	WCM Administrative Policy and Procedure	
	Policy Title	Research Billing Compliance Audit Program
	Policy Number	CPO-C-400.70
	Department/Office	Office of Compliance
	Effective Date	July 30, 2024
	Last Reviewed	N/A
	Approved By	Clinical Compliance Oversight Committee (CCOC)
	Approval Date	July 30, 2024

Purpose

The purpose of the Weill Cornell Medicine (WCM) research billing compliance audit program is to (i) confirm that clinical services associated with a clinical research study are appropriately billed to patients and third-party payers and (ii) ensure adherence to all regulations governing medical billing practices related to clinical research, including but not limited to the Center for Medicaid & Medicare Services (CMS) National Coverage Decision.

Policy

As an essential component of the WCM compliance program, the Compliance and Privacy Office (CPO) conducts routine internal reviews of professional fee billing for clinical services provided to research subjects enrolled in clinical trials or other human subject research studies. These reviews are designed to validate that clinical services associated with research studies are billed accurately and in accordance with applicable federal guidelines. The reviews are conducted according to the annual research billing compliance audit workplan schedule.

The research billing compliance audit program uses audits and other evaluation techniques to monitor compliance and implement corrective action when necessary. Specifically, the program aims to:

a) Ensure consistent payment responsibility for clinical services across all study documents;
b) Reduce billing risks between research and routine standard-of-care services;
c) Reduce the risks of inappropriate billing to research participants and/or third-party payers;
d) Ensure appropriate recovery of clinical service cost associated with clinical research studies; and
e) Ensure Principal Investigators (PIs) and their study teams implement the corrective actions for issue(s) identified during internal reviews to mitigate future risks.

When internal review findings require corrective actions, the respective PI and study team are responsible for implementing these actions.

Scope

This policy applies to all WCM Workforce Members engaged in research-related studies involving human subjects.

Definitions

Billing Grid Review determines the accuracy of the study's coverage analysis by comparing all study documents to ensure each identifies and consistently distinguishes financial responsibility for all study-related services.

Clinical Trial Agreement (CTA) is a legal agreement (contract between WCM and the clinical trial sponsor) that governs the conduct and obligations of the clinical trial for all involved parties.

Coverage Analysis (previously known as the Human Research Billing Analysis Form (HRBAF) is used to prospectively identify services required by a study protocol, specifying when services will occur, who provides them, and outlining financial responsibility. In July 2021, the HRBAF was phased out and replaced by the coverage analysis in the OnCore system.

Guided Random Selection considers the study's total and target number of enrolled subjects, funding source (federal, industry, or institutional), and billing grid type (HRBAF or coverage analysis) to balance chosen studies for the audit workplan.

Impact is the estimated potential harm to the institution. When ranking studies to prioritize in the audit workplan, high-impact research could be from departments treating high-risk medical conditions, older/ongoing studies, and those with large participant enrollments.

Open to Accrual is when a study actively enrolls participants or accepts new subjects.

Probe Review is an unannounced audit triggered by an alleged issue or concern reported via the hotline, insurance, sponsor, patient inquiry, or a pattern of payment denials.

Retrospective Review determines billing accuracy by reviewing past research charges from a sample of research subjects within the selected study to ensure charges were dispositioned correctly to the participant, their insurance, or the research study.

Prospective Review determines billing accuracy by assessing charges in the research work queue before they are released for billing to the patient, their insurance, or the research study.

Risk-Based Research Billing Audit is a 2-step review that evaluates the accuracy of the coverage analysis and a sample of research charges (retrospectively or prospectively) to ensure billing accuracy.

Speed of Onset is the time it takes for a risk event to manifest or occur again. When ranking studies to prioritize in the audit workplan, a high speed of onset could be related to sponsor type; federally funded studies might have a faster onset speed than institutionally sponsored ones.

Vulnerability is susceptibility to risk. Studies of high vulnerability may include those from departments that treat high-risk medical conditions, older studies, or studies with more expensive or frequently billed services.

Workforce Members include faculty, staff, students, volunteers, trainees, and other persons whose conduct, in the performance of work for WCM, is under the direction and control of WCM, whether WCM pays them.

Procedure

A. Study Selection for the Research Audit Workplan

Studies to be audited by the CPO are selected using a "wide open" search run by the Joint Clinical Trials Office (JCTO). The list of studies generated is then filtered by study billing risk, study type (e.g., interventional), current status (e.g., Open to Accrual), and protocol type (e.g., treatment or diagnosis). After filtering, studies that meet the criteria are selected for inclusion in the audit workplan for the fiscal year.

A Guided Random Selection process is implemented to ensure equitable representation, and at least one study from each department and across divisions is included. If a department does not have a study that meets the criteria for inclusion in the work plan, a "placeholder" is added to the workplan to accommodate any prospective study information if any were to prepare a coverage analysis for a new study within the fiscal year. Alternatively, a

placeholder may be filled in for the work plan year by conducting a follow-up review of a previously audited study from the department to ensure that all corrective actions have been implemented.

Studies are prioritized for audit based on an evaluation of potential Impact, Vulnerability, and Speed of Onset factors. Annually, the audit schedule is established and initially presented to the Research Billing Compliance Audit Workplan workgroup for awareness and guidance and then to the Clinical Compliance Oversight Committee (CCOC) for acceptance.

B. Risk-Based Research Billing Compliance Audit

Each clinical trial selected for audit undergoes a systematic 2-step audit review:

i. Billing Grid Review: This review assesses the accuracy of the study's coverage analysis by performing a concordance review with the study protocol, informed consent, budget, and/or CTA.

ii. Retrospective or Prospective Review: Following the Billing Grid Review, a sample of research subjects within the selected study is reviewed retrospectively or prospectively to ensure billing accuracy.

