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Date: November 14, 2019

To: Dr. Andrea Giuffrida, Vice President
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Dr. Joseph Schmelz, Assistant Vice President
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From: John Lazarine, Chief Audit Executive
Internal Audit & Consulting

Subject: Audit Report – Industry Sponsor-Funded Clinical Trials Billing (19-07)

As part of our FY 2019 Audit Plan, we recently completed the Industry Sponsor-Funded Clinical Trials Billing Audit. Attached is the report detailing the results of this review.

We appreciate the cooperation and assistance we received from the Clinical Research Trials Management and staff and the VPR CTO for the support provided throughout the review.

Respectfully,

John Lazarine, CIA, CISA, CRISC
Chief Audit Executive
Internal Audit & Consulting Services

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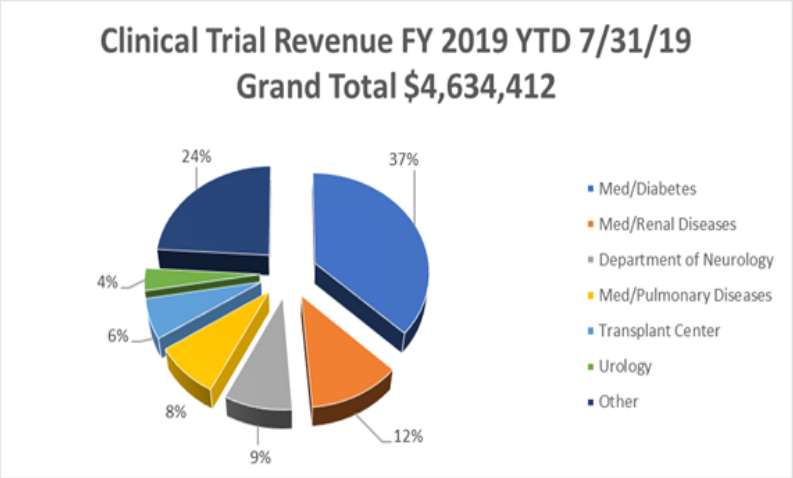
UT Health San Antonio
Internal Audit & Consulting Services

Audit Report (19-07)
Industry Sponsor-Funded Clinical Trials Billing
November 14, 2019

Summary of Audit Results

Background Information

Researchers at UT Health San Antonio manage over 96[1] clinical trials conducted outside the Mays Cancer Center which involve investigations of new drugs or medical devices on human subjects. Funding for these studies comes from industry sponsors such as pharmaceutical companies and federal agencies. As of fiscal year 2019 (9/1/2018-7/31/19), the Institution received approximately $4.6 million[2] in clinical trial revenue (97% from industry and 3% from grants). The chart below illustrates the departmental recipients of this revenue within the Institution.



In accordance with Institutional policy[3], "The Office of the Vice President for Research Clinical Trials Office (VPR CTO) is responsible for developing institutional policy and processes, training, oversight and monitoring of issues pertaining to budgeting and billing for clinical services provided as part of a research study. These operations must support applicable regulatory requirements (e.g. FDA and CMS) as well as University of Texas System policy and guidance."

"As part of an institutional review and approval prior to study activation, the VPR CTO will review billing plans for studies with clinical services, regardless of payor for the services – e.g. the sponsor, participant or insurance. This review and approval will be initiated prior to or at the time of IRB study submittal. The VPR CTO will also advise research teams on the applicability of this policy and institutional budgeting and billing processes in the event of a discrepancy between this policy and a government or private foundation grant policy, or conflicts with industry sponsors regarding interpretation and application of budgeting and billing rules." Outside of the VPR CTO, clinical trial billing is decentralized and is highly dependent on the Principal Investigator (PI) and associated research team to ensure compliance and accuracy. "The PI is responsible for ensuring that budgeting and billing of clinical services that are required by the study plan are performed according to applicable regulations and policies."

