Yale

# Research Studies with Billable Clinical Services

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| **Responsible Officials** | Dean, Yale School of Medicine and Deputy Dean for Scientific Affairs (Clinical Departments), Yale School of Medicine | **Originally Issued** | 04/01/2019 |
| **Responsible Offices** | Yale Center for Clinical Investigation and Office of Sponsored Projects | **Revision Date** | |



## Scope

This Policy establishes requirements regarding the billing of clinical procedures and services received by study participants in a clinical trial or research study (herein referred to as “research study”).

## Purpose of the Policy

The purpose of this Policy is to establish sound internal control standards to assure the integrity of billing procedures in the Yale School of Medicine’s research studies which require or offer clinical diagnosis, treatment, observation, or other clinical services. Additionally, this Policy is issued to ensure compliance with sponsor terms and conditions, regulations, and Yale School of Medicine’s policies related to billable research study services.

## Policy Statement

Yale School of Medicine is committed to ensuring the appropriate billing of clinical procedures and services associated with its research studies. This commitment applies to all research studies regardless of the source of funds or Yale School of Medicine department performing the research study.

## Definitions

**Billable Services** (herein referred to as "billable services")
Any service rendered to a research subject that, if he/she was not on a study, would normally generate a bill from either Yale-New Haven Hospital or Yale Medicine to the research subject/patient or the patient's insurer. The service may or may not be performed by the research staff of the study or may be provided by professionals within either Yale-New Haven Hospital or Yale Medicine (examples include x-rays, MRIs, CT scans, specimens sent to central labs, or specimens sent to pathology).

1. No distinction is made whether the service is paid for by the research subject or insurance (Standard of Care) or by the study's funding mechanism (Sponsored Research).
2. A billable service includes new services or orders placed in Epic for research subjects.

**Informed Consent Form** (herein referred to as "ICF")
The document used by the investigator to obtain the informed consent of the individual who wishes to participate in the research study. The ICF includes specific information about the study including but not limited to what research services/procedures will be performed and the associated financial obligations of the research subject, his/her insurer, and/or the sponsor.

**Institutional Review Board** (herein referred to as "IRB")
The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Institution. The IRB is responsible for reviewing and approving human subjects research. The IRB can be either a Yale body or a body with which Yale has contracted to review/approve protocols.

**Medicare Coverage Analysis** (herein referred to as "MCA")
MCA is an independent review of a research study to determine which clinical procedures and services are billable to the research subject, third-party payer or sponsored award. The MCA includes a review of the clinical trial documents, published practice guidelines, and Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) to determine the billing status of items and services that are documented in the research protocol and/or research plan.

**Research Study Services** (herein referred to as "services")
Includes but is not limited to tests, clinical procedures, and treatments related to the conduct of the research study. These services fall into one of the following three categories:

1. Services billed to the research study sponsor;
2. Standard of care services related to the research study that should be billed to the research subjects and/or his/her insurer; and
3. Unanticipated or non-research related services that would be billed to the research subject and/or his/her insurer.

## Policy Sections

### 1. Sponsored Research Studies

All human subjects research study agreements supported by any external entity shall be reviewed and negotiated by an appropriate Authorized Official (AO) within the Office of Sponsored Projects (OSP). As part of the agreement review and approval process and to assist in an effective clinical billing process, OSP will ensure the language addressing financial responsibilities contained in the ICF and the agreement align and are evidenced by an accompanying budget.

In rare circumstances, the AO may execute an agreement prior to the IRB's approval of the protocol and ICF. In these situations, OSP must be notified by the Human Research Protection Program of the approved protocol and a final review of the documents must be completed by OSP to ensure consistency with the contractual language.

## 2. Medicare Coverage Analysis

Yale requires that all research studies involving the provision of billable clinical procedures and services must undergo a Medicare Coverage Analysis (hereafter referred to as MCA). By this policy, Yale School of Medicine is requiring The Yale Center for Clinical Investigation's (hereafter referred to as YCCI) Central Medicare Coverage Analysis Unit, to complete a coverage analysis on all qualifying trials. Furthermore, 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.

## 3. Research Study Budget

In order to develop the budget, YCCI will perform a coverage analysis to identify those expenses which are research related or which are standard of care. Final approval of the budget is the responsibility of the Principal Investigator.

Budget development requires the use of Yale Medicine and Yale New Haven Health System (YNHHS) published research fee schedules to ensure that the sponsor fully reimburses Yale for the costs of conducting the study. In those cases where the published fees may not align with the expectations of the sponsor, all budgets must be in accordance with institutional policies.

## 4. 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.

## 5. 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. 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.

## 6. 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.

## 7. 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.

**8. 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).

## Roles and Responsibilities

### Human Research Protection Program

- Ensures that IRB policies, procedures and practices are compliant with University policies, federal regulation and state law requirements.
- Provides guidance to the IRBs on emergent issues and ensures consistency across the University IRBs.

### Institutional Review Board

- Reviews, approves, and provides continuing oversight of research involving human subjects.
- Ensures the protocol and ICF adequately describe financial obligations
- Ensures the protection of human subjects in the design and conduct of human subject research through dissemination of guidance, training and monitoring activities.

### Office of Sponsored Projects

- Structures relationships and negotiates agreements with external parties funding research at Yale, such as federal agencies, foundations, and for-profit corporations.
- Ensures that the terms of the clinical trials agreements align with the IRB approved protocols including the Informed Consent Form and proposed budget.
- Ensures agreements are consistent with University requirements related to the ethical conduct of research.
- Ensures that research grant and contract funds are not expended for human subjects' research which has not been approved by an IRB of record.

### Principal Investigator

- Ensures the research study is conducted according to the IRB approved protocol and in accordance with University policies, federal, state and local regulations, terms of the sponsored award/investigator statement and other applicable regulations.
- If a patient or insurer is inappropriately billed for costs of study-related tests, treatment, procedures and/or services, the PI should ensure those payments are refunded and billed to the appropriate entity.
- Ensures study participants are adequately informed of their financial obligations.
- Ensures the study framework is created in OnCore
- Works hand-in-hand with YCCI and the study team to develop a detailed schedule of events and procedures, equipment, items, services, and human participant visits required to carry out the schedule of events.
- Ensures the accuracy of the billing grid.
- Works with the Clinical Research Billing Quality Assurance group to resolve any billing issues.
- Ensures that the services provided are documented and billed appropriately.

### Yale Center for Analytical Sciences

- Registers applicable clinical trials using the Protocol Registration System (ClinicalTrials.gov)
- Supports the reporting of results of applicable clinical trials using the Protocol Registration System (ClinicalTrials.gov)

## Yale Center for Clinical Investigation

- Works hand-in-hand with the PI and study team to develop a detailed schedule of events and procedures, equipment, items, services, and human participant visits required to carry out the schedule of events.
- Ensures that a detailed MCA is completed for all research studies regardless of funding source, identifying items and services that can be billed to insurance versus items that cannot.
- Develops and negotiates final budget directly with sponsor and/or Clinical Research Organization (CRO).
- Coordinates MCA and budget negotiation with OSP.
- Conducts clinical research billing quality assurance activities.

## Related Information

IRB Policy 200 Informed Consent for Human Research

## Contact Information

- Human Research Protection Program : 203.785.4688 E-mail: HRPP@yale.edu
- Office of Sponsored Projects : 203.785.4689.
- Yale Center for Clinical Investigation : 203.785.3482 Email: YCCI@yale.edu
- Yale Clinical Trials.gov Team : 203.737.5946 Yale.CTgov@yale.edu

## Revision History

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