

Research Billing Compliance Quality Assurance Training

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Who is required to take research billing compliance?

All faculty, fellows, students and staff that perform human subject related research and/or perform services related to human subject research such as:

- Principal Investigators
- Research Trial Study Teams (Clinical Research Coordinators, Clinical Research Assistants)
- Billing, Coding, and Charge Entry Staff
- Patient Services and Patient Collections

Why is training so important?

- Navigating and complying with the numerous federal regulations around clinical trials billing is perhaps one of the most complex operational and regulatory challenges faced by academic medical centers and health care systems
- Accurately billing for clinical trial services requires a tremendous amount of effort to coordinate operations. Monitoring encounters, reviewing documentation and charge determination are all required activities, in order to appropriately mitigate compliance risks
- A lack of adequate controls can increase the risk for false claims and insurance fraud allegations, both of which can result in stiff penalties.

Research Billing Compliance Policy

Due to the complexity of clinical research billing and management, a Clinical Research Billing Taskforce was formed in 2018 and charged with the development and implementation of a research policy which would address all research studies identified with billable services as well as to identify the critical components involved with research billing compliance.

Effective April 1, 2019, all Medicare Qualifying Trials (MQT) will be required to adhere to this policy which can be found on the YCCI website under the "For Researchers Tab"

Link for Policy:

[Yale School of Medicine Research Billing Compliance Policy](#)

Yale School of Medicine Policy: Research Studies with Billable Clinical Services

- Policy Sections:
 - **Sponsored Research Studies**: Office of Sponsored Projects (OSP) ensures that language addressing financial responsibilities contained in the ICF and the agreement align and are evidenced by an accompanying budget.
 - **Medicare Coverage Analysis**: Yale requirement for all research studies with billable services to undergo a Medicare Coverage Analysis (MCA). YCCI has formed a centralized unit which is tasked with completing a coverage analysis on all qualifying trials. **All finalized budgets will be reviewed and signed off by this unit to ensure that the MCA is accurately represented within the clinical trial budget.
 - **Research Study Budget**: In order to develop the budget, YCCI will perform the MCA to identify those expenses which are research related or which are routine costs. Budget development is based on the use of Yale Medicine and YNHHS published fee schedules in order to ensure that the sponsor fully reimburses Yale for the cost of conducting the study.

Yale School of Medicine Policy: Research Studies with Billable Clinical Services

- Policy Sections (cont'd):
 - **Research Study Financial Considerations and Liabilities:** The PI shall ensure that there is clear and consistent language in the approved protocol, ICF, and the sponsor agreement/budget regarding research related services and standard of care services (routine costs). The PI is also responsible for ensuring that the study participant is well aware of the procedures and services occurring at each visit and which will be covered by the research study and under what circumstances the research subject and/or his/her insurer may have a potential financial obligation. The PI is also obligated to include in the ICF the Clinical Research Billing Unit contact information should the research subject have any billing questions.
 - **Billing Information and Supporting Systems:** All Yale research studies with billable services are required to use Yale's Clinical Trial Management System (OnCore) for tracking, maintaining and monitoring research study services, and calendar. The PI is responsible for ensuring that a study framework identifying the services that will be billed to the sponsor or study account or to the research subject or third- party payer during a research encounter is created within the OnCore environment prior to any study visits occurring.

Yale School of Medicine Policy: Research Studies with Billable Clinical Services

- Policy Sections (cont'd):
 - **Billing Information and Supporting Systems (cont'd)**: This framework must reflect the information contained in the protocol, ICF, and agreement, if applicable. In order to avoid potential billing problems, the study team shall enter into OnCore all newly consented research subjects on the day they are consented. Additionally, subsequent visits shall be recorded within two (2) days of the visit to promote effective and efficient billing compliance.
 - **Billing Compliance Quality Assurance**: A critical element of Yale School of Medicine is the billing compliance framework which includes quality control oversight of all research study billable procedures and services. YCCI's Clinical Research Billing Quality Assurance group is charged with this oversight function which includes proactive protocol risk assessments and continuous monitoring of clinical trials identified as high risk. The purpose of these ongoing reviews are to identify any study coverage analysis inconsistencies between Yale Medicine and Yale New Haven Health System (YNHHS) Corporate Business Services and to assist in the appropriate billing of services.

