

22-108 Clinical Research Billing

EXECUTIVE SUMMARY

Auditing & Advisory Services (A&AS) has completed an assurance engagement of clinical research billing. This engagement was performed at the request of the UTHealth Houston Audit Committee and was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*.

Background

A systematic review of research studies is performed to analyze the schedule of activities to determine if any activity should generate a research-covered charge in the clinical billing system. All applicable clinical research visits for the identified research studies are scheduled in Epic and/or other applicable billing systems. The UTHealth Houston Handbook of Operating Procedures (HOOP) 214 *Clinical Research Billing* requires the identification of clinical research patients, delineation of routine costs versus research charges, and appropriate billing.

Objectives/Scope

Our objective was to determine whether controls around the research billing processes within Epic are adequate and functioning as intended. Specifically, to determine if:

- Clinical research billing policies and procedures are in place.
- Identification and inclusion of billable research studies in Epic is appropriate.
- Management and monitoring of clinical research billing are appropriate.

Scope Period

Active research projects included in Epic as of November 28, 2022.

Conclusion

We noted the following opportunities for improvement:

#	Observation Summary	Risk	Risk Rating
1	Oversight of billing compliance for clinical research related services is not currently performed.	Inaccurate or incomplete billing of research-related charges resulting in fees and/or penalties.	High
2	Documentation of the completion and approval of coverage analysis is not consistently maintained. Additionally, coverage analysis approval and guidance for the roles and responsibilities for the research team is not consistently communicated.	Inaccurate or incomplete billing resulting in fees and/or penalties. Noncompliance with record retention requirements.	Medium

22-108 Clinical Research Billing

3	Policies and procedures for clinical research billing have not been updated to align with current practices.	Inaccurate or incomplete clinical research billing and inconsistent application of institutional policies and procedures.	Medium
---	--	---	---------------

OBSERVATIONS & MANAGEMENT RESPONSES

#1 - Monitoring for Billing Compliance

Cause

Oversight of billing compliance for clinical research related services is not currently performed.

Risk

Inaccurate or incomplete billing of research-related charges resulting in fees and/or penalties.

Condition

We noted the last periodic monitoring of clinical research billing performed by the Clinical Research Finance (CRF) team was completed in February 2019, with follow-up procedures during 2020. The monitoring review covered processes followed by the research team while using the legacy EMR application prior to the Epic implementation.

We selected a sample of 10 research projects included in Epic to review the departmental processes in place for the management and monitoring of clinical research billing. The following items were noted:

- All ten projects have informal research billing processes.
- Seven projects did not perform a reconciliation of research charges.
- Seven projects do not use Epic for research-related patient scheduling, monitoring visits, or research charge review.
- Eight projects had one or more participants who were not linked to the project in Epic. Additionally, three studies had patients linked in Epic that were not included on the participant list for the project.
- Three projects listed one or more inactive users in the Epic Study Administrative Record (SAR) used to manage the project.
- Procedures for the completion of the SAR do not require a periodic review or update of research team members responsible for completing clinical research billing in Epic.

Criteria

HOOP 214, *Clinical Research Billing*, Policy and General statement includes the following:

“This policy explains the need to identify clinical research patients, delineate the routine costs versus research charges, and ensure that appropriate billing occurs.”

The Procedure states:

“The CRF team will ... oversee a monitoring program for clinical research billing and research project expenses.”

The Operational Responsibilities state:

“It is the responsibility of the PI (Principal Investigator) to ensure that the clinical research billing of his or her studies is in compliance with all laws and regulations and adhere to University policy. The PI, his or her research staff, department administrators, and the CRF Team must work together to ensure the components of accurate billing are in place.”

Recommendation(s)

Implement a monitoring process to provide assurance clinical research billing is in compliance with federal, state, and institutional guidelines and policies. Included in the monitoring process should be a requirement to document and communicate the results, as well as the resolution of any identified issues.

22-108 Clinical Research Billing

Rating

High

Management Response

Due to the additional bandwidth required to educate/train research staff across the institution for the implementation of two new systems (G&C management system 2020 and Epic 2021/2022) the CRFA team placed monitoring activities on hold. The CRFA team has been working with the IRB to develop plans for streamlining monitoring activities (combining efforts with IRB monitoring staff) and ensuring all new hires working in clinical research are identified and required training is provided. We will resume monitoring activities beginning with the new fiscal year.

Responsible Party

Kristin Parks, Director, Clinical Research Finance and Administration

Implementation Date

September 1, 2023

#2 – Coverage Analysis Approval, Notification, and Guidance

Cause

Documentation of the completion and approval of coverage analysis is not consistently maintained. Additionally, coverage analysis approval and guidance for the roles and responsibilities for the research team is not consistently communicated.

