
UCLA Interim Pricing for Budgeting and Contracting of Procedure 915.1: Clinical Studies

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

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

Effective Date: July 1, 2014

Supersedes: New

- I. BACKGROUND**
- II. PURPOSE & SCOPE**
- III. DEFINITIONS**
- IV. PRICING PROCEDURE**
- V. PROCEDURE FOR ACQUIRING PRICING IN CERTAIN SITUATIONS**
- VI. RESPONSIBILITIES**
- VII. REFERENCES**

I. BACKGROUND

Informal and limited research pricing guidance may cause confusion and inconsistency in procedural cost budgeting for Clinical Studies. Such procedural cost variance may result in several risks, including but not limited to: funding deficiency that may result in a study account deficit, challenging budget negotiations with sponsors, noncompliance with clinical research billing requirements, and/or the Federal Anti-Kickback Statute. A transparent research pricing procedure that allows for consistency and appropriate budgeting and contracting is essential for UCLA to remain competitive in performing innovative clinical research and maintaining compliance with applicable laws and University policies.

Many institutions, including UCLA, have developed standardized research pricing procedures based on Centers for Medicare and Medicaid Services (CMS) reimbursements. CMS pricing is widely used as a research pricing anchor, as it is readily available.

II. PURPOSE & SCOPE

This interim Procedure has been established to offer immediate assistance to Principal Investigators (PI) for budgeting and contracting of Clinical Studies. This interim Procedure complies with UCLA Policy 915, Clinical Studies Coverage Analysis, the Recovery of Costs requirement of the UC Operating Memo 95-05 and UCLA Policy 913, Disposition of Unexpended Balances in Fixed Rate and Fixed Price Contracts and Nonrefundable Grants.

This interim Procedure will remain in effect from the effective date above until it is superseded by a final procedure reviewed and approved by the Clinical Research Governance Committee.

III. DEFINITIONS

For the purposes of this Procedure:

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.

For-Profit Clinical Study is a Clinical Study that is funded extramurally by a for-profit organization.

Non-Profit Clinical Study is a Clinical Study that is funded extramurally by a governmental or non-profit organization, or internally funded through departmental/division funds, and/or other discretionary funds utilized by the PI (including but not limited to PI and staff time and effort used to conduct the Clinical Study).

Procedural Research Cost(s) is any procedure, service or item, including but not limited to those procedures, services and / or items identified by: Current Procedural Terminology (CPT), Diagnosis-Related Group (DRG), Ambulatory Payment Classifications (APC), and International Classification of Diseases (ICD) codes required by a Clinical Study that can, though not necessarily will, be charged to a patient or third party payer (e.g. CMS, medical insurance providers, etc.) by either the hospital or faculty practice billing groups.

Research Fee Schedule(s) refers to the annually published research pricing for all hospital/technical and professional/physician fees that are required for budgeting all applicable Procedural Research Costs associated with performance of any Clinical Study.

IV. PRICING PROCEDURE

This Procedure is intended to minimize institutional risk of charging for-profit entities less than Federal and State payers, and minimize risk of department deficit caused by inflationary increases in Procedural Research Costs through the duration of a Clinical Study.

The following pricing guidelines shall be followed in the budgeting and contracting of any Clinical Study and exceptions to the guidelines contained herein shall be submitted to the Pricing and Charges Subcommittee of the Clinical Research Governance Committee for review and approval.