Yale School of Medicine Policy: Research Studies with Billable Clinical Services

- Policy Sections (cont'd):
 - **Clinical Trials.gov Registration**: Medicare may pay for research study services under three policies: (1) the Clinical Trial Policy (CTP), (2) the Investigational Device Exemption (IDE) policy, and (3) the Coverage with Evidence Development (CED). In order for Medicare to pay for services under these policies, the study must be registered in ClinicalTrials.gov and a National Clinical Trial (NCT number) identifier assigned. The NCT number should appear for any research subject in a recruiting, active, or not recruiting clinical trial for any services being billed to Medicare.
 - **Record Retention**: All records associated with research billing are to be recorded and stored in the institutional systems of record (i.e. Epic, OnCore, and IRES).

Medicare Coverage Analysis, AKA “SOC vs. RS” Designations:

- Once a study is identified as a Medicare Qualifying Trial and prior to budget determination, YCCI’s centralized coverage analysis unit will conduct a Medicare Coverage Analysis (MCA). This analysis will be completed by YCCI’s central unit regardless of who is responsible for the drafting and negotiation of the budget. As a result, any budgets performed outside of YCCI will undergo a QA process to confirm that the negotiations align with the analysis (which is represented in the OnCore calendar).
- A coverage analysis will be done for all studies that have the potential to bill a third-party payer, for billing compliance purposes. A fee of \$3,965.00/drug study (inclusive of Yale University overhead) is charged to corporate/industry/pharma sponsors for the preparation and completion of a Medicare Coverage Analysis if an MCA is required. YCCI will invoice the sponsor for the MCA fee. Yale Medicine departments will not be charged for the coverage analyses that are being completed for federally funded studies, Investigator initiated studies, unfunded studies, etc.
- Preparing an MCA involves determining the underlying eligibility of the study for Medicare coverage and reviewing clinical events specified in the protocol to determine which can be reimbursed by Medicare.

Medicare Coverage Analysis, AKA “SOC vs. RS” Designations (cont’d)

- It is dependent upon a systematic review of research related documents to determine the billing status of both the study itself and the items/services provided to the research participants that are outlined in the research documents over the course of the study.
- An MCA is based on extremely thorough research and supported by national and local guidelines which are compliant with both state and federal government regulations.
- Examples of sources used and cited: NIH, NCCN, ACC, JAMA, NEJM, CMS NCD and LCD, specialty societies, etc.
- YCCI provides investigators the completed MCA for review and approval.
- When the analysis is complete, the investigator receives a study-specific billing summary that lists all items and services to be provided as part of the clinical trial with notations of what should be billed to the research sponsor and what can be billed to Medicare. These billing grids are a valuable tool to ensure appropriate billing

Formalized Coverage Analysis

Procedures	Cost	Pre-Screening 1@ 60 Days	Group A/B Screening	Module 1 Treatment (Group A)			Pre- Progression Follow-Up 1 (Module 1/2)	Comments
				C1D1	C1D8	C1D15		
		Pre-Screening	Group A/B Screening	C1D1	C1D8	C1D15		This is not a billable item or service.
Prescreening Consent		R						This is not a billable item or service.
Eligibility Criteria		R						This is not a billable item or service.
Demographics		R						This is not a billable item or service.
AE/SAE Assessment		R	R	R	R	R	R	This is not a billable item or service.
Venipuncture		R	S1	S1	S1	S1	S1	Venipuncture is a medically necessary component of laboratory blood testing. To the extent that the laboratory blood tests are covered as part of this analysis, so too is the venipuncture.

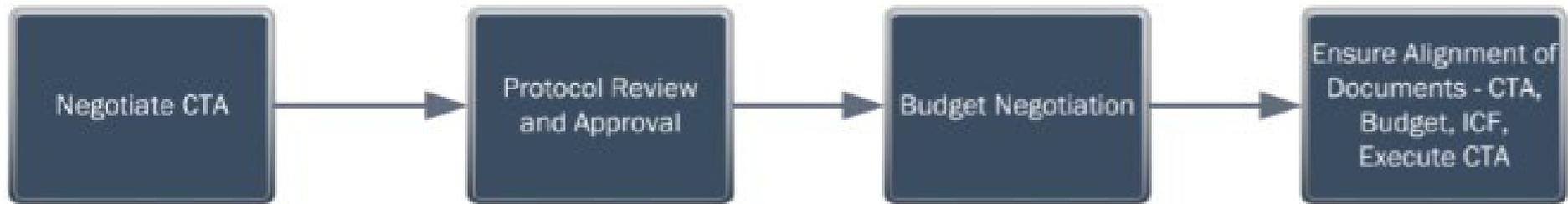
Research Billing Compliance Manual

In addition to the Yale School of Medicine Research Billing Compliance Policy, an online manual was created in order to educate faculty and staff on the research billing compliance workflow and the critical components that encompass clinical trial billing and management.

