UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT & ADVISORY SERVICES

Clinical Research Billing
Project #21-045

June 2021

University of California
San Francisco

Audit & Advisory Services
UCSF Box 0818
1855 Folsom Street
San Francisco, CA 94143
tel: 415.476.3851
fax: 415.476.3326
www.ucsf.edu

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Winona Ward
Assistant Vice Chancellor, Office of Sponsored Research

SUBJECT: Clinical Research Billing, Project #21-045

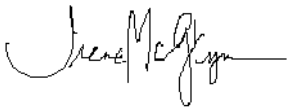
As a planned internal audit for Fiscal Year 2021, Audit and Advisory Services ("A&AS") conducted a review of clinical research billing processes. The purpose of this review was to validate that the processes for clinical research billing designation are functioning as intended.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the "IIA Standards").

Our review was completed and the preliminary draft report was provided to department management in February 2021. Management provided us their final comments and responses to our observations in June 2021. The observations and corrective actions have been discussed and agreed upon with department management and it is management's responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,



Irene McGlynn
Chief Audit Officer
UCSF Audit and Advisory Services

EXECUTIVE SUMMARY

I. BACKGROUND

Clinical research studies involve research using human volunteers, or study participants, in the aim of understanding better or treating disease. The process of billing for research-related procedures and services, or Clinical Research Billing (CRB) is a result of accurate and appropriate set up of the study. The Office of Clinical Trial Activation (OCTA) serves as the central office for clinical research study activation at UCSF, where protocol review occurs, simultaneously with review by the Institutional Review Board (IRB), the committee charged with reviewing the study to ensure the ethical and equitable treatment of study subjects. Whereas the IRB reviews the complete application and supporting documentation to support the IRB Application, including consent, notes on ethical issues, and data supporting the protocol, the OCTA coordinates calendar build, Coverage Analysis (CA), budget creation and negotiation services, and research charge review. The minimum documents required for submission to the OCTA for clinical trial activation are:

- the protocol;
- funding document (for non-industry sponsored studies);
- the sponsor budget and contract (for industry sponsored studies); and
- the Informed Consent Form (ICF).

All clinical trials or research studies requiring CA must have a record in the Online Collaborative Research Environment (OnCore), the clinical trial management system that enables the management of research, safety, regulatory, financial, biospecimen and operational data. The OnCore system is supported by the UCSF OnCore Team. Study subjects incurring charges at UCSF for any events or procedures (either related to the study or standard of care) must be enrolled in OnCore.

During the CA process, coverage analysts determine in detail which clinical procedures and services are billable to insurance and which are not, resulting in billing designations by reviewing clinical trial documents, published practice guidelines, and Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs). OCTA coverage analysts ensure that the study procedure charges, research budget and sponsor-institutional agreement align with each other. The final coverage analysis is the guide to properly direct study patient's charges.

Charges for every patient linked to a clinical research study in APeX go through a manual charge review process. Research Revenue Cycle analysts route charges according to the coverage analysis. This process is streamlined by the bridge between OnCore and APeX. The CA and billing grid denoting billing designations will be pushed into APeX and used to pre-bucket charges, making it easier to match charges to the CA before any bills are released.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to validate that the processes for clinical research billing designation are functioning as intended to ensure accuracy of billing for clinical research studies. Specifically, we reviewed compliance with charge review policies and

procedures, clinical research billing process oversight and processes for updating clinical trials systems, with a high-level review of Coverage Analyses controls and processes and informed consent documentation. Verification of billing accuracy was determined to be out of scope for this review.

The scope of the review covered transactions and activities for FY20 at UCSF West Bay.

Procedures performed as part of the review included evaluating clinical research billing designation processes for approving, notifying, managing and monitoring of clinical research functions as they relate to billing designation. For more detailed steps, please refer to Appendix A.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in January 2021.

III. SUMMARY

Based on work performed, opportunities for improvement were identified and specific observations are listed below.

