropriate system controls, including user access and interfaces, are in place.

Conclusion

The research participant payment card administration and system functionality requires improvement, as the program lacks defined processes and controls needed to effectively track and monitor research participant payment activities. Standard user account access definitions were not established and are in development, however, monitoring of compliance with these definitions needs to be developed. The research payment program policies and procedures need to be implemented to define roles and responsibilities and clinical research team requirements for study set up, participant set up and payment processing. In addition, department and SPA monitoring controls need to be developed to ensure compliance with procedures and sponsor payment arrangements. System control improvements are needed for consistent data requirements, appropriate system security access, and proper interfaces to ensure accuracy of research participant payments and to prevent misappropriation of funds.

In 2019, concerns were raised by UT Southwestern and other UT components about the limitations of the Greenphire system resulting in a UT System led Request for Proposal (RFP) and the selection of a preferred vendor. However, after assessment of the system controls and security features by UT Southwestern and the other UT components, it was determined that the new system chosen did not meet the needs of the institutions, so UT Southwestern will initiate its own RFP process. SPA, in coordination with key research partners, Supply Chain, and other stakeholders, is developing a project plan to confirm existing system functionality, define required functional and technical requirements, and evaluate improvements to the existing tool or other comparable systems. This plan is scheduled to kick off in mid-April with a formal RFP to be issued in June 2020 and a decision for an improved payment card system by October 2020 that meets the needs of the Medical Center.

Executive Summary

Included in the table below is a summary of the observations noted, along with the respective disposition of these observations within the Medical Center internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions.

Priority (0)	High (2)	Medium (3)	Low (0)	Total (5)

The key improvement opportunities are summarized below.

1. **Enhance or Implement a Robust Research Payment System -** The current system used for providing payments to research subjects is currently not set up sufficiently to provide internal controls to prevent inaccurate reporting or misappropriation of funds.

2. **Develop Program Oversight and Monitoring -** Adequate program oversight does not exist for ensuring the clinical research teams have properly set up payment accounts and paid participants in accordance with protocol requirements. Lack of clearly defined procedures, defined roles and responsibilities and monitoring can result in financial, operational and compliance errors and irregularities going undetected for an extended period.

3. **Develop Robust Mandatory New User and Refresher Training Programs -** New user and refresher training is not available to educate research team members on system and payment transaction processing requirements. Training programs provide users with instructions to ensure procedures are consistently followed. Lack of clearly defined training increases the risk of financial, operational and compliance errors and irregularities going undetected.

4. **Ensure Completion of Payment Card Industry (PCI) Compliance Training and Annual Reporting Requirements -** Required PCI new user and refresher training for handling credit cards has not been completed for Clincard users. In addition, each department using the Clincard system has not completed the annual required self-assessment guide. Lack of understanding of proper handling requirements for credit cards can result in theft or loss of funds, non-compliance with PCI requirements and may impact reputational risk.

5. **Ensure Users Process Sponsor Payments for Only Medical Center Sponsored Studies -** Clincard payments are processed on behalf of sponsors outside of the Medical Center's Clincard account, by research team members and cannot be accessed by the SPA team for monitoring increasing the risk of inaccurate or inappropriate payments going undetected for an extended period and reputational risk.

Executive Summary

Management has plans to address the issues identified in the report and, in some cases, has already implemented corrective actions. These responses, along with additional details for the key improvement opportunities listed above are listed in the Detailed Observations and Action Plans Matrix (Matrix) section of this report.

