UNIVERSITY OF Cincinnati **Category:** CoM- Office of Clinical Research (OCR) **Applicable for:** CoM Clinical Research Professional Faculty and Staff	**COLLEGE OF MEDICINE** **Operating Procedure/Guideline** **Coverage Analysis and Research Encounter Form Submission Process for Human Subjects Research at UC Health** **Effective Date: 06/01/2023** **Prior Effective Date: 06/01/2023**	**Document Owner:** CoM Office of Clinical Research Compliance Administrator **Responsible Office(s):** CoM Office of Clinical Research **Disseminated:** Office of Clinical Research 06/01/2023

Background

This document details the procedures for research encounter forms to be built and submitted to ensure proper billing of research related charges for clinical research at UC Health. This is a system-wide standard operating procedure that applies to clinical research conducted in the facilities of University of Cincinnati (UC) and affiliated facilities (UC Health, LLC, University of Cincinnati Physicians Company {UCPC}, LLC) and all University of Cincinnati and UC Health Clinical Research Professional Staff that conduct clinical research in these facilities.

Guidelines

Research encounter forms must be created for research studies that involve billable study procedures and/or services of UC/UC Health. The REF must be submitted immediately following each research related visit (encounter) that includes billable study items. This is in order to distinguish billable study charges from standard of care (SOC) charges, ensuring that research procedures and services are billed to the proper research account internally, and patients who are research subjects are not personally billed for study billable procedures and services.

Definitions

Research Encounter Form (REF): A key component to accurate research billing and collections. REFs document study billable services rendered by the institution and providers by capturing diagnosis and procedure codes, which serve as the basis for proper billing and receipt of payment for research related services.

Coverage Analysis (CA): The process of reviewing a clinical trial protocol and determining which items and services will be billed to the study sponsor, other funding sources, the subject, or a third-party payer, such as health or medical insurance, or a government assistance program. (Also known as Medicare Coverage Analysis)

Research Related Procedures and Services: Clinical procedures or services that are required

and provided for the purposes of an approved clinical research study.

Billable Research Study Items: Research related procedures and services that have a fee associated, that are normally billable to the research study account, and not the research subject or the subject's insurance.

Standard of Care (SOC) Charges: Fees associated with clinical procedures or services that take place as part of a patient's standard medical care and are not charged to any research study in which the patient may be enrolled.

Process

- Studies submitted to the OCR are initially evaluated for a coverage analysis (CA). This process is included in the online contract submission process.
    - Study teams will be notified of studies that qualify and undergo a full CA.
        - CPT codes for all procedures are produced during a CA.
        - A draft of the CA will be developed and sent to the study team.
        - It is expected that the study team review the CA draft and respond with their approval of the CA draft or any requests for adjustments to the CA draft within two weeks of receipt.
            - If the study team does not respond with any requests for edits or adjustments to the CA draft within two weeks, the CA draft will be considered final.
    - Studies that are not qualifying clinical trials for a CA; the study team will be contacted informing them their study does not qualify for a CA.
        - If the study does not qualify for a CA, the study team will be notified and asked to provide CPT codes for all research related procedures and services during the submission for UCH research approval process.
        - Once CPT codes for all billable study services and procedures have been provided to the OCR either from the CA for qualifying studies, or from the study team for studies that do not qualify for a CA, the UCH Research Billing Analyst will create/build the REF.
    - The REF will be sent to the study team along with the notification for UC Health Research Approval from the OCR.
- Amendments
    - Any amendments to the contract, study budget, or study procedures requiring changes to any CPT codes or to the CA, must be submitted to the appropriate team within the OCR.
        - For UCH contracting amendments: UCP-ClinicalTrials@UCHealth.com
        - For UCH budget amendments and updates to CPT codes Research-finance@UCHealth.com or send to the OCR budget staff directly.
            - It is best practice to copy all emails and parties with budget amendments.

        Based on budget, CA, or contract amendment(s), the REF will be updated to indicate the amendment(s).
    - The amended documents will be sent to the study teams once they are finalized.

- Individual Study REF Submission process:
    - A REF must be completed for each research encounter involving orders and/or procedures that will be billed to the study.
    - The REF form must be submitted before the close of business on the day of the encounter to both the technical and professional billing personnel by e-mailing the form to both of the following e-mail addresses:
        - Technical: Office of Clinical Research (finance): research-finance@uchealth.com
        - Professional: UCPC Physicians Billing: ucp-clinicaltrialbilling@uchealth.com
    - For research activities that occur outside of normal business hours, the completed research encounter form must be e-mailed to both email addresses above by close of business on the next business day.

Organizational units may institute policies more, but not less, restrictive than these guidelines if desired.

Related Documents/Links

Research Encounter Form

KEY WORDS

- Research Encounter Form (REF)
- Coverage Analysis (CA)
- Research Related Procedures and Services
- Billable Study Items
- Standard of Care Charges