Objective and Scope

The objective of this audit was to review the adequacy and effectiveness of the processes and controls over the billing of industry sponsor-funded clinical trials, excluding those conducted by the Mays Cancer Center (Cancer Center). The scope of the review included industry sponsor-funded clinical trials ongoing during the period of September 1, 2018 to February 28, 2019. In order to test the close-out procedures, we expanded

[1] IA obtained this information from VPR CTO for informational purposes. The VPR CTO began tracking the number of clinical trials as of FY18. Prior to FY18 there was no central location to obtain a listing of all active clinical trials.
[2] The $4.6 million in clinical trials revenue does not include funding generated from the Mays Cancer Center. This figure was obtained from PeopleSoft primarily from three fund codes (48002 Clinical Studies (97%), 48007 Federal Clinical Studies (2%), and 48017 Non-NIH Federal Clinical Studies (1%)).
[3] UT Health SA's Handbook of Operating Procedures (HOP) Policy 7.7.1 'Budgeting and Billing for Clinical Services Provided as Part of Research Involving Human Subject'-"This policy applies to research whenever clinical items or services are provided as part of the protocol, regardless of funding source (industry sponsor, federal grant, foundation grant, or other source)."

the scope to include transactions from FY 17 and FY 18 (September 1, 2017 to February 28, 2019). The audit team selected a sample[4] of departments based on the amount of funding received and recorded in PeopleSoft and evaluated the design and implementation of controls over the billing of industry sponsor-funded clinical trials.

In order to gain an understanding of the overall billing process and procedures regarding these clinical trials, we interviewed management and staff from UT Health Physicians Patient Financial Services, Office of Sponsored Programs, Research Administration (CTO and IRB), School of Medicine (seven departments reviewed and Office of Research), Institutional Compliance and Privacy Office, and Health IT.

The focus of this review was to opine on the status of the controls currently in place over industry sponsor funded clinical trials. In order to determine whether appropriate billing controls were in place, we reviewed the billing processes of each department within our sample, which also included the system(s) utilized. Our review also included obtaining and analyzing pertinent supporting documentation, sponsor contracts (to include coverage analysis/budgets), and payment receipts/reconciliation documentation. We conducted our audit in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*.

Summary of Results

The audit found the adequacy and effectiveness of the processes and controls over the billing[5] of industry sponsor-funded clinical trials to be insufficient. Effective processes and controls ensure billings and payments are complete and accurate, and are compliant with pertinent federal and state requirements as well as UT System and Institutional policies and procedures.

Many of the findings from this industry sponsor-funded clinical trials billing audit were similar in nature to those reported in the clinical trials billing audit completed in 2013. We noted several action items were implemented as a result of the 2013 audit, including:

- Creation of the Research Administration - Clinical Trials Office (VPR CTO)
- Creation of Institutional policy 7.7.1 Budgeting and Billing for Clinical Services Provided as Part of Research Involving Human Subjects
- Creation of standard operating procedures under the VPR CTO for closing out study accounts.
- Implementation of a Clinical Trials Management System (Velos eResearch)
- The VPR CTO now develops the budget and coverage analysis to ensure fees charged for services adequately cover Institutional costs and are consistently applied across all the trials.

The control deficiencies noted within this audit, as well as the 2013 audit, have been categorized as opportunities for improvement relating to Governance and Financial Management.

Ineffective Governance and Oversight Over the Clinical Trials
Roles and responsibilities for clinical trial billing were generally defined within Institutional policy but not adhered to mainly due to various interpretations of the policy. Key financial oversight controls, such as the monitoring of clinical trials budgets, reconciliation of payments received, and project close-out procedures were generally not assigned, performed, or monitored.

Inadequate Financial Management of the Clinical Trials
Adequate processes and controls are not in place to ensure appropriate financial management for sponsor funded clinical trials.

[4] Sample included seven departments, representing approximately 75% of the total revenue collected during the period of September 1, 2018 through February 28, 2019.
[5] Industry sponsored clinical trials billings can occur in the following ways: (1) charges that are the responsibility of the funding sponsor, (2) charges derived from the clinical trial in-part is the responsibility of the patient and/or their insurance payor, or (3) charges derived from adverse effects of the trial may be divided between the sponsor and the patient payor.

Billing

- Invoicing documentation for sponsor payments was not consistently retained, instead allowing sponsors to auto-pay without submission of supporting documentation.
- Research teams rely heavily on information in the sponsors' databases for payment validation versus a UT Health institutional financial system of record (PeopleSoft).

Financial Review and Monitoring

- Reconciliations between study records and sponsors' payments were not consistently conducted.
- Reconciliations for completed clinical trials were not completed to ensure all payments were received from the sponsor.