Before starting a scheduled audit, a Research Billing Compliance Audit Notice is sent to the Department's Chief Administrative Officer, compliance leader, and liaison. The notice outlines the audit objective, explains the 2-step review process, and defines the audit scope. It includes a questionnaire that must be completed and returned to the CPO, along with requested study documents, procedure information, and contact information of actively involved research staff.

A Probe Review differs from a Billing Grid and Retrospective/Prospective Review in that it is unannounced, unscheduled, and usually initiated based on an alleged issue or concern. The type of audit(s) conducted in response to a Probe Review depends on the specific content of the reported issue or concern.

C. Reporting Audit Results

a. Billing Grid Review

The Department will receive an **Audit Memo** outlining findings and any required changes to the coverage analysis. Changes may include, but are not limited to:

1. Adding or removing CPT codes;
2. Correcting billing dispositions;
3. Correcting the schedules of services or procedures;
4. Adding footnotes to explain exceptional circumstances; and
5. Outlining changes needed to resolve contradictions in the protocol, consent form, and/or the study budget or CTA.

b. Retrospective/Prospective Reviews

For Retrospective/Prospective Reviews, a **Compliance Audit Report (CAR)** is issued to the Department. It outlines identified risks for incorrect billing and other compliance issues, root causes of deficiencies or violations, and recommendations for corrective actions.

Primary Findings

Primary findings of non-compliance indicate potential billing risk and include, but are not limited to:

1. Double billing;
2. Incorrect billing to the wrong payment source;

a. Research services billed as standard-of-care (SOC) to the patient or their insurance or
b. SOC services billed as research;

3. Electronic Medical Record (EMR) encounters for research-related services not linked to the study;
4. Charges for research-related services incorrectly dispositioned;
5. Research-related services rendered but not billed/posted; and
6. Research service posted with a $0.00 charge or deleted.

Secondary Findings

Secondary and incidental findings of non-compliance may indicate a potential billing, coding, and/or documentation risk and include, but are not limited to:

1. Lack of documentation of the informed consent process and/or failure to upload the signed consent (Rs02 – Informed Consent SOP) form to the participant's EMR;
2. Documentation errors related to copying and pasting notes (CPO-C 400.61 Copy & Paste Restriction in the Electronic Medical Record), pre-charting, Epic template, or smart phrase usage;
3. Missing "off study" dates in OnCore for participants who completed the study protocol;
4. Untimely completion of service notes documentation (3.07 Clinical Documentation: Timely Completion of Medical Record Entries);
5. Absence of study-related documentation in the EMR.
6. Reportable Events, as defined by the Institutional Research Board (IRB) (100.1 Human Research Protections Program).

D. Corrective Action Response

In response to the Billing Grid Audit Memo and CAR, the Department must provide the CPO with the following:

a. A preliminary management response;
    i. If the CPO finds the preliminary management responses unsatisfactory, further discussion and cooperation must be undertaken to achieve an acceptable response within a reasonable period.
b. A plan of action for resolution;
c. A completion timeline;
d. Identification of the action owner(s) responsible for implementation; and upon acceptance,
e. A final response can be submitted.
f. The PI must attest that they have reviewed and endorsed the final management response(s) and agree to apply the coverage analysis recommendations to all other ongoing studies.

For the Billing Grid review, a revised coverage analysis must be completed and submitted to the CPO, Joint Clinical Trials Office (JCTO), and, if applicable, the Cancer Clinical Trials Office (CCTO).

For the Retrospective/Prospective Review, audit results will be reported to the department's Chief Administrator Officer, Compliance Leader and Liaison, the JCTO, and IRB if applicable (i.e., for reportable events). The Central Business Office (CBO is notified when the audit results require a patient or insurance refund. Per CMS guidelines, all refunds must be processed within 60 days.

E. Quarterly and Annual Reports

Each Department's quarterly and annual compliance reports will include a summary of compliance findings, including identified risks, the root cause of deficiencies or violations, and recommendations for corrective actions.

The CPO will provide written and live quarterly and annual compliance reports to the Research Administration and Cornell University leadership, including the Audit, Risk, and Compliance Committee of the Board of Trustees.

Compliance with this Policy

All members of the WCM workforce are responsible for cooperating with research billing compliance audit efforts and adhering to this policy. Failure to comply will be evaluated case-by-case and could lead to corrective action, including termination. Instances of non-compliance that potentially involve a lapse of professionalism may lead to the Office of Professionalism being engaged for evaluation and intervention.

Contact Information

You can direct any questions about this policy to the WCM Compliance and Privacy Office:

• Email: Compliance@med.cornell.edu
• Phone: 646-962-6930

If you know or suspect a violation of this policy may have occurred, promptly notify your supervisor and/or the WCM Compliance and Privacy Office. **Anonymous reporting is also available through the Cornell Compliance Hotline.**

• Hotline Online: www.hotline.cornell.edu
• Phone Number: 866-293-3077

References

Rs02 – Informed Consent SOP

Research Billing Compliance Handbook

CPO-C 400.61 Copy & Paste Restriction in the Electronic Medical Record

3.07 Clinical Documentation: Timely Completion of Medical Record Entries

100.1 Human Research Protections Program

Policy Approval

This policy was reviewed and approved by the Clinical Compliance Oversight Committee (CCOC).

Version History

Date	Author	Revisions
07/30/2024	Office of Compliance	Original date of issue.