1. There is a lack of clarity in the oversight of where Informed Consent Forms are stored.
2. The current manual mechanism of identifying incorrect charges to ensure appropriate billing according to the Coverage Analysis could be strengthened.
3. Data mismatches were found within OnCore showing patients were allowed to enroll in OnCore while studies showed expired IRB status.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (MCA)

No.	Observation	Risk/Effect	Recommendation	MCA
1	***There is a lack of clarity in the oversight of where signed Informed Consent Forms are stored.*** The Informed Consent Form (ICF) provides critical information that a patient needs to fully understand their participation in a study, including a summary of any costs associated with participation and how those will be billed. The Informed Consent Form (ICF) should be signed and dated to document consent. Fourteen protocols, activated between September 2019 to April 2020, and 87 total patient records accrued within the protocols, were reviewed to validate that the Informed Consent Form (ICF) – both the template and signed copy – was located in OnCore and in APeX, respectively. While it is not a requirement for ICF templates to be uploaded in Oncore, the following was identified during the course of our review in regard to inconsistency in ICF template and signed ICF compliance: • 5 out of 14 ICF templates were not uploaded into OnCore • 29 out of 87 executed signed ICFs could not be located for patients accrued in the study • 1 out of 14 protocols did not have either an ICF template in OnCore, and the signed ICF in APeX could not be located for the two patients who had accrued in the study According to UCSF HDFCCC, Medical Center and APeX Scanning Guidance policies and guidelines[1], a copy of the signed ICF should also be uploaded into APeX in the "Scanned Documents" tab. However, in addition to the noted exceptions, above, there were	By not having signed ICFs in a centralized location, it is difficult to verify that informed consent was properly obtained.	A policy for uploading signed ICFs into APeX should be considered since it is a required document to enroll a patient into a study.	A. CRC guidance documents (APeX Job Aid, Study Start Up Checklist, etc.) were updated to clarify how to upload signed ICFs into the patient's chart in APeX. A communication was sent out to CRCs regarding the updates during the course of this review. B. The process of uploading ICFs into APeX will be reviewed to ensure CRC understanding. **Responsible Party:** Associate Director of Operations, Research Revenue Cycle **Target Completion Date:** B. 12/31/2021

[1] UCSF Medical Center Policy 6.02.02, Informed Consent (page 3); UCSF HDFCCC Policy for Obtaining Informed Consent of Potential Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials (page 3); UCSF APeX Guide on Scanning Documents (page 10)

No.	Observation	Risk/Effect	Recommendation	MCA
	variations in where the ICF was located in OnCore, if it was in the system. Some are located in the CA Console and some are located in the "attachments" section of the PC console, making it difficult to efficiently verify informed consent. There is a field in OnCore that indicates when consent from a patient was obtained, but it does not itself link to the consent document. This indicates that there is a lack of clarity for CRCs on where informed consent documentation should be kept. The OCTA requires an ICF as part of required documentation for clinical trial activation. Currently, the form is uploaded into OnCore in either the Coverage Analysis Console or the Protocol Coordinator Console, or both. The patient-signed ICSF should be scanned into the patient's record in APeX before the patient becomes active on a study.			
2	***The current manual mechanism of identifying incorrect charges to ensure appropriate billing according to the Coverage Analysis could be strengthened.*** Charge review is done in APeX by the Research Revenue Cycle team, in which charge reviewers reference the Coverage Analysis for the study as they perform review of charges. Information from the Coverage Analysis is notated in APeX account notes to justify the charge routing. If a reviewer requires more information, a request for additional information is made to the CRC, and charges are default billed to the study, rather than to the patient or patient insurance. CRCs review a monthly ZZ statement (West Bay) or XX statement (East Bay), which is a charge review report used to confirm the billing designation is correct and that the correct patient, date and procedure is associated with the charge. If there are errors, the CRC will then need to notify the Research Revenue Cycle team that the charges need to be corrected, but there is currently no other mechanism for identifying corrections other than the ZZ statement. Ultimately, these corrections to charges must be requested by the CRC via a ticket to the Research Revenue Cycle team who will then address the issue.	The risk of not monitoring research denials is that potential revenue may be missed, as well as opportunities to streamline clinical research billing processes.	Efforts to complete the build of a research denials report in APeX should continue, with a deadline for implementation of these reports or dashboards.	During the course of this review, internal coding review was established in Research Revenue Cycle, with a goal of 95% accuracy. Additionally, one staff was enrolled in Clarity training and will therefore have report writing capabilities for research denials reporting. A report to identify denials will be developed and utilized for monitoring denied charges. **Responsible Party:** Associate Director of