The issues identified, along with recommendations and management action plans, are detailed in the attached table of Issues and Recommendations. Also included as Appendix A is a summary of the current control environment (e.g. working effectively, adequate or limited, or no control noted), for further reference, a glossary of clinical trial terminology is included in Appendix B. We would like to thank clinical research trials management and staff and the VPR CTO for the support and assistance provided during this audit.

Summary of Priority Findings

Based on the results of this audit, there were no findings considered to be Priority to the Institution. The UT System Internal Audit finding classification system includes Priority, High, Medium, or Low classifications. 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. Non-Priority Findings are ranked as High, Medium, or Low, with the level of significance based on an assessment of applicable risk factors and probability of a negative outcome occurring if the risk is not adequately mitigated.

Distribution
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Approved for Release  John Lazarine Chief Audit Executive, Internal Audit & Consulting Services

Issues and Recommendations

	Observation/Condition	Recommendation	Management Action Plan	Due Date	Responsible Party
Governance					
1	**Roles and Responsibilities** Roles and responsibilities for industry sponsor-funded clinical trial billing were generally defined within Institutional policy but not adhered to mainly due to various interpretations of the policy. Key financial oversight controls, such as the monitoring and oversight of clinical trials contracts, reconciliation of payments, and project close-out procedures were generally not assigned, performed, or monitored. Billing for clinical trials is complex and requires coordination and care to ensure that medical services performed as part of a clinical trial are billed appropriately. Clinical researchers routinely depend on the clinical services provided by healthcare organizations to perform conventional care or research care/procedures that are dictated by the research protocol. Inadequate controls over the billing process when medical services are performed could result in the participant or the participant's health insurance plan being incorrectly charged for services determined to be the responsibility of the clinical trial sponsor. Current policies and procedures adequately address budgeting and billing for clinical services provided as part of research involving human subjects, but do not address industry sponsored clinical research conducted outside the clinical practice. *Business Impact:* *Lack of financial monitoring and oversight may result in financial loss due to billing errors,*	(1) The VPR CTO should provide guidance and oversight for the initiation, administration and closure of all clinical trial studies (excluding those managed by the Mays Cancer Center.) (2) The VPR CTO should update and communicate to relevant parties' Institutional policy and supporting procedures to include guidance on all aspects of an industry sponsored clinical trial.	*We are committed to addressing the recommendations in the audit report and the plan of actions for all observations and recommendations is presented below.* *We will form an ad-hoc working group to address the issues identified in the audit report and formulate the institutional structure for managing and oversight of industry sponsored research billing. The working group will be co-chaired by Joseph Schmelz (AVPR) and Christopher Green (OSP). Subject matter experts from finance, business affairs, clinical trials operations, researchers and research team members and sponsored programs will be recruited to participate in the working group. [Target date for first meeting NLT: December 13, 2019]* *Key milestones for the project are as follows:* • *Identify process improvements to the current industry sponsor billing*	12/13/19 4/30/2020	*Dr. Joseph Schmelz, Assistant Vice President for Research Administration is responsible for all action items noted.*

	Observation/Condition	Recommendation	Management Action Plan	Due Date	Responsible Party
	penalties, and loss of new trials when guidance is not available for all aspects of an industry sponsored clinical trial. According to the HOP Policy 7.7.1, The Office of the Vice President for Research Clinical Trials Office (VPR CTO) is responsible for developing institutional policy and processes, training, oversight and monitoring of issues pertaining to budgeting and billing for clinical services provided as part of a research study. One of the services provided by the VPR CTO is billing sponsors for initial start-up fees. We identified one occurrence where the VPR CTO and the research team both billed a sponsor a start-up fee of $12,800 due to confusion on billing procedures. The sponsor identified the error and only paid the fee once. Prior to 2013, clinical trial budgets were not consistently prepared in accordance with the Office of Clinical Research directives. As a result, the VPR CTO now develops the budget and coverage analysis to ensure fees charged for services adequately cover Institutional costs and are consistently applied across all the trials. The VPR CTO does not perform any governance (oversight/monitoring) functions for sponsor-funded clinical trials beyond the initial setup. ***Risk Rating: High***		*process.* • *Identify process improvements to the payment for services within UT Health SA.* • *Develop and revise policy and procedures based on the recommendations and best practices.* • *Implement adjustments to information technology systems as needed.* • *Develop training program.* • *Develop metrics and monitoring plan.* • *Implement and assess impact.*	4/30/2020 6/30/2020 9/30/2020 7/30/2020 6/30/2020 10/31/2020	

