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## UCLA Policy 915: Clinical Studies Coverage Analysis

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Issuing Officer: Associate Vice Chancellor, Health Sciences and  
Executive Vice Dean, David Geffen School of Medicine

Responsible Office: Dean's Office, David Geffen School of Medicine

Effective Date: July 1, 2014

Supersedes: UCLA Policy 915, dated March 1, 2013

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### I. PURPOSE AND SCOPE

This Policy describes the shared responsibility for performing the Coverage Analysis Process in development of a Clinical Study budget. If a Clinical Study 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 Study, then the Coverage Analysis Process shall be performed, as set out in this Policy, unless provided an exception by the David Geffen School of Medicine Clinical Trials Administration Office (CTAO).

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).

### II. DEFINITIONS

For the purposes of this Policy:

**Clinical Study** is a research study or trial that enrolls and/or treats research participants at any UCLA 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), and/or Full Accounting Unit (FAU). A Clinical Study 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 Study budget grid that identifies all protocol required procedures and services, lists the corresponding CPT/HCPCS code and UCLA 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 Study is a Qualifying Clinical Trial and b) ensure costs for Clinical Study services and procedures are distributed between research costs and routine costs to ensure proper billing of such costs to either the Clinical Study Sponsor or a Third Party Payer.

**Principal Investigator (PI)** is a UCLA employee, generally an academic appointee or individual who has been granted an exception to serve as a PI under UCLA Policy 900, who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of any Clinical Study.

**Qualifying Clinical Trial** is a Clinical Study 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 Study, 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.).

### III. POLICY STATEMENT

A Clinical Study must have a budget that accurately and appropriately allocates the costs associated with performance of the Clinical Study to the responsible payer (i.e. a Sponsor, Third Party Payer, or internal funding source) and adheres to UCLA Procedure 915.1, Pricing for Budgeting and Contracting of Clinical Studies. 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 Study 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 UCLA operated facility. The PI and/or their department may be responsible for any financial consequences resulting from non-compliance.

### IV. PROCEDURES

The parties below share the responsibility to ensure that Clinical Study costs are properly analyzed and assessed.

#### **PI, Study Coordinator, Fund Manager, Department Administrator, collectively, the Study Team**

- A. Complete a **Qualifying Clinical Trial Form** (QCT Form) to determine if the Clinical Study qualifies for reimbursement from a Third Party Payer. The PI must confirm and certify the accuracy of the information provided in the QCT Form.
  1. If the Clinical Study is a Qualifying Clinical Trial, then a Coverage Analysis Matrix 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.
  2. In collaboration with CTAO, the study team documents the rationale for differentiation of routine costs and Research Procedures (e.g., NCDs, Local Coverage Determinations (LCDs), UCLA 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).
  3. 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.

4. If the Clinical Study requires use of an investigational and/or approved medical device or is an exempt Investigational New Drug (IND) Clinical Study, the PI must complete the required QCT Supplement Form in accordance with the instructions set forth therein. Device trials may require the UCLA Value Analysis Committee review and approval, and the Director of Reimbursement to submit approval directly to a Medicare Administrative Contractor.
  5. Submit the completed QCT Form and, as applicable, a Coverage Analysis Matrix, QCT Supplement Form and supporting documentation (collectively, Coverage Analysis Documents) to the CTAO for review and certification that the Coverage Analysis Process has been completed.
  6. Upon CTAO's request, provides clarification, additional supporting documentation and/or revises the coverage analysis documentation previously provided to comply with this Policy and applicable law. In the event any discrepancies or inconsistencies remain unresolved, the appropriate Chairs and the Vice Chancellor, Associate Vice Chancellor or Assistant Vice Chancellor of Health Sciences and/or Research will be consulted.
  7. If the Clinical Study is not a Qualifying Clinical Trial, all costs associated with performance of the Clinical Study must be provided by the Sponsor. An abbreviated coverage analysis review may be performed upon receipt of a signed Principal Investigator Research Only Attestation. In the event the Sponsor will not provide all costs of performing the Clinical Study, contact CTAO for guidance.
- B. The PI ensures that copies of the final certified coverage analysis documents are maintained with the Clinical Study records.
- C. The PI ensures that an updated Coverage Analysis Matrix is completed and submitted to CTAO for any protocol amendments that add or remove any items, procedures, and/or services of a Qualifying Clinical Trial.

#### **Clinical Trial Administration Office (CTAO)**

- A. CTAO Clinical Research Analysts/Administrators (CRAs) review and certify the PI has completed the Coverage Analysis Process and any outstanding issues have been satisfactorily addressed in accordance with applicable law and this Policy.
- B. CRAs coordinate the distribution of the final certified coverage analysis documents to the applicable campus contract and/or grant office. The final certified coverage analysis document shall be maintained with the Institution's official contract/grant file.

#### **Chairs and Vice Chancellors for Health Sciences and Research**

In the event a discrepancy or inconsistency in the coverage analysis documents remains unresolved, an ad hoc review group including the CRAs, PI, department chair and Vice Chancellor, Associate Vice Chancellor or Assistant Vice Chancellor for Health Sciences and/or Research may be convened in order to achieve resolution prior to certification of the coverage analysis documents.

#### **V. REFERENCES**

1. 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.
2. Referenced Forms available at UCLA Clinical Trials website <http://clinicaltrials.ucla.edu> – “For Faculty/Staff” link.
  - A. QCT Form
  - B. QCT Supplement Form

- C. Coverage Analysis Matrix
- D. Principal Investigator Research Only Attestation
- 3. UCLA Interim Procedure 915.1, Pricing for Budgeting and Contracting of Clinical Studies

**Issuing Officer**

**/s/ John C. Mazziotta**

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**Associate Vice Chancellor, Health Sciences  
and Executive Vice Dean, David Geffen School  
of Medicine**

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**Questions concerning this policy or procedure should be referred to  
the responsible department listed at the top of this document.**

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