

The logo for UCIrvine, featuring the letters 'UCI' in a large, bold, serif font, followed by 'RVINE' in a smaller, all-caps serif font. A vertical line separates the 'UCI' and 'RVINE' parts.The text 'INTERNAL AUDIT SERVICES' in a serif font, positioned to the right of the UCIrvine logo. A vertical line separates the logo from this text.

Clinical Research Billing Systems

Internal Audit Report No. I2017-202

January 30, 2017

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INTERNAL AUDIT SERVICES
IRVINE, CALIFORNIA 92697-3625

January 30, 2017

**BEVERLY ALGER
RESEARCH COMPLIANCE OFFICER
SCHOOL OF MEDICINE - COMPLIANCE**

**Re: Clinical Research Billing Systems Audit
Audit No. I2017-202**

Internal Audit Services has completed the review of Clinical Research Billing Systems and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Mike Bathke

Mike Bathke
Director
UC Irvine Internal Audit Services

Attachment

C: Audit Committee
Kathy Lapierre, Director, Compliance Auditing, School of Medicine
Patience Vega, Director, Revenue Audit

I. MANAGEMENT SUMMARY

In accordance with the fiscal year (FY) 2016-2017 audit plan, Internal Audit Services (IAS) reviewed the current implementation status of the OnCore clinical trial management system (CTMS). In addition, a limited scope review of clinical research billing risk assessment processes and billing adjudication processes was performed. Many processes in clinical research billing risk assessment and billing adjudication appear to be functioning satisfactorily. However, certain processes could be further enhanced. The following opportunities were noted.

OnCore CTMS system – The OnCore CTMS is currently utilized by five School of Medicine (SOM) departments in deploying subject management, visit tracking, and invoicing in a limited-scope program. However, OnCore is not currently utilized by other SOM departments and has not been mandated for use in all clinical research. This observation is discussed in section V.1;

Clinical Trial Participant Registration and Tracking – Registration of clinical trial participants is dependent on research teams either sending participants' informed consent forms to the Research Revenue Integrity (RRI) department, or entering the participant information and dates of consent into the OnCore CTMS. An independent process to identify clinical trial participants may help to ensure that the participants are properly registered. This observation is discussed in section V.2.;

Coverage Analysis – Currently, two dedicated Research Revenue Integrity staff complete required coverage analyses for clinical trials. However, on occasion, a disruption in resources and/or heavy workload has caused a backlog in coverage analysis preparation/alignment. Delays in coverage analysis completions result in less than optimal operations and may increase risk in modified and/or legacy clinical trials. This observation is discussed in section V.3.

II. BACKGROUND

The OnCore clinical trial management system is a web-enabled application that enables researchers to streamline data collection, track enrollment, and manage workload in clinical research, among other capabilities. OnCore was purchased in 2009 and was utilized in the UC Irvine Chao Family Comprehensive Cancer Center (CFCCC). In 2011, system administration for OnCore was transitioned from CFCCC to Health Affairs Information Systems (HAIS), as OnCore moved from a

department installation to an enterprise system. In 2013, SOM - Office of Research Support Services (RSS) began to create centralized applications in OnCore for use in clinical trial activities.

For example, RSS created protocol records in OnCore pursuant to a June 2013 UCOP Office of Ethics, Compliance and Audit Services (ECAS) clinical research billing readiness plan mandate. RSS has also built clinical calendars in OnCore so that the calendars could be used by RRI to create coverage analyses for clinical trials.

Research Revenue Integrity works closely with other departments that support clinical research, and provides both pre-award clinical research risk assessment and post-award billing adjudication. RRI is part of the Revenue Integrity department that reports to the Medical Center Chief Financial Officer. An additional key department in clinical research is the Office of Research Compliance (ORC), part of the Compliance and Privacy Office, which reports to the Vice Chancellor, Health Affairs. The ORC supports clinical research by ensuring clinical research billing compliance.

III. PURPOSE, SCOPE AND OBJECTIVES

The purpose of the audit was to determine the current implementation status of the OnCore CTMS. In addition, a limited scope review of clinical research billing risk assessment processes and billing adjudication processes was performed. The scope of the audit included calendar years 2015 and 2016.

Audit objectives included a review of the following:

1. Review the current implementation status for the OnCore clinical trial management system (CTMS), and determine any current system gaps;
2. Review certain pre-award clinical research billing risk assessment processes, and determine any current process gaps;
3. Review certain post-award clinical research billing adjudication processes and determine any process gaps.

IV. CONCLUSION

The OnCore CTMS is currently utilized by five SOM departments in deploying subject management, visit tracking, and invoicing in a limited-scope “Champions” program. However, OnCore is not currently used by many other SOM departments, and has not been mandated for use in all clinical research.

With regard to clinical research billing risk assessment and billing adjudication, many processes appear to be functioning satisfactorily. However, certain processes could be further enhanced. Registration of clinical trial participants is overly dependent on research teams’ notification to RRI. In addition, occasional disruptions in available RRI pre-award resources and/or heavy workloads have caused a backlog in the preparation and alignment of clinical trial coverage analyses, which are a critical component of clinical trials risk assessment and billing.

Observation details were discussed with management, who formulated action plans to address the issues. These details are presented below.

V. OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. OnCore Clinical Trial Management System

Observation

In 2011, the OnCore CTMS became a UC Irvine Health enterprise system. Approximately \$750,000 has been spent between March 2012 and January 2016 on fees for the OnCore application licensing and system interfaces. In addition, approximately \$150,000 is spent annually for software licensing, maintenance and support, and system interfaces. Currently however, there is not any requirement for all departments to use the OnCore system to track their clinical trial subjects, visits, or finances. Departmental and central office OnCore users perceive that a significant amount of revenue is not collected due to the use of standalone, manual tracking systems (instead of OnCore) by departments conducting clinical trials.

- The manual tracking systems are insufficient for departments to recover funds that they are owed for activities conducted.

- The use of standalone systems has precluded data-driven decision support for senior management, whereas centralizing accounts receivable functions available in OnCore would yield valuable data about the volume of unbilled/uncollected receivables.

The OnCore CTMS is the proper system to use for managing clinical trials, however certain organizational limitations currently challenge the full usage of OnCore, as follows:

- Many departments are unfamiliar with OnCore and are uncertain whether/why they would want to select OnCore over their own manual tracking systems.
- OnCore users currently select which processes/modules they want to use in combination with their own manual tracking systems, creating a blended environment in which not all departments are using the OnCore system in the same way.
- Some UCI systems, including the Institutional Review Board (IRB) database, cannot integrate with OnCore. Conversely, the EPIC electronic health record system integrates well with OnCore, and is planned for implementation at UC Irvine in November 2017.

Institutional clinical research billing processes can be streamlined if departments use OnCore functionality for subject management and visit tracking. In addition, department clinical trial revenue can be fully realized if departments use OnCore for invoicing and accounts receivable management.

Management Action Plan

UC Irvine Health has dedicated resources to train, provision, and provide ongoing help desk support to departments to use OnCore for subject management, visit tracking, and invoicing. If all departments are required to use OnCore, SOM can implement the following roll-out plan:

Within six months of a senior leadership requirement to use OnCore, SOM can train, provision, and provide ongoing help desk support for regulatory, clinical coordination, and financial staff for all new studies.

Also within six months of a senior leadership requirement to use OnCore, SOM can assess the value proposition and resource needs to train departments to use OnCore for “open to accrual” legacy studies, so that senior leadership can assess the return on investment of this additional scope.

2. Clinical Trial Participant Registration and Tracking

Background

In clinical research, the registration process influences the funding pathway for clinical trial adjudication. Research Revenue Integrity is responsible for ensuring that clinical research participants are properly registered.

Observation

RRI utilizes signed Informed Consent forms (ICFs) to register and track clinical research participants. However, the process is dependent on research teams either sending participants’ ICFs to RRI, or entering the subject information and dates of consent into the OnCore clinical trial management system. An independent process to identify clinical trial participants may help to ensure that the participants are properly registered.

Failure to properly register clinical trial participants may result in the improper billing of services.

Management Action Plan

RRI currently manages a Research Patient List (RPL) of all subjects that departments have disclosed are actively enrolled in a clinical trial. This list serves as our data source, and is reconciled routinely to services performed at UC Irvine. Any discrepancies are thoroughly reviewed and the Quest registration system updated accordingly.

Effective immediately, RRI will be actively involved in the Research enterprise implementation of Oncore subject management. With each research team adopting the Oncore processes for compliant subject management, RRI will perform quality assurance of each status from consent, to treatment, to off study.

The November 2017 EPIC implementation, in conjunction with the Oncore interface, will further automate the information flow of clinical trial research subject status.

In addition, effective immediately the Office of Research Compliance will implement processes to proactively search for open research studies without registered participants, in order to locate additional clinical trial participants. ORC will send periodic reminders to research teams and include reminders in the administrative training for new clinical researchers and coordinators, reminding them to send ICFs for all research participants to RRI, or enter the ICFs directly into OnCore.

3. Coverage Analysis

Background

Coverage analyses are completed by Research Revenue Integrity. Coverage analyses are prospective reimbursement analyses that are completed to determine anticipated costs in a clinical trial, to determine whether the sponsor/study or Medicare/3rd party payer can be billed, and to ensure that expenditures are aligned among the protocol, contract, budget, and other clinical trial documentation.

Observation

Currently RRI Pre-Award has two full time equivalent (FTE) dedicated to completing coverage analyses for all new studies and every amendment for ongoing clinical trials. However, on occasion, RRI Pre-Award may have a disruption in resources and/or heavier workload, which has caused a backlog in coverage analysis preparation and alignment. In November 2016, the backlog was twenty coverage analyses, which represented 5 percent of all active clinical trials that require a coverage analysis.

In addition, departments are not utilizing a centralized document repository to provide essential documents for coverage analysis. It is crucial for coverage analysts to have access to all protocol documents to complete a thorough review.

Delays in coverage analysis preparation and alignment may result in less than optimal operations and may increase risk in modified or legacy clinical trials.

Management may want to review whether current available resources in RRI Pre-Award are sufficient for pre-award processes.

Management Action Plan

Effective immediately, our plan is to gather metrics to assist in determining the appropriate FTE requirements for the number of studies that require coverage analysis.

In addition, we plan to maintain a relationship with an independent consultant to address resource insufficiencies going forward with respect to eliminating backlogs in coverage analyses.