

## 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).

### 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 (i)-2 (ns)-1 (ur)-7 (e)4 (r)3 ( )3 (i)-2 (nc)4 (l)(t)-16 (i)-6 (nn-1 (e)-6 (al

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**



## **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