Clinical Research Charge Review
Standard Operating Procedures

I. Objective

To document standard operating procedures for review and adjudication of research (study) related charges in accordance with the applicable OnCore Billing Grid, or in lieu of an OnCore Billing Grid, in accordance with the study billing type and information available in OnCore, which represent the primary source record utilized for the management of clinical research studies at UCLA Health Sciences.

II. Source Records Utilized for Research Charge Processing

CareConnect research-related charges will be processed and posted to the UCLA study fund account listed in CareConnect within thirty (30) calendar days from the date the billing encounter is closed in Care Connect. Research charges will be adjudicated in accordance with the most current information available in OnCore at the time of charge processing, including applicable research rate(s) and applicable payer (study account vs. patient/insurance/other guarantor), and in accordance with UCLA Research Pricing Policy 915.1, and the applicable UCLA Research Charge Master. Research charges will be processed in accordance with the information available in OnCore, which includes:

A. Current Qualifying Clinical Trial determination, in accordance with the Federal Medicare Clinical Trial Policy (NCD 310.1);
B. Current released OnCore billing grid, or in lieu of, the following data will inform charge processing:
    i. Certified budget (OnCore financials console); and/or
    ii. Final Billing Type (OnCore annotations).

III. Roles and Responsibilities

Clinical Research Faculty & Staff Responsibilities

Clinical research faculty, research staff, and clinical staff facilitating patient care for research participants at UCLA Health will ensure all study participant visits and associated patient care are encountered within three (3) business days of the date of the subject's visit and/or clinical services are ordered.

Clinical research faculty, research staff, and clinical staff facilitating patient care for research participants at UCLA Health will ensure all study participant visits are linked to the respective research study in CareConnect prior to the visit encounter, but no later than the day of the encounter.

In the event an individual identifies research-related clinical visit(s) and/or service(s) were provided without being associated with a clinical research study in CareConnect, individual(s) are required to notify the Centralized Research Business Partners (CRBP) by emailing UCLAHSCRBP@mednet.ucla.edu. The CRBP team should be notified as soon as such information becomes known, so the CRBP team may assist with associating

the specific patient encounter and corresponding services to the applicable clinical research study and facilitate any additional action(s). Notification to CRBP should include the following information:

- Study IRB Number
- Date of service(s)
- Subject's MRN
- Corresponding study visits in OnCore
- Specific items/services requiring association to the study

Principal Investigator (PI) and/or approved delegate(s) are required to review, validate and when applicable, correct CareConnect research-related charges via the CareConnect Research Billing Review Activity, also referred to as, "Tier I Review" to ensure the following:

A. Study participant charges are being routed to the appropriate payer (e.g., study account vs. patient/insurance/guarantor) in accordance with the Source Records listed in Section II above.

B. Accurate research rates are listed for charges directed to the study fund account, in accordance with the Source Records listed in Section II above, UCLA Research Pricing Policy 915.1, and the applicable UCLA Research Charge Master.

The Principal Investigator and/or approved delegates are responsible for reviewing CareConnect charges associated with research subjects and validating or correcting the payer associated with the charge in accordance with the Source Records defined in Section II herein. Tier I Charge Review and payer options currently include the following, which are subject to revision/updates that shall be communicated from time to time:

- study related billable to study, OR
- study related billable to patient/insurance, OR
- non-study related, billable to patient/insurance.

Principal Investigator and/or approved delegates are provided **ten (10) calendar days to complete Tier I Review in CareConnect.** Research rate price override requests will be reviewed by CRBP and validated via the Source Records listed in Section II herein. Only those charge correction requests validated via the Source Records contained in Section II above, and those that comply with Research Pricing Policy 915.1 will be processed by CRBP. CRBP will communicate any denied charge correction request(s) to the Principal Investigator and/or approved delegate(s). Principal Investigators are provided three (3) business days to escalate denied request(s) by email as described in Section V(A) herein, entitled, "Escalation."

