UC Riverside, School of Medicine Policies and Procedures
Policy Title: Clinical Research Protocol Implementation
Policy Number: 950-12-002

Responsible Officer:	Senior Associate Dean, Research
Responsible Office:	Biomedical Science, Clinical Research
Origination Date:	July 2, 2021
Date of Revision:	
Scope:	SOP for Protocol Implementation

I. Policy Summary

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct or performance of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at University of California Riverside Health (UCR Health), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

II. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

III. Policy Text

A. Describes the process for protocol implementation of clinical research. Attachment templates include:

1. Protocol Implementation Checklist

IV. Responsibilities

The UCR School of Medicine – Research Office (UCR Research Office) develops, implements, and maintains Standard Operating Procedures (SOPs). The need to devise a new or revise an existing SOP is based upon conditions such as changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activity and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related

activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members	
Principal Investigator (PI)	Sub-Investigator (Sub-I)
Clinical Research Coordinator (CRC)	Clinical Graduate Student Research (CGSR)
Clinical Research Manager (CRM)	Clinical Research Assistant (CRA)
Other Research Staff as appropriate	Administrative and Support Staff

V. Procedures

After IRB approval and the sponsor Site Initiation Visit (if applicable), the delegated research team members should complete the Protocol Implementation Checklist (See Attachment A: Protocol Implementation Checklist) or other similar form. This should be completed prior to enrolling subjects to the clinical research study.

The PI and delegated research team members will ensure that:

- The budget is finalized, and the contract is executed with appropriate OSP (Office of Sponsored Programs) account created.
- The Sponsor Research & Program (SRP) and Financial Operations Officers has been notified of the study and the study has been added to the Research Master File to allow for appropriate billing of services and flagging of subjects within the Electronic Health Record .
- All essential regulatory documents are completed, organized, and filed appropriately.
- All Sub-Investigators and key personnel will have IRB acknowledgment for their role in the study.
- Written IRB approval for the study and supportive study documents have been received and final documents are available to the study team.
- Study activities are conducted only after IRB approval and in accordance with the approved protocol.
- All protocol specific documentation, worksheets, and checklist tools are finalized and available to the research team.
- Study-specific source documents, as well as screening and enrollment materials, are prepared.
- Any applicable in-service and training sessions with the research team members and ancillary support staff have been completed.
- The site is in receipt of an adequate investigational product (IP) supply and that records are maintained for delivery and inventory. Appropriate IP security and storage are available.
- A delegated primary research team member has been identified and assigned to the research study.

- If applicable, the PI and all delegated research team members are thoroughly familiar with the appropriate use of the IP, as described in the protocol, in the current Investigator's Brochure, and in other information provided by the sponsor.
- The Delegation of Authority Log will be updated and outline specific roles and responsibilities delegated by the PI to the research team members.

The PI will personally conduct or supervise the clinical research study to ensure the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, and applicable regulations.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the research study. The delegated team members will meet all the qualifications specified by the applicable regulatory and sponsor requirements. Evidence of such qualifications will be provided through a current curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

VI. Applicable Regulations, Guidance and Policies

Regulation/ Guidance/Policy Title	
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure by Clinical Investigator
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPPA Privacy Rule
45 CFR 164	Subparts A and E HIPPA Privacy Rule
49 CFR 107	Transportation: Hazardous Materials Program Procedures
49 CFR 171	Transportation: General Information, Regulations, and Definitions
UCR IRB	Research Participant Resources
UCR Research Integrity	Research Integrity
UCR Sponsor Program	Sponsored Programs
UCR Environmental and Safety	Environmental Health & Safety | (ucr.edu)
UCR Business & Financial Services	Business & Financial Services | (ucr.edu)
UCR Office Compliance	Office Compliance
ICH GCP	Guideline for Good Clinical Practices: E6 Integrated Addendum
FDA Guidance for Industry	Information Sheet Guidance for Clinical Investigators
FDA Frequently Asked Questions	Frequently Asked Questions – Statement of Investigator (Form FDA 1572) | FDA

Approvals:

COMPLIANCE COMMITTEE (07/28/2021)

Paul Hackman Digitally signed by Paul Hackman Date: 2021.08.05 16:19:24 -07'00' 08/05/2021

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