



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.21, **Medicare Coverage Analysis (MCA) for all Clinical Trials**

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to establish institutional requirements for Medicare Coverage Analyses (MCAs) for human-subjects clinical trials conducted at TTUHSC El Paso. This policy is intended to ensure compliance with applicable federal regulations, including Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) 310.1, applicable Medicare billing requirements, and institutional clinical research billing compliance standards.

REVIEW: This HSCEP OP will be reviewed October 1 of each odd-numbered year by the associate director and senior director of the Office of Research (OR), with recommendations for revisions submitted to the vice president for research (VPR) or designee.

POLICY/PROCEDURE:

I. Introduction

TTUHSC El Paso requires that all applicable human-subjects clinical trials undergo a Medicare Coverage Analysis (MCA) prior to study activation, budget finalization, and execution of the Clinical Trial Agreement (CTA), as applicable. The MCA serves to identify study-related items and services that may appropriately be billed to Medicare and/or third-party payers and those that must be funded by the study sponsor or other funding source.

Compliance with this policy is required to ensure:

- Appropriate clinical trial billing practices;
- Compliance with federal billing regulations and CMS requirements;
- Accurate allocation of research-related costs;
- Consistency between study budgets, contracts, informed consent documents, and billing designations.

II. Applicability

This policy applies to:

- A. All TTUHSC El Paso investigators, study teams, departments, and research personnel involved in the conduct or administration of human-subject clinical trials;
- B. All qualifying clinical trials conducted under TTUHSC El Paso oversight, regardless of funding source.

III. Definitions

External Coverage Analysis Vendor: An external vendor contracted to perform the coverage analysis.

Medicare Coverage Analysis (MCA): A systematic review of all procedures, tests, and visits in a clinical trial protocol to determine which items are standard of care and which are research-only.

Research-Only (R): Procedures, tests, and visits required solely for research purposes, to be covered by the sponsor/funding source.

Standard of Care (SOC) aka Routine Costs: Procedures, tests, and visits considered routine and billable to insurance or patient.

Qualifying Clinical Trial (QCT): A clinical trial that meets the federal criteria established by CMS for coverage of routine costs.

IV. **Institutional Requirements**

A. Medicare Coverage Analysis (MCA) Requirement

All applicable clinical trials must undergo an MCA review prior to:

- Finalization of the study budget;
- Execution of the Clinical Trial Agreement (CTA);
- Study activation.

B. MCA Review and Approval

The finalized MCA must be reviewed and approved by the Principal Investigator (PI) and/or designated study personnel.

Departments are responsible for ensuring alignment between:

- The MCA;
- The study budget;
- The Clinical Trial Agreement (CTA);
- The Informed Consent Form (ICF).

C. Protocol Amendments and Study Changes

Departments and study teams are responsible for notifying the Office of Research or designated clinical research finance personnel of protocol amendments or study changes that may impact:

- Billing designations;
- Study procedures;
- Budget assumptions;
- Coverage determinations.

D. Distribution of MCA

Departments are responsible for ensuring that finalized MCA documentation is distributed to all applicable institutional billing, compliance, and service areas prior to study activation.

V. **MCA Fees and Financial Responsibility**

MCA fees established by the institution's contracted vendor shall be considered required clinical trial start-up costs.

- For industry-sponsored clinical trials, MCA fees must be incorporated into the study budget as a "Compliance Fee", where applicable and sponsors should be invoiced accordingly.
- For federally funded studies, MCA fees may be treated as indirect costs (IDC), where allowable.

To facilitate timely processing, the Office of Research may temporarily utilize institutional funds pending study activation and account establishment. Departments are responsible for completing any required cost transfers within 30 days of fund activation. If a study is not activated, the contract is not executed, or a study account is not established, the department will remain financially responsible for the MCA fee.

VI. **Compliance**

Compliance with this policy will be monitored by the Office of Research and may be subject to institutional audit and review.

Failure to comply with this policy may result in delays to study activation or other institutional corrective actions, as appropriate.

VII. **Amendments**

TTUHSC El Paso reserves the right to modify, amend, or terminate this policy at any time.