We would like to take the opportunity to thank the departments and individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,

Valla Wilson, Vice President for Internal Audit and Chief Audit Executive

Audit Team:
Elias Dib, Senior Internal Auditor
Van Nguyen, Supervisor Internal Audit
Melinda Lokey, Director of Internal Audit

Executive Summary

cc: Melody Bell, Assistant Vice President, Academic Information Systems
Deepika Bhatia, Director, Compliance Research and Academics, Office of Compliance
Byron Davis, Chief Information Security Officer, Information Security
Arnim E. Dontes, Executive Vice President, Business Affairs
Lance Holmes, Financial Analysis Manager, Sponsored Programs Administration
Sharon Leary, Assistant Vice President, Accounting and Fiscal Services
W. P. Andrew Lee, M.D., Executive Vice President for Academic Affairs and Provost, Dean, University of Texas Southwestern Medical School
Megan Marks, Ph.D., Assistant Vice President, Sponsored Programs Administration
Marc E. Milstein, Vice President, Information Resources and Chief Information Officer
Heather Mishra, Associate Vice President, Academic & Administration Information Resources
Rhonda Oilepo, Director, Human Research Protection Program
Adolfo Ortuzar, Director, IR Operations and Compliance, Academic and Administrative Information Resources
Wendy Pechero, Assistant Director, Research Operations
Wade Radicioni, Director of Operations and Analytics, Academic Affairs
Natalie Ramello, Vice President and Institutional Chief Compliance Officer, Office of Compliance
Nancy Rollins, M.D., Associate Dean, Clinical Research
Nathan Routen, Information Security Architect, Information Security
David W. Russell, Ph.D., Vice Provost and Dean for Research
Michael Serber, Vice President, Finance and Institutional Chief Financial Officer
Cameron Slocum, Vice President and Chief Operating Officer, Office of Academic Affairs
Thomas Spencer, Ph.D., Assistant Vice President, IR Operations and Compliance, Academic and Administrative Information Resources
Julia Spesivtseva, Director, Clinical Research Services

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High 🟡 **1. Enhance or Implement a Robust Research Payment System** The current system used for providing payments to research subjects is currently not set up sufficiently to provide internal controls to prevent inaccurate reporting or misappropriation of funds. Internal control system deficiencies include: • Conflicting access allows the same user, including Principal Investigators (PIs), to request and approve participant payments. • The Clincard system has data logic that does not allow proper interface to the other primary research systems (Velos and eIRB) to facilitate monitoring and consolidated reporting of clinical research activities and increases the risk of incorrect or fraudulent payments. • The system is not set up on active directory so that terminated employee access is automatically removed. .	1. Continue with plan to evaluate other system options through an RFP process for the consideration of implementing a new system with sufficient controls. 2. In the interim, coordinate with vendor and Information Resources to correct and implement the following system controls: a. Clearly define Clincard system access user roles and responsibilities by establishing appropriate account and security permissions and removing access roles with conflicting duties. b. Develop procedures to ensure consistent application of the permissions to research study team members. c. Define periodic procedures to review system access and confirm appropriate segregation of duties are in place.	**Management Action Plans:** 1. We will define key system requirements and processes required in a new system. The RFP is planned for June 30, 2020 with a final decision by October 31, 2020. Based on the results of the RFP process, decision on system to be used going forward will be made. 2a. We reviewed system access and initiated a communication plan to notify department leadership of the conflicting roles and to remove conflicting roles. 2b. We updated the new user access request process to confirm appropriate segregation of duties are in place at the time of set up. We will also consult with department leadership to set up alternative controls and additional monitoring controls if roles cannot be separated. 2c. Going forward as an interim solution, monthly monitoring will be implemented to confirm conflicting access is not assigned. Terminated employees and employees who transfer out of departments to other roles will be removed from Greenphire. SPA will contact the SAM group to routinely obtain termination reports.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
	d. Coordinate with Information Resources to implement Clincard system single sign-on to automatically remove access when a research team member leaves the Medical Center or moves to another role. 3. Coordinate with Information Resources to develop data reporting between Velos and Clincard to transfer key data between both systems and validate information entered into the Clincard system. 4. Update existing Clincard study and participant information to agree to Velos and eIRB to allow for consolidated reporting of research payment activities. 5. Develop reporting capabilities to promptly identify studies that have been closed in Velos and should be closed in the Clincard system.	2d. We will develop a plan to coordinate with the vendor and Information Resources to implement single sign-on for the Clincard system. 3. We will coordinate and develop a plan with Information Resources to define key fields between Clincard and Velos to aid in validation and coordinated reporting. 4. We will develop and execute a plan to update existing Clincard study and participant data to agree to Velos and eIRB to aid in consolidated reporting and monitoring activities. 5. As of March 2020, all studies reported as closed by the research teams were closed in Clincard. Going forward, we are coordinating with Information Resources to develop a report to identify studies that are closed in Velos and need to be closed in Clincard.