Financial Management					
2	Adequate and effective processes and controls are not in place to ensure appropriate financial management of industry sponsor-funded clinical trials. **<u>Billing</u>** The audit identified inadequate controls regarding the invoicing and collection processes and procedures for six of the seven departments reviewed. Observations[6] noted include the following: • Sponsors who elected an auto-pay[7] plan did not provide payment documentation that would allow UT Health SA staff to reconcile services provided to payments received. This became especially difficult when the sponsor's payment included several clinical trials. • Research teams rely heavily on the sponsors' database for payment validation and retention of supporting documentation versus a UT Health Institutional system of record[8]. • One department uses a web application (not approved by the Office of the CIO) designed for small businesses to generate invoices and track payments and were unaware of a central system to use. • Inconsistent and unvalidated methods such	(1) Clinical trial research teams should fully utilize the Institution's clinical trial management system (Velos) to ensure there is a consistent document of record for clinical trial billing events. (2) Billing and collections should be properly monitored at the departmental and Institutional levels to reduce the risk of financial loss and possible reputational damage.	*Management action plans for all observations and recommendations are listed on pages 5-6*	*See Pages 5-6*	*See Pages 5-6*

6 Observations are depicted in Appendix A Summary of Control Environment for the seven departments reviewed.
7 Sponsor auto-pay refers to payments submitted by the sponsor electronically to UT Health SA when the sponsor has determined all pertinent milestones have been completed based on their own database.
8 UT Health SA's financial system of record is PeopleSoft, with the Mays Cancer Center utilizing the Velos System as their system of record for tracking clinical trial information to include financial transactions.

	as paper files, spreadsheets, a UT owned system (Velos[9]), and the sponsor's database[10] were used to track billing events. The inconsistent level of detail obtained and retained from each method creates a significant problem if the Institution were to attempt to track any of the financial transactions and reconcile to PeopleSoft[11] and in some cases, Epic[12]. *Business Impact:* *Due to the lack of pertinent documentation, internal and external audits may be difficult or unable to be completed.* **<u>Financial Review and Monitoring</u>** • Reconciliations between study records and sponsor payments were not consistently conducted by any of the seven departments reviewed. • Reconciliations for completed clinical trials were not consistently completed (for three of the four applicable departments) to ensure all payments were received from the sponsor. Departments relied on the sponsor's reconciliation to ensure all sponsor-paid services were accounted for properly. • Reconciliations were not conducted by any of the seven departments reviewed, or by the VPR CTO, to determine whether the appropriate parties had been billed for completed services. The VPR CTO reviews the payments and directs (scrubs) the charges in Epic to be billed for standard of				

9 Velos is a clinical trial management system that is used to assist the research team in the tracking and reporting of patient related activities.
10 A Sponsor Database is a database solely owned by a specific sponsor and accessed by the research team via web access for the duration of the trial.
11 PeopleSoft is the Institution's financial system of record.
12 Epic is the Institution's patient medical file system of record.

	care (billed to patient or insurance provider). However, there are no oversight processes in place to ensure the appropriate party is billed, such as independent validation through spot checks. *Business Impact:* *Lack of proper monitoring controls may lead to revenue loss and/or incorrect billing processes, which could result in the participant or the participant's health insurance plan being charged for services determined to be the responsibility of the clinical trial sponsor. Additional penalties could be assessed for billing errors involving a government entity.* ***Risk Rating: High***				

