Weill Cornell Medicine	Policy Title	Research Billing Compliance Audit Policy
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	Department	Compliance and Privacy Office
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Research Billing Compliance Audit Policy

1. *Purpose*

This policy sets forth to ensure a consistent interpretation and effective application of Medicare, Medicaid, and other third-party payor billing requirements relating to professional fee reimbursement for services associated with clinical research.

2. *Scope/Applicability*

This policy applies to all research-related studies involving human subjects conducted at Weill Cornell Medicine (WCM) that have the potential for billing compliance risk.

3. *Definition*

OnCore is a research clinical trial management system that centralizes billing designation information to ensure consistency across multiple teams and systems.

Coverage Analysis and Billing Grid is a systematic review of all procedures detailed in the study protocol to determine how each service and/or procedure should be billed for each visit to ensure institutional billing compliance.

Billing Risk to prevent erroneous or fraudulent claims between research and routine standard-of-care services and inappropriate billing of research participants and/or third- party payers.

4. *Policy*

Billing compliance risk will be assessed in research studies that require the creation of a coverage analysis/billing grid, formally known as the Human Research Billing Analysis Form (HRBAF).

- Studies originating before 7/1/2021 should have a HRBAF; its use will continue for the lifecycle of the research study.
- Studies originating after 7/1/2021 require the creation of the billing grid in Oncore.

The study team generates the coverage analysis/billing grid, which the Department Compliance Liaison approves. The Compliance and Privacy Office (CPO) will initiate approval for those departments that don't have an active Compliance Liaison.

A. Billing compliance reviews will be conducted on an ongoing basis in one of the following manners:

- Random verification that the coverage analysis/billing grid identifies all items/services and distinguishes financial responsibility for all study-related services as outlined in the schedule of events in the study protocol.
- Random confirmation that grant funds are used according to the appropriate fee schedules.
- Prospective routine and random audits of select departmental principal-investigator (PI) and co-investigators.
- Retrospective review of all billing for a selected study or a single research subject within a selected study.
- A probe review based on an alleged issue or concern, e.g., via the hotline or other report, insurance, sponsor, patient inquiry, or a pattern of payment denials.

A formal, risk-based audit review will be conducted to verify the consistent interpretation and effective application of study-related charges and ensure that designated research billing systems are utilized to the full extent and in adherence to all rules and regulations governing medical billing practices related to clinical research.

This will be achieved through a central review of research study administrative documentation in OnCore, tracking trends and reconciling enrollment with Weill Research Gateway-Human Subjects (WRB-HS), and performing a concordance review of OnCore billing grid with the study protocol, the IRB application, informed consent, and budget, when applicable.

B. The audit results will be outlined as follow:

- This CPO will compile a risk-based audit report addressed to the department's Compliance Leader and Liaison and the Joint Clinical Trials Office (JCTO). This report will include a summary of the compliance audit findings, including risks identified, the root cause of deficiencies or violations, and recommendations for corrective actions. The recommendations given will dictate the seriousness and complexity of the deficiencies noted.
- The department will be required to provide a management response, a plan of action for resolution, and a completion timeline. Immediate and preventive measures for resolution will be monitored to ensure timely compliance.

C. Quarterly and Annual Reports.

Clinical research billing compliance efforts will be reported in each department's quarterly and annual compliance reports. The reports will include the following:

- The research study tracking log showing all active research studies.
- The total number of active studies, with a flag of those identified with billing risk, and the total number of enrolled research participants identified in OnCore.
- A summary of research billing compliance audit results and actions taken and/or pending from the department.

4. Related Documents

Coverage analysis

5. Policy Authorization

TBD Date