In the event the Principal Investigator(s) and/or research personnel have CareConnect research charge-related inquiries that arise following Tier I and Tier II charge review in CareConnect, Study Teams are responsible for requesting charge inquiries and/or corrections, via email submission to UCLAHSCRBP@mednet.ucla.edu, in a timely manner and as indicated by the timeframes outlined below. Charge corrections, that intend to route charges to patient(s)/insurer(s), are required to be emailed to CRBP within sixty (60) calendar days from the date of service. Principal Investigator(s) and research staff are required to notify CRBP via email to UCLAHSCRBP@mednet.ucla.edu concerning charge corrections requiring refund to patient(s)/insurer(s) as

soon as possible upon identifying the charge-related issue. Charge corrections to the study may not be accommodated after 90 days from the date of service.

Centralized Research Business Partners (CRBP) Responsibilities

CRBP will perform Tier II Review and process research-related CareConnect charges after the Principal Investigator and/or approved delegates have completed Tier I Review in the Research Billing Review Activity in accordance with the Source Records for Research Charge Processing referenced in Section II above. CRBP is provided ten (10) calendar days to complete the Tier II review in CareConnect.

CRBP will review charges during the CareConnect Tier II Review process. Any charge corrections completed by CRBP shall be communicated to the submitter via email and include rationale for such correction, and instructions for escalatory review, should the Principal Investigator wish to submit for such review. For clarity, both CRBP and charge escalation review members, shall arbitrate research charge direction and/or research rate price override requests in accordance with the Source Records listed in Section II herein, and in accordance with applicable laws and university policies.

Charge corrections requested by the Principal Investigators and/or delegates which deviate and/or are contrary to the Source Records listed in Section II above, may be in violation of the Federal False Claims Act.

In general, validated research charges that complete Tier II review, and are identified as study-related costs, will post to the corresponding study fund account listed in CareConnect within (20) calendar days.

IV. Research Charge Redirect and/or Price Override Requests

Price override requests are required to have first been approved by the UCLA Clinical Research Finance Team, and must be requested in CareConnect by the Principal Investigator and/or approved delegate(s) during the defined timeframe provided herein for Tier I Review.

In the event research personnel requests that study related charges and/or rates be processed contrary to the Source Records contained in Section II above, or if CRBP may have a question as to whether a charge direction and/or price override request is or is not consistent with the Source Records referenced in Section II above, the following procedure should be followed:

All relevant details related to research personnel's request to process charges contrary to source documentation should be emailed by CRBP to the UCLA Research Finance Team at CoverageAnalysis@mednet.ucla.edu within three (3) business days of initial study team's request. Requests should include the following information:

- Identification of specific charge(s) in question.
- Rationale and/or documentation related to specific charge redirect and/or pricing override request.

- Research team point of contact.

The Research Finance Team will review and respond to CRBP's request(s) within three (3) business days of receipt, with one or more of the following responses(s):

- Confirmation as to charge direction,
- Redirection or research rate(s) for specific charge(s) in question, rationale and/or documentation informing confirmation above.
- Identification of study document revision(s), if applicable.
- Request for additional information from study team, research revenue cycle, and/or other stakeholders to support request adjudication. Document and report each request to the Research Charge Resolution Workgroup.

V. Escalation

In the event that research personnel disagrees with applicable stakeholder analysis and conclusions, the Principal Investigator may request escalation to the Research Pricing and Charges Committee for final arbitration. For clarity, all escalatory reviews shall be adjudicated in accordance with the Source Records listed in Section II herein, and in accordance with applicable laws and university policies.

Issuing Officers:

DocuSigned by:
Signature Arash Naeim, MD 5ACCF04A4996496... Date 31-Jul-2024
Arash Naeim
Chief Medical Officer for Clinical Research

DocuSigned by:
Signature Jennifer Lehmann F9D56BD042D44B7... Date 28-Aug-2024
Jennifer Lehmann
Director, Hospital Revenue Cycle

DocuSigned by:
Signature Anton Loman 278ED5DBB2EB47B... Date 31-Jul-2024
Anton Loman
Director, Faculty Practice Group Billing Services

CC: Donald W. Yoo, Chief Compliance Officer, UCLA Health Sciences