Appendix A
Summary of Control Environment

Clinical Trial Expected Process Controls for Sponsor Contract Agreements	*Adequacy of Internal Controls for 7 Research areas with Clinical Trials Sponsor Agreements for the period 9/1/18 - 2/28/19.*						
Clinical Trial Start-up/Enrollment	***A***	***B***	***C***	***D***	***E***	***F***	***G***
	Were controls adequate in regards to proper review and approval of sponsor contracts?						
Contract with Clinical Trial Sponsor							
Contract is reviewed to ensure budget is appropriate	✓	✓	✓	✓	✓	✓	✓
Contract is reviewed to ensure the coverage analysis (responsible for various fees) is accurate	✓	✓	✓	✓	✓	✓	✓
Milestones/budget uploaded into Institutional system of record for payment and tracking purposes	✓	X	X	✓	X	X	✓
Billing Process	*Were controls adequate to ensure all financial transactions were conducted in accordance with the contract and Institutional policy?*						
Invoicing Sponsor/contractor	***Invoicing Sponsor/contractor***						
Validation of charges to contract/budget	✓	✓	✓	✓	✓	✓	✓
Validation of charges to services performed (completed milestones)	✓	X	X	✓	X	X	✓
Collection of Payment from Sponsor/contract	***Collection of Payment from Sponsor/contract***						
Validation payment agrees with invoice (completed milestone)	X	X	X	X	X	X	✓
Validation payment (ach) agrees with completed milestone	X	X	X	X	X	X	✓
Oversight/Monitoring of Billing Process	***Oversight/Monitoring of Billing Process***						
Validation that invoicing and payments are correct	X	X	X	X	X	X	X
Monitoring of financial transactions to ensure all charges are appropriately billed and paid	X	X	X	X	X	X	X
Ensuring all financial transactions are properly documented and recorded in Institutional System of Record	X	X	X	X	X	X	X
Clinical Trial Close-Out Process	*Were controls adequate in regards to proper close-out procedures for sponsor contracts?*						
IRB Review	***IRB Review***						
IRB ensures all research protocol was followed	✓	✓	✓	n/a	✓	n/a	n/a
Financial Close-out	***Financial Close-out***						
Reconciliation of contract to completed milestones and payments received	✓	X	X	n/a	X	n/a	n/a
Percentage of Collected Revenue by Research Area Reviewed							
Sampled departments percentage of revenue collected ($1.5 million) for the period of 9/1/18 to 2/28/19	*36%*	*10%*	*9%*	*7%*	*6%*	*4%*	*3%*

Tickmark Legend for Chart

✓ *Controls were found to be adequate*

X *Controls were found to be inadequate thereby increasing the risk of financial loss*

n/a Not applicable

Additional Notes

For the period of September 1, 2018 to February 28, 2019 UT Health collected approximately $1.5 million in revenue for sponsor-paid clinical trials conducted outside the Mays Cancer Center. Audit reviewed 7 of the 27 research areas, representing approximately 75% of total revenue collected for the period under review. The remaining 25% was comprised of approximately 20 research areas representing 2% or less of the total revenue collected for the period under review.

Appendix B
Glossary of Clinical Trials Terminology

DEFINITIONS

Budget: The budget details the cost of each procedure required by the study.

Calendar: Schedule of all of the procedures required by the study that are assigned to each participant in the clinical trial.

Clinical Trial: A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Clinical Trial Agreement/Contract: An agreement between the Health Science Center and the financial sponsor. Consists of the protocol, budget and coverage analysis.

Coverage Analysis: Identifies the party responsible for the costs of each clinical service performed as part of a clinical trial. The coverage analysis indicates all of the procedures required by the study plan as well as the number of times a procedure is performed.

EPIC: Electronic medical record system used by UT Health San Antonio to store patient information and bill patients and insurance providers.

Industry sponsored clinical trials billings: Occur in the following ways: (1) charges that are the responsibility of the funding sponsor, (2) charges derived from the clinical trial in-part is the responsibility of the patient and/or their insurance payor, or (3) charges derived from adverse effects of the trial may be divided between the sponsor and the patient payor.

Informed Consent: A process in which researchers communicate with potential and enrolled participants about a clinical study. The goal of the informed consent process is to protect participants. All important information about the study must be given to the potential participant in a written document that is clear and easy to understand.

Informed Consent Form: The consent document which a participant signs prior to being enrolled in a clinical trial.

Milestone: Time points in the study in which the institution expects payment from the research sponsor.

Principal Investigator (PI): The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol: The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Research Team: Includes the Principal Investigator, Data Manager, Study Coordinator and Study Nurse who are responsible for administration of the clinical trial.

Sponsor: The organization or person who funds the clinical study and is responsible for analyzing the study data.

Standard of Care (SOC): Items and services related to the care of a patient participating in a clinical trial delineated as routine patient care (i.e., items and services that a third-party payer would cover if the patient was not enrolled in a clinical trial).

Velos: Clinical Trial Management System application that supports the management of common administrative, financial and research activities such as subject enrollment, calendars, budgets and various project statuses.