- A. Non-Profit Clinical Study pricing published in the Research Fee Schedule(s) will reflect current pricing that is based on the Department of Health and Human Services (DHHS) Rate Agreement that is negotiated annually between UCLA and the DHHS.
- B. For-Profit Clinical Study pricing published in the Research Fee Schedule(s) will reflect pricing that is at a minimum of CMS reimbursement plus 50% (e.g. 150% applicable CMS reimbursement). For-Profit Clinical Study pricing will be used for external contracting purposes with for-profit sponsors.
- C. PIs will ensure that Procedural Research Costs for any Clinical Study budget appropriately reflect the costs as determined by the applicable Research Fee Schedule(s) published and available at the time of Institutional Review Board submission for the Clinical Study. Use of Non-Profit or For-Profit Clinical Study pricing will be determined by the source of Clinical Study funding and support.
- D. The internal charges appropriated by UCLA hospital and faculty practice billing groups to internal Clinical Study account(s) (charges to the FAU/research accounts) shall be appropriated at the present-day CMS pricing (e.g. 100% applicable CMS reimbursement). Clinical Study budgets and respective research accounts must comply with UCLA Policy 913.
- E. Flexibility to negotiate pricing higher than those published in the Research Fee Schedules for For-Profit Clinical Studies must comply with fair market value guidelines, UC Operating Requirement No. 95-5, and UCLA Policy 913. Procedural Research Cost(s) may not exceed the usual and customary charge of the UCLA Health System (e.g. full-published charge commonly provided to uninsured payers).
- F. Flexibility to negotiate appropriate pricing for procedures, services, or items for which there are no associated CPT, DRG, APC, ICD codes, must maintain compliance with fair market value guidelines, UC Operating Requirement No. 95-5, and UCLA Policy 913.

V. PROCEDURE FOR ACQUIRING PRICING IN CERTAIN SITUATIONS

If a Clinical Study:

1. Requires budgeting inpatient services, including but not limited to hospitalization and ancillary services, surgery, or overnight observation/recovery, a written request for pricing shall be submitted to the Medical Center Charge Master in advance of budget negotiation and external budget submission.
2. Utilizes facilities and/or services provided by the Clinical and Translational Research Center (CTRC), PIs are responsible for submitting a written request for pricing from the CTRC in advance of budget negotiation and external budget submission.
3. Includes Radiology and Nuclear Medicine setup fees, these fees must be obtained by the PI in advance of budget negotiation and external budget submission. Radiology and Nuclear Medicine setup fees may be obtained by submitting an application and startup quote request to the appropriate Radiology and Nuclear Medicine department contact.
4. Requires Investigational Pharmacy services for investigational product storage, maintenance, preparation, dispensing, and/or accountability, PIs are responsible for submitting a written request for pricing from Investigational Pharmacy in advance of budget negotiation and external budget submission. Investigational pharmacy must also formally review and approve any exception to waive the requirement to centrally store, maintain, prepare, dispense, or account for investigational product.

VI. RESPONSIBILITIES

Clinical Research Governance Committee

The Clinical Research Governance Committee is the governing committee charged with developing policies, strategies, and priorities related to clinical research pertaining to, and on behalf of the UCLA Campus and Health System. Responsibilities include:

- Tasking a subcommittee to review the external and internal research procedures associated with both Clinical Studies;
- Forming a comprehensive research pricing procedure that will supersede this interim Procedure; and
- Reviewing pricing outliers to ensure Procedural Research Costs are consistently and appropriately applied.

Clinical Trials Administration Office

- Responsible for coverage analysis certification and clinical trial contract review and execution; and
- Identifying outliers to this interim Procedure and bringing cases for discussion to the Pricing and Charges Subcommittee tasked with reviewing this Procedure.

Principal Investigators

- Ensure Procedural Research Costs are incorporated into Clinical Study budgets in accordance with this Procedure; and
- Provide justification to Clinical Research Governance Subcommittee in the event that Procedural Research Costs incorporated into any budget are greater than UCLA Health System's usual and customary pricing, or lesser than the pricing included in the published Research Fee Schedule(s).

VII. 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. UCLA Policy 915: Clinical Studies Coverage Analysis (all definitions therein are incorporated by reference into this Research Pricing Policy);

3. UCLA Policy 913: Disposition of Unexpended Balances in Fixed Rate and Fixed Price Contracts and Nonrefundable Grants;
4. Federal Anti-Kickback Statute;
5. UC Operating Requirement No. 95-5;
6. Medical Center Charge Master: Hospital Corporate Finance Representative Responsible for Publication of Annual Research Fee Schedule;
7. Physician Payments Sunshine Act.

Issuing Officer

/s/ John C. Mazziotta

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

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