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	Currently, there are efforts to build a standard reporting structure directed towards denials analysis which would help to identify denials or errors ahead of the monthly ZZ /XX statement review, but this effort has been ongoing for the past year.			Operations, Research Revenue Cycle **Target Completion Date:** 8/31/2021
3	***Data mismatches were found within OnCore showing patients were allowed to enroll in OnCore while studies showed expired IRB status.*** Two of the 14 protocols reviewed had an expired IRB status in OnCore, but due to a data mismatch between iRIS and OnCore, patients were listed as still open to accrual in OnCore. Within OnCore, the CRC is responsible for monitoring IRB status and updating it if necessary, but this does not always occur. There were previous plans to do an OnCore/iRIS integration that would aid in the alignment of data in both systems, but these plans were delayed. Though iRIS is the system of record for protocol status, a status mismatch in OnCore could potentially cause improper study activity to occur in a situation where a sponsor is inadvertently billed for services in an expired protocol where a patient has accrued.	The data mismatch between OnCore and iRIS is not being monitored, which could potentially lead to study patients to be improperly enrolled and on treatment, creating a potential risk for inaccurate billing.	1) Determine if any subjects have been enrolled post-IRB expiration, and evaluate if study activities occurred during an approval lapse and flag those activities for review of protocol violation. 2) Consider an iRIS and OnCore integration plan regarding alignment in management of data. 3) Ensure CRCs are aware of the rerquirment to, process for, and importance of closing out	1) A process to review IRB expiration dates occurred to determine if any patients were enrolled post-IRB expiration, and no errors were identified. **Target Completion Date:** Completed 2) Create an OnCore report that lists expired IRB reviews within OnCore and notifying appropriate teams to update OnCore if expired. **Responsible Party**: Associate Director, Clinical Information Systems **Target Completion Date:** 8/31/2021 3) Implement a communications and training plan including:

No.	Observation	Risk/Effect	Recommendation	MCA
			studies in OnCore upon IRB expiration.	a. Targeted emails sent to CRC listserv b. Incorporate additional emphasis on the importance of and process for study close-out into the CRC Training curriculum c. Topic to be included in planned upcoming Town Hall session for CRCs d. OCTA OnCore trainer to hold office hours related to this topic e. Addition of instructive content to the Clinical Research Resource HUB (hub.ucsf.edu) **Responsible Party**: Associate Director of Training, CTSI **Target Completion Date:** 8/31/2021

APPENDIX A

To conduct our review the following procedures were performed for the areas in scope:

- Obtained and reviewed UCSF policies on clinical research billing-related processes to determine if current processes reflect policies
- Interviewed key department personnel in the Office of Clinical Trial Activation (OCTA), Research Revenue Cycle, Clinical Information Systems and Clinical Systems Business Applications teams to understand their role in the clinical research billing process
- Reviewed a sample of protocols for completeness and accuracy, including review of Informed Consent Forms (ICF) and coverage analyses
- Determined the process for monitoring clinical research encounters for alignment with the Coverage Analyses and appropriateness of charges
- Assessed process controls for oversight over clinical research billing processes to ensure alignment with the Coverage Analysis
- Assessed processes for updates to clinical trial systems, including change management and stakeholder input in decision-making