Risk

Inaccurate or incomplete billing resulting in fees and/or penalties and noncompliance with record retention requirements.

Condition

We selected a sample of 10 research projects included in Epic and reviewed the notice of the completion of the coverage analysis and approval by the Clinical Research Finance (CRF) team. CRF procedure includes providing guidance to the research team for the management of clinical research billing procedures with the notice of coverage analysis approval. We noted the following:

- One project with no documentation of coverage analysis completion, approval, or guidance provided for research team responsibilities.
- One project with no documentation retained of coverage analysis approval.

Criteria

HOOP 214, *Clinical Research Billing*, requires the CRF team to provide education for clinical research staff. The policy states:

“The CRF team will document clinical research billing policies, provide education for clinical research staff, review coverage analysis, and oversee a monitoring program for clinical research billing and research study expenses.”

State of Texas Records Retention Schedule

- Clinical Trials and Clinical Investigations – Research data and documents gathered or created in the course of a clinical trial involving drugs, devices or biologics to be retained for AC+15 where AC is “After Completion.”
- Clinical Research and Human Subjects Research – Research data and documents gathered or created in the course of a clinical research study not involving drugs, devices or biologics for AC+7 where AC is “Final project close-out or final reporting of publication of a project, whichever occurs later.”

Recommendation(s)

- Review processes to ensure communication of the completion and approval of coverage analysis to the principal investigator and research team is consistently documented and maintained for applicable projects.
- Determine whether an analysis is warranted of clinical research trial or study data available for legacy projects.

Rating

Medium

22-108 Clinical Research Billing

Management Response

We have outsourced coverage analysis build to Huron Consulting Group. The clinical studies identified were started well before the process was outsourced. We will review active studies opened before this engagement and will confirm coverage analysis is on file.

Responsible Party

Kristin Parks, Director, Clinical Research Finance and Administration

Implementation Date

October 31, 2023

#3 – Policies and Procedures

Cause

Policies and procedures for clinical research billing have not been updated to align with current practices.

Risk

Inaccurate or incomplete clinical research billing and inconsistent application of institutional policies and procedures.

Condition

HOOP 214 – *Clinical Research Billing* was developed December 2014 and lists the operational responsibilities for employees involved in clinical research billing. A new electronic health record system (Epic) was implemented in May 2021 requiring new or updated procedures for clinical research billing.

Criteria

HOOP 128, *Policy and Procedure Development and Maintenance*, states:
“The Responsible Executive or designee must review and recommend revisions to HOOP policies as necessary or not later than five years after the most recent update using the applicable process...”

Recommendation(s)

Review and update policies and procedures to align with current practices.

Rating

Medium

Management Response

Revised HOOP 214 (reflecting recent changes to coverage analysis and clinical research billing processes) was approved by HOOP committee on May 10, 2023. Is moving forward to Executive Compliance Committee.

Responsible Party

Kathleen Kreidler, Associate Vice President, Sponsored Project Administration

Implementation Date

July 30, 2023

We would like to thank Sponsored Projects Administration staff and management who assisted us during the engagement.



Daniel G. Sherman, MBA, CPA, CIA
Vice President & Chief Audit Officer

22-108 Clinical Research Billing

OBSERVATION RATINGS

Priority	An issue that, if not addressed timely, has a high probability to directly impact achievement of a strategic or important operational objective of UTHealth Houston or the UT System as a whole.
High	An issue considered to have a medium to high probability of adverse effects to a significant office or business process or to UTHealth Houston as a whole.
Medium	An issue considered to have a low to medium probability of adverse effects to an office or business process or to UTHealth Houston as a whole.
Low	An issue considered to have minimal probability of adverse effects to an office or business process or to UTHealth Houston as a whole.

NUMBER OF PRIORITY OBSERVATIONS REPORTED TO UT SYSTEM

None

MAPPING TO A&AS FY 2022 RISK ASSESSMENT

Reference	Risk
FIN 36	Patient Charges will be held to determine whether related to research, which can delay billing for non-research related charges.
FIN 122	Research billing module in Epic will make managing billing for service difficult.
FIN 124	Research bills sent to granting agencies are not submitted on a timely basis or are not correct.

DATA ANALYTICS UTILIZED

None

ENGAGEMENT TEAM

VP/CAO - Daniel G. Sherman, MBA, CPA, CIA
Supervisor - Daniel G. Sherman, MBA, CPA, CIA
Lead - Chandra Jones, CPA, CIA, CHIAP®
Staff - Shara Vialva

END OF FIELDWORK DATE

March 29, 2023

ISSUE DATE

May 30, 2023

REPORT DISTRIBUTION

Audit Committee
Kevin Dillon
Kathleen Kreidler
Kevin Morano
Kristin Parks
Ana Touchstone
Michael Tramonte