Category: CoM- Office of Clinical Research (OCR) **Applicable for:** CoM Clinical Research Professional Faculty and Staff	**COLLEGE OF MEDICINE** **Operating Procedure/Guideline** **Submission Process for UC Health Research Approval** **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 procedures for the submission, review, and approval or denial of clinical research that is to be entered in EPIC, UC Health's Electronic Medical Records (EMR) system. 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

Clinical research conducted in University of Cincinnati and UC Health facilities must comply with all applicable local, state and federal rules and regulations, be consistent with institutional standards for conducting clinical research, and contribute to appropriate tracking of research costs. This SOP describes the procedures for identifying, approving, and tracking clinical research studies that are entered into UC Health's EPIC EMR.

Definitions:

Clinical Research: For the purposes of this SOP, clinical research is defined as any systematic investigation that will involve direct interaction with research participants or their families/legally authorized individual/caregiver in a clinical setting and/or the analysis of individually identifiable specimens or data. Any study, i) in which a patient or their family member is asked to provide informed consent, or ii) is an Institutional Review Board (IRB) approved study that has requested to be conducted at UC/UC Health that involves a waiver of consent, must comply with this SOP. In addition, any study performed using space or equipment rented from UC/UC Health for research activities must also comply with this SOP.

Ancillary Research Service: UC Health Ancillary Research Services includes Investigational Pharmacy, Investigational Imaging, and UC Health Laboratory.

Clinical Trial Agreement (CTA): A legally binding agreement that governs the conduct of a clinical trial, sets forth obligations of all parties and manages the relationship, proprietary information, study drug/device, study results, intellectual property, publications and financial support.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the

institution with which it is affiliated.

Process

The Principal Investigator or designee must perform (as applicable) the following steps prior to conducting clinical research at UC Health. It is not necessary to complete each step in a specified order, but all steps must be completed prior to conducting any research activity. To facilitate a quicker and more efficient approval process, it is recommended study teams be in communication with ancillary services prior to submitting this form to the Office of Clinical Research (OCR).

- **Submission Form for UC Health Research Approval:** This form is required for all human subject research studies. This form describes the research study, identifies the UC and/or UC Health location(s) in which research participants may be seen, and provides study specific information needed for EPIC.
    - Link to form: UC Health Research Submission and Approval
- **Executed Clinical Trial Agreement (CTA):** Prior to UC Health approval to conduct research, a CTA must be executed by UC Sponsored Research Services and Office of General Counsel. The OCR will monitor the UC REDCap Research Submission system for executed contracts prior to approving the research and sending an approval letter.
- **IRB Approval:** Approval from an accepted IRB for the clinical research must be obtained. The University of Cincinnati IRB (UC IRB) is University if Cincinnati's local IRB and considered UC Health's local IRB. The UC IRB maintains a list of other IRBs that are acceptable.
    - Approval by UC Health is not automatic upon approval by an accepted IRB. UC Health has the right to disapprove clinical research that it does not deem appropriate.
    - **Ancillary Research Services Approval:** It is suggested that contact with the ancillary services be initiated prior to IRB submission. Submission to the Office of Clinical Research will trigger an automated alert sent to the ancillary services requesting review. Ancillary services will approve studies digitally. Study teams will be notified of ancillary service approval.

- If a member other than the Principal Investigator (PI) will be submitting the Research Approval form, he/she will be asked to attest that the Principal Investigator agrees with the information provided in the submission.
- Unless a specific request is made for updated documents, previously submitted documents held by the OCR may be used in the review process.
- The OCR will notify the PI or designee of receipt of all necessary documents for research review and will send notification of study approval or denial as soon as possible within reason, given the review needs of any individual trial.
    - Please Note: Research approval will not be released until all documents have been received, reviewed, and approved.

Study identification in EPIC:

- Once a study is reviewed and approved, the OCR coordinates with UC Health IS&T for upload of the study to the UC Health Electronic Medical Records (EMR) System, EPIC.
- The standard naming convention for all studies entered into EPIC is as follows:

- The PI Last Name-The Trial or Study short name.
    - UC / UC Health research locations include, but are not limited to:
        - UCMC (University of Cincinnati Medical Center)
        - UCPC (UC Physicians Company, Non-Hospital based clinical)
        - WCH (West Chester Hospital)
        - TDC (The Drake Center)

Key Words

- Research Approval
- Ancillary Research Services
- Investigational Pharmacy
- Investigational Imaging
- Office of Clinical Research

References / Citations

- UCH-OCR-REV-SOP-007: Research Subject Safety Notification to Clinical Care Teams in EPIC
- UCH-OCR-REV-SOP-009: Process for Ancillary Research Services Review Prior to Submission for UC Health Research Approval