Observation	Recommendation	Management Response
		Action Plan Owners: 1. – 5. Assistant Vice President, Sponsored Programs Administration 1. – 5. Financial Analysis Manager, Sponsored Programs Administration 2d. – 5. Assistant Vice President, Academic Information Systems **Target Completion Dates:** 1. June 30, 2020 2a. Completed 2b. Completed 2c. May 31, 2020 2d. June 30, 2020 3. June 30, 2020 4. July 31 2020 5. June 30, 2020

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High 🟡 **2. Develop Program Oversight and Monitoring** Adequate program oversight does not exist for ensuring the clinical research teams have properly set up payment accounts and paid participants in accordance with protocol requirements. Key oversight activities requiring improvement: o Increased formal guidelines and procedures are needed to provide study team requirements for study and participant set up, processing of payments and account reconciliations. Study set up forms, the "Study Initiation Protocol" form (SIP), are not reconciled to the approved contract. Also the form does not allow for complex payment schedules to be correctly set up in the Clincard system. This results in increased risk of processing inaccurate payments. o Monitoring controls and defined responsibilities for monitoring have not been defined for SPA or department research personnel. Issues include study set up forms and protocols may not agree with the contract, and payment schedules may not agree to contractual terms.	1. Develop policies and procedures to clearly define key program operating procedures, including: a. Update the SIP form to allow for complex payment schedules to be summarized. b. Define responsibility to ensure the SIP form agrees to the approved study contract before being entered into the Clincard system. c. Set up of Clincard study requirements that are consistent with the approved sponsor contract. d. Participant set up requirements to ensure all Clincard transactions are made only to participants approved in Velos. e. Payments made in accordance with approved study contracts and validated and approved prior to entering into the Clincard system.	**Management Action Plans:** 1. We are developing institution-wide policies and procedures for the financial management of clinical trial subject payments. 2. A monitoring plan will be developed to include SPA responsibilities and department responsibilities. Will vet with Provost Office and key department research leaders to obtain feedback. 3. Procedures will include requirement for reporting to the IRB all payments made outside of the approved study contract. 4. Planned RFP will include required system functionality, including payment approvals, required supporting documentation and payment correction procedures. **Action Plan Owners:** 1. – 4. Assistant Vice President, Sponsored Programs Administration 1. – 4. Financial Analysis Manager, Sponsored Programs Administration 1. – 2. Assistant Director, Research Operations

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Lack of clearly defined procedures, defined roles and responsibilities and monitoring can result in financial, operational and compliance errors.	2. Develop monitoring procedures and designate institutional and department level responsible parties for key monitoring procedures to identify inaccurate or inappropriate payment transactions. 3. Ensure procedures include reporting to the IRB for approval all payments made outside of the provisions of the study contract. 4. Include in the planned RFP, improvements to system functionality, required payment approvals and required supporting documentation.	**Target Completion Dates:** 1. April 30, 2020 2. April 30, 2020 3. April 30, 2020 4. July 31, 2020