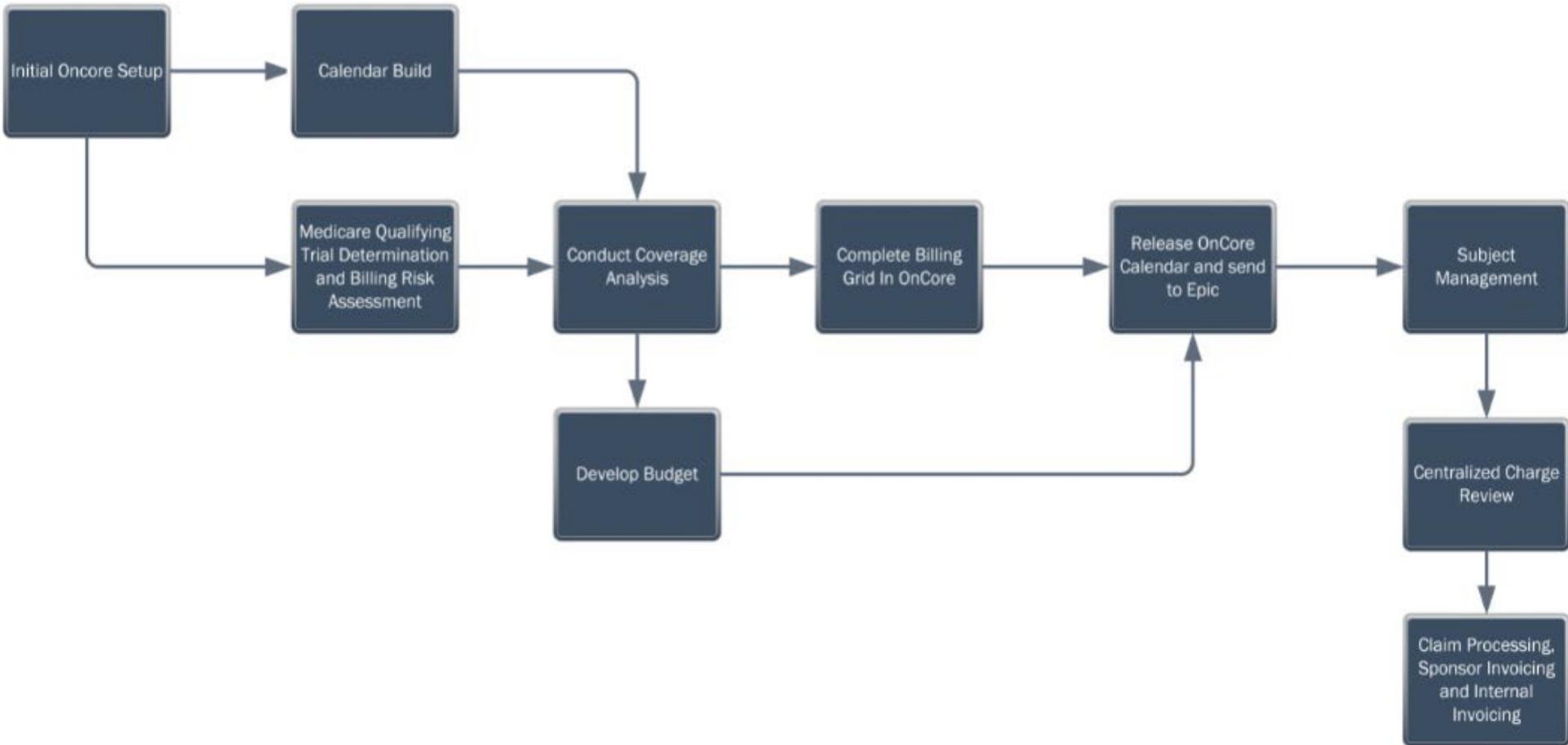
Link for Billing Manual:

[Research Billing Compliance Manual](#)

Research Billing Compliance Workflow: Part I



Research Billing Compliance Workflow: Part II



Protocol Billing Compliance Risk Assessment

Once a research study is identified as a MQT, the Billing Compliance Quality Assurance Team completes a risk assessment determination as to whether a clinical trial is high, moderate, or low risk for research billing compliance purposes. This assessment reviews multiple factors including the following:

