



## UNIVERSITY OF SOUTH ALABAMA

### Coverage Analysis

EFFECTIVE DATE: May, 2017

#### **Purpose and Scope**

This Policy describes the shared responsibility for performing the Coverage Analysis in development of a Clinical Trial budget. If a Clinical Trial requires patient care items and services (i.e., billable items/procedures/services such as those with Current Procedural Terminology (CPT), Healthcare Common Procedural Coding System (HCPCS), Diagnosis-Related Group (DRG) and International Classification of Diseases (ICD) codes) performed in furtherance of the Clinical Trial, then the Coverage Analysis Process shall be performed, as set out in this Policy, unless provided an exception by the University of South Alabama Office of Research. This Policy shall apply to all Clinical Studies regardless of funding source (i.e. extramural industry funding, extramural non-profit or government funding, and/or intramural funding).

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#### **Definitions**

**Clinical Trial:** is a research study or trial that enrolls and/or treats research participants at any USA operated facility, which may result in any charges that the hospital and/or faculty practice group could charge to a patient, their medical insurer (including but not limited to government programs). A Clinical Trial can be sponsored by extramural industry funding, extramural non-profit or government funding, private sources outside the University and/or with University discretionary funds.

**Coverage Analysis Matrix:** is a Clinical Trial budget grid that identifies all protocol required procedures and services, lists the corresponding CPT/HCPCS code and USA research price, or designates the item/service as a routine cost, as defined under the National Coverage Determination (NCD) and Center for Medicare and Medicaid Services (CMS) Clinical Trials Policy (CTP).

**Coverage Analysis Process:** is an analysis to a) determine if the Clinical Trial is a Qualifying Clinical Trial and b) ensure costs for Clinical Trial services and procedures are distributed

between research costs and routine costs to ensure proper billing of such costs to either the Clinical Trial Sponsor or a Third Party Payer.

**Principal Investigator:** (PI) Please see USA policy on Principal Investigators.

**Qualifying Clinical Trial:** is a Clinical Trial that meets the requirements outlined in CMS CTP, which may qualify for reimbursement of routine costs from a Third Party Payer.

**Research Procedures:** are the services and items required by the approved Institutional Review Board protocol and do not meet the definition of routine costs as defined by CMS.

**Sponsor:** is the organization that funds a Clinical Trial, often used interchangeably with funding agency. Third Party Payer/Payor is an organization other than the patient (first party) or health care provider (second party) involved in the financing of personal health services (e.g. Medicare, Medicaid, CHIPS, CSS, Aetna, Anthem Blue Cross, etc.).

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## Policy Statement

A Clinical Trial must have a budget that accurately and appropriately allocates the costs associated with performance of the Clinical Trial to the responsible payer (i.e. a Sponsor, Third Party Payer, or internal funding source). In order to ensure costs are allocated to the appropriate entity, the Coverage Analysis Process must be performed. PIs have primary responsibility for ensuring the Coverage Analysis Process is performed in compliance with applicable law and this Policy. PIs must document the proper allocation of Clinical Trial costs between Sponsor or internal funding source, as referenced above, and Third Party Payers through the Coverage Analysis Process described in this Policy.

Clinical Studies that do not comply with this Policy may not be able to begin or utilize services of a USA operated facility. The PI and/or their department may be responsible for any financial consequences resulting from non-compliance.

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## Procedures

a. The PI, Study Coordinator, Research Coordinators, Grant Administrators and any other members of the Study Team ("Study team") share the responsibility to ensure that Clinical Trial costs are properly analyzed and assessed.

b. The study team shall Complete Tab 1 of Coverage Analysis Template to determine in a Clinical trial is a Qualifying Clinical Trial. The PI must confirm and certify the accuracy of the information provided in the Coverage Analysis Form.

- c. If the Clinical Trial is determined to be qualifying, then Tab 2 of the Coverage Analysis Template must be completed that identifies and differentiates routine costs that may be billed to the participant and/or any Third Party Payer from the Research Procedures and Services.
- d. Documentation should be used for differentiation of routine costs and Research Procedures (e.g., NCDs, Local Coverage Determinations (LCDs), USA routine care practices, acceptable peer-reviewed literature, professional medical organizations or associations and/or PI or Chair-provided written justification, collectively referred to as supporting documentation).
- e. The Sponsor or other eligible source of funding or support, other than a Third Party Payer, must provide for the costs of performing all Research Procedures.
- f. Completed Coverage analysis should be submitted to the Office of Research for review and certification that the Coverage Analysis Process has been completed.
- g. Upon the office of Research's request, the study team will provide clarification, additional supporting documentation and/or revises the coverage analysis documentation previously provided to comply with this Policy and applicable law.
- h. If the Clinical Trial is not a Qualifying Clinical Trial, all costs associated with performance of the Clinical Trial must be provided by the Sponsor.
- i. The PI ensures that copies of the final certified coverage analysis documents are maintained with the Clinical Trial study records.
- j. The PI ensures that an updated Coverage Analysis Matrix is completed and submitted to office of Research for any protocol amendments that add or remove any items, procedures, and/or services of a Qualifying Clinical Trial.
- k. The office of Research reviews and certifies the PI has completed the Coverage Analysis Process and any outstanding issues have been satisfactorily addressed in accordance with applicable law and this Policy.
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## References

Center for Medicare & Medicaid Services (CMS) – National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) as subsequently modified by the Clinical Trial Policy (CTP) update of 2007.

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## **Related Documents**

Coverage Analysis Template

## **History**

First Published May 2017

## **Next Review Date**

May 2019

## **Responsible Party**

Vice President Office of Research and Economic Development