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium ● **3. Develop Robust Mandatory New User and Refresher Training Programs** New user and refresher training is not available to educate research team members on system and process requirements for processing Clincard payment transactions. Training programs provide users with instructions to ensure procedures are consistently followed. Lack of clearly defined training increases the risk of financial, operational and compliance errors and irregularities going undetected.	1. Define responsibility for administering training and develop new user and refresher training programs to provide guidance on required system procedures and defined roles and responsibilities. 2. Establish mandatory training requirements as a prerequisite before granting user access to the system. 3. Develop refresher training schedule and monitor completion for all users. 4. Provide reporting to department leaders and include escalation procedures for those users who do not complete required training.	**Management Action Plans:** 1. The SPA team is developing a formal training plan to include content coordinated from the IRB/Office of Human Research Protection Program, Office of Clinical Research Personnel, Academic Information Resources, Office of Compliance and other key stakeholders. 2. Security access procedures will be updated to require training before system access is granted to new users. 3. The refresher training schedule will be developed to include communication plan in April with kick off of training. We will coordinate with the SPA training team to develop plan to administer and track training completion in the Taleo portal for improved monitoring. 4. We will develop and execute a monitoring plan and identify reporting and escalation procedures to ensure timely training completion. **Action Plan Owners:** Assistant Vice President, Sponsored Programs Administration Financial Analysis Manager, Sponsored Programs Administration

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Target Completion Dates: April 30, 2020
Risk Rating: Medium ● 4. **Ensure Payment Card Industry (PCI) Compliance Training and Annual Reporting Requirements are Completed** Controls are not in place to ensure required PCI compliance training is conducted for new users as well as refresher training for existing employees. In addition, each department using the system has not completed the annual required self-assessment guide to confirm appropriate card handling security and protection procedures are in place. The Medical Center policy ISR – 155 *"Payment Card Industry Security"* requires all employees handling credit cards to be trained, have annual refresher training, and departments to complete an annual self-assessment questionnaire to ensure appropriate card handling procedures are in place. Lack of training and understanding of proper handling requirements for credit cards can result in theft or loss of funds, non-compliance with PCI requirements and may impact the ability to provide timely and convenient payment options for research participants.	Coordinate with Information Security to ensure completion of: a. The required annual self-assessment guide for all departments using the research payment system. b. New user and annual refresher training for all Clincard users.	**Management Action Plans:** In coordination with the Information Security team, we will provide listing of departments and users using the payment processing system for new user and refresher training and completion of the self-assessment guide. **Action Plan Owners:** Assistant Vice President, Sponsored Programs Administration Financial Analysis Manager, Sponsored Programs Administration Information Security Architect, Information Security **Target Completion Dates:** June 30, 2020

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium ● 5. **Ensure Users Only Process Payments for Medical Center Sponsored Studies** Clincard payments are processed on behalf of sponsors, and outside of the Medical Center's Clincard account, by research team members. These payments cannot be accessed by the SPA team and are not monitored by the research teams increasing the risk of inaccurate or inappropriate payments going undetected for an extended period and reputational damage in the event research participants are not paid appropriately by the sponsor.	1. Consider discontinuing practice of Medical Center research team members entering participant payments on behalf of sponsors and outside of the Medical Center's Clincard account due to the risks of misappropriation of funds and reputational risks. 2. Update policy and supporting procedures to require research team members to provide necessary information to study sponsors for processing of the participant payments when the Medical Center is not the approved payment processor. 3. For new study contracts, add requirement to specifically exclude research team members from processing Clincard payments on behalf of the sponsor and outside of the Medical Center's Clincard account.	**Management Action Plans:** 1. We will communicate with departments to identify studies where Medical Center employees are processing participant payments on behalf of the sponsor and not on behalf of the Medical Center. 2. We will add to the policies and procedures the restriction on processing payments directly on behalf of the sponsor. 3. We will update the study contract template to include restriction on Medical Center employees processing payments on behalf of a sponsor. **Action Plan Owners:** Assistant Vice President, Sponsored Programs Administration Financial Analysis Manager, Sponsored Programs Administration **Target Completion Dates:** 1. May 31, 2020 2. April 30, 2020 3. May 31, 2020

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

	Degree of Risk and Priority of Action	
Risk Definition- The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	**Priority**	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.
	High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.
	Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the subsequent pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.