- Study Type: Oncology vs Non-Oncology
- Intervention: Interventional vs Non-Interventional
- Treatment Route: IV, injection, procedure vs Oral or N/A
- Phase: Phase 1-2, 3-4, Pilot, Registry, Expanded Access, N/A
- Target Accrual: <10 subjects vs =>10 subjects
- Billing Type: Mixed Billing vs Services are all research or Services are all standard of care
- # of Clinical Services: High Volume vs Low Volume
- Medicare Population: High Volume vs Low Volume or N/A

Clinical Trial Billing QA Process and Workflow

- Once the assessment is complete and the risk level determined, randomly selected trials will have prospective reviews performed by a QA research analyst. If there are any findings identified, the research analyst will determine the source of the oversight as well as address any possible preemptive actions to mitigate any future risk.
- Study related findings will be reviewed with the PI and his/her study team. These discussions will include billing opportunities, documentation recommendations, and collaborative efforts between YCCI and the PI/study team.
- All findings will be accompanied with a corrective action plan (CAP) and execution due dates.
- Follow-up on the CAP as well as continuing education, as needed, will be scheduled at the time of the review meeting.

Factors/Sources that Determine Billing:

- Medicare Coverage Analysis (MCA) or Research vs SOC designations
- Clinical Trial Agreement/Budget
- Informed Consent Form
- Protocol
- OnCore Designations
- Medical Record Documentation

Clinical Trial Billing QA Process and Workflow

Potential Sources of Errors/Compliance Findings:

- **Calendar oversights:** Review of the protocol schedule of events along with the OnCore calendar should be carefully reviewed and scrutinized for any discrepancies and should be addressed with the calendar builder prior to approval.
- **Discrepancies with ICF versus the MCA or R versus SOC Designations:** The consent form and the MCA should be consistent with the patient's financial liability versus the sponsor liability, as it relates to clinical trial services.
- **Late Consents:** Entering untimely consents into OnCore may result in charges bypassing review for trial relation and inappropriately being billed to the incorrect party. Per the YSM policy for "Research Studies with Billable Services", all consents must be entered by the end of the day that the patient is consented.

Potential Sources of Errors/Compliance Findings (continued):

- **Untimely Subject Management:** By not occurring visits within the 24-48 timeframe, several potential issues may arise including non-compliant billing, emails requesting clarification as to whether the service is trial related, and patient complaints regarding incorrect YM and/or YNHH billing.
- **Unclear Medical Record Documentation:** Ideal medical record documentation should include the HIC number and if possible, the treatment cycle and day. When placing an order for a trial, please identify that the reason for the order is a research study and notate the HIC number. Concise documentation ensures correct charge review and eliminates the need for excessive emails requesting additional clarification from the study team.

The Consequences....

- The University of Alabama agreed to pay \$3.39 million to resolve its liability in two whistleblower actions brought against it alleging that false claims were submitted to the Medicare program and the National Institutes of Health in connection with clinical trials for researcher time spent on patient care when no patients had been seen and for double-billing both Medicare and the sponsor of the research grant for the same items and/or services. The two whistleblowers were a physician who was formerly employed by the university and the affiliated faculty practice plan and a research compliance officer from the university.
- Emory University agreed to a \$1.5 million settlement in a False Claims Act case for falsely billing Medicare and Medicaid for services the clinical trial sponsor agreed to pay (and, in some cases, actually did pay, resulting in double payment to Emory for the same service). This case was brought by a whistleblower who was a former research finance manager at Emory.

The Consequences....

- Rush University Medical Center paid \$1 million to resolve its liability for inappropriate clinical trial charges submitted to Medicare and Medicaid for services and items provided by Rush and its staff to patients enrolled in oncology clinical trials.
- Tenet USC Norris Cancer Hospital settled its civil monetary penalty liability with the Office of Inspector General (OIG) for \$1.9 million after self-disclosing overbilling with oncology trials as a “reportable event” pursuant to its corporate integrity agreement requirements. Tenet disclosed that it improperly received government reimbursement for (1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted; (2) items or services intended to be free of charge in the research informed consent; (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or (4) items or services that were otherwise not covered under Medicare’s Clinical Trial Policy.

This concludes our presentation of YCCI's Research Billing
Compliance Training. Questions can be directed to:

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To receive credit for this training module please click on the link
below , complete the quiz and click on submit.

[https://assessment-module.yale.edu/ycci-clinical-research-
compliance-quiz](https://assessment-module.yale.edu/ycci-clinical-research-compliance-quiz)