**OFFICE OF CLINICAL RESEARCH FOR INDIANA**

**COVERAGE ANALYSIS AND CLINICAL RESEARCH BILLING POLICY**

## ABOUT THIS POLICY

Effective Date: 11/1/2019
Last Updated: 7/17/2024
Responsible Unit: Office of Clinical Research for Indiana
Responsible Administrator: J. Carmel Egan, PhD.

## PURPOSE

This policy addresses the steps by which clinical research studies and related materials will be reviewed to determine whether items and services therein can be billed to third party payers (including Medicare), invoiced to research sponsors, or covered by healthcare partner or departmental resources.

## SCOPE

This policy applies to all research projects being conducted by IU and IU Health investigators where charges for protocol-directed items, services, and procedures occur within any healthcare billing system. This policy is applicable regardless of project funding source or research participants' insurance - federal, state, or commercial.

## POLICY STATEMENT

It is the policy of the Office of Clinical Research for Indiana that all clinical services rendered during a clinical research study are to be billed to the appropriate study account, third party payer, or individual in compliance with applicable state and federal regulations, in particular the Center for Medicare and Medicaid Services National Coverage Determination for Routine Costs in Clinical Trials (CMS NCD 310.1, July 2007).

## DEFINITIONS

Coverage Analysis (CA): Detailed review of clinical research items, services, procedures, and Medicare billing rules to determine the appropriate payer/funding source for each. The Coverage Analysis consists of a Qualifying Clinical Trial (QCT) checklist, a billing grid with procedure designations, and a document alignment review.

CMS: Centers for Medicare and Medicaid Services.

Routine Costs[1]: Items and services that would ordinarily be provided to beneficiaries and covered by insurance (including Medicare). These include items that are:

- typically provided absent a clinical trial (conventional care)
- required solely for the provision of the investigational item or service (e.g. administration of a non-covered chemotherapeutic agent),
- provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item
- needed for reasonable and necessary care arising from the provision of an investigational item or service-in particular, for the diagnosis or treatment of complications.

Qualifying Clinical Trial[2]: A research study that evaluates covered benefits, has therapeutic intent, enrolls patients with diagnosed disease (healthy controls allowed,) and is considered "deemed" to have desirable characteristics in accordance with the CMS Clinical Trial Policy; or an Investigational Device Exemption (IDE) study having received approval for coverage from CMS through their approval request process.[3]

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[1] Derived from the Medicare Clinical Trials Policy NCD 310.1 https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA

[2] Derived from the Medicare Clinical Trials Policy NCD 310.1 https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA

[3] Medicare Coverage Related to Investigational Device Exemption (IDE) Studies https://www.cms.gov/Medicare/Coverage/IDE/index.html

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## BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) 310.1 states: "Medicare covers the routine costs of qualifying clinical trials… as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply." IU Health will use the CMS rules as the standard for all clinical research billing, regardless of patients' insurance.

The requirements and methodologies set forth in this policy help ensure that procedures are in place to identify those costs that are billable to insurance, including Medicare so that patient bills are accurate; research project budgets accurately reflect the cost of conducting a project; and, research agreements reference the appropriate financial terms in order to conduct the project.

Together, IU and IU Health personnel are responsible for ensuring that research patient charges are correctly identified and assigned to the appropriate payer. As a healthcare provider, IU Health is responsible for ensuring that routine costs are segregated from research charges; that appropriate research discounts are applied; that the CMS research required elements are appended to charges/claims for Medicare (and Medicaid, as applicable) beneficiaries; and, that patient charges are invoiced and/or released from the research bill hold. IU Health also serves as the IU clearing house for any research patient account issue, investigates discrepancies, and ensures that processes for managing research patient care expenses are fluid, efficient, and compliant.

## PROCESS REQUIREMENTS

Under this policy, IU and IU Health study teams and the Office of Clinical Research (OCR) or designee are responsible for the following:

1) All research projects being conducted by IU and IU Health investigators where charges for items, services, and procedures occur within the IU Health system must be documented by the study team in the IU clinical research management system (OnCore) before enrollment begins. Protocol status updates must be submitted by the study team **within 48 hours** of changes.
2) All research subjects participating in applicable IU clinical research studies must be registered in OnCore by the study team **within 48 hours** after obtaining informed consent. Subject status updates must be submitted by the study team **within 48 hours** of changes.
3) OCR or designee shall create a coverage analysis (CA) with billing determinations for applicable clinical research studies in collaboration with IU Health Revenue Cycle Services (RCS) personnel and the Principal Investigator (PI) or her/his designee. A preliminary CA will be completed using draft versions of the study protocol; informed consent; clinical trial agreement (CTA) or notice of grant award; and, proposed budget. The final CA must be based on finalized documents.
4) The final CA must be approved by the PI or designee before study initiation to ensure that all clinical services rendered during the course of the study are billed appropriately. OCR or designee will archive the final CA, billing grid and approvals in OnCore.
5) OCR or designee will confirm that billing determinations and language regarding financial responsibility are consistent between the CA, clinical trial agreement or grant award, study budget and informed consent during final document alignment review before study initiation. OCR or designee will review and update the CA when the study protocol is amended with changes to the protocol-directed items, services, or procedures.
6) OCR or designee shall create a study calendar in OnCore for each study and will update the calendar as needed in collaboration with the study team.
7) The study team shall record subject visits in OnCore and review procedures for accuracy **within 48 hours** of the visit.

8) OCR or designee and the PI or designee will work with IU Health RCS to ensure that all questions, disputes, and denials are reconciled in accordance with the approved coverage analysis.

9) The study team shall approve payment for all appropriately invoiced research charges to IU Health RCS in a timely manner to comply with IU Health RCS requirements.

## PROCEDURE EXCEPTIONS

1) Research protocols that do not generate charges through IU Health Revenue Cycle billing systems are exempted from this procedure.

2) Exception to the 48-hour consent entry window is granted only when a subject signature is required on the ICS ***and*** when consent discussions/processes are conducted remotely. Date of consent should be entered into OnCore within 48 hours of study team's verification of the signature. If the consent is being entered late under this exception, the study team should note the late consent entry in the Subject Console > Consent > Other Consent Status comments field.

## SANCTIONS

Individuals found to be in violation of this policy may be subject to research-related sanctions, up to and including permanent suspension or debarment from engaging in research at Indiana University as well as additional discipline up to and including termination pursuant to applicable University policies/procedures.

### ADDITIONAL CONTACTS

| *OCR Teams* | *Email* |
|---|---|
| Financial Compliance | ocrfin@iu.edu |
| Research Systems | oncore@iu.edu |
| IU Health Clinical Trials & Research Charge Team | clinicaltrials@iuhealth.org |

### RELATED INFORMATION

- IU-OCR Coverage Analysis Standard Operating Procedure
- IU Health Research Policy IU Clinical Trials Management System Policy – https://policies.iu.edu/policies/ca-01-clinical-trials-management-system/index.html
- Medicare Clinical Trial Policy – https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true
- Affordable Care Act Regulations – https://www.congress.gov/bill/111th-congress/house-bill/3590

### HISTORY

Updates on 7/17/2024.

Updates on 7/1/2023.

Inaugural Policy effective date 11/1/2019.