Status Active PolicyStat ID 16268606

Last Approved	09/2024
Last Revised	09/2024
Next Review	09/2027
Owner	Valerie Dixon: Chief Compliance & Privacy Officer
Policy Area	Health Enterprise: Compliance Policy
Applicability	UCI Health - Orange

FDA Inspections of Clinical Investigators

I. PURPOSE

The purpose of this policy is to establish uniform standards for FDA inspections of clinical investigators within UCI Health and the College of Health Sciences departments.

II. SCOPE

This policy applies to all faculty, providers, employees, contractors, consultants, students, and volunteers engaged in the conduct of FDA-regulated clinical investigations within UCI Health and the College of Health Sciences.

III. DEFINITIONS

A. Clinical Investigator (also called Principal Investigator, Lead Researcher) is an individual responsible for the conduct of a clinical investigation, under whose immediate direction the drug or device is administered.

B. Clinical Investigation (also called clinical research, clinical trial, research study, or protocol) is any experiment that involves a test article and one or more human subjects.

C. Clinical Trial Units are the centralized research operational departments within UCI (e.g., Stern Center for Cancer Clinical Trials, Center for Clinical Research, Alpha Clinic, etc.).

D. UCI Inspection Team consists of the clinical investigator, an assigned project manager, and other Department or clinical trial unit staff identified to participate in an FDA inspection, from pre-inspection preparation through post-inspection follow-up.

E. Form FDA 482 is the written Notice of Inspection issued by the FDA inspector to the clinical investigator.

F. Form FDA 483 is the list of Inspectional Observations noted in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the Food Drug & Cosmetics Act which were observed during an FDA inspection.

G. Establishment Inspection Report (EIR) is the final written FDA report submitted to FDA headquarters for evaluation. It is publicly available through the Freedom of Information Act (FOIA).

IV. POLICY

A. It is the policy of UCI Health that all staff conducting FDA-regulated clinical investigations adhere to federal, state, and local laws, including FDA regulations. The clinical investigator and UCI inspection team must permit, at reasonable times, properly authorized officers, or employees of the FDA to access, inspect, and copy any required records related to the clinical investigation including their obligations and responsibilities to the FDA. When tasks are delegated, the clinical investigator must provide adequate supervision and is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical investigation. It is the expectation of UCI Health and the UCI Office of Research that the clinical investigator, in conjunction with the UCI inspection team, initiates oversight and personally manages all aspects of FDA inspections and any responses. Clinical investigators and UCI inspection team members should adhere to the procedures outlined in this policy.

B. In the instance that a clinical investigation transitioned between Departments or clinical trial units at any point prior to an FDA inspection, the current Department or clinical trial unit assumes responsibility for oversight and management of the FDA inspection and any responses.

C. In the instance that the clinical investigator is unavailable (e.g., left UCI, out of the country, on leave, etc.) and the clinical investigation is closed, the clinical investigator's Department or the clinical trial unit in which the clinical investigation was conducted assumes responsibility for oversight and management of the FDA inspection and any responses.

D. If inadequate inspection oversight is identified at any time before, during, or after an FDA inspection, the Compliance and Privacy Office is to be promptly notified. The Compliance and Privacy Office may escalate the inspectional oversight plan to executive leadership, including but not limited to, the Dean of the appropriate School, and ultimately the UCI Vice Chancellor for Health Affairs. The purpose of the escalation is to alert relevant executive leadership of the need for institutional support and reinforcement of Department or clinical trial unit oversight, such that the FDA inspection, including any responses to the FDA, is adequately overseen and managed in accordance with the procedures outlined in this policy.

V. PROCEDURE

Each Department or clinical trial unit should maintain its own standard operating procedures for oversight and management of an FDA inspection and any responses.

A. **Before the Inspection:**

1. Upon notification from the FDA of an inspection, the clinical investigator, or designee, must immediately notify the following stakeholders and UCI officials:
    a. Study Sponsor
    b. Governing Institutional Review Board (IRB)
    c. All UCI study co-investigators and study team members
    d. Directors, UCI Office of Research Human Research Protections (HRP)
    e. UCI Health Investigational Drug Services (IDS) Pharmacy, as applicable
    f. Principal Auditor, UCI Internal Audit Services (IAS)
    g. Research Compliance, UCI Health Compliance and Privacy Office
    h. Vice Dean for Clinical Research, UCI School of Medicine (SOM)
    i. UCI Health Clinical Area Managers, as applicable
    j. UCI Health Information Management (HIM), as applicable
    k. UCI Health Information Services Security Team, as applicable
    l. Other UCI leadership, as applicable
2. The clinical investigator, or designee, clinical trial unit, and/or Department must ensure adequate staff and resources are available throughout the course of the inspection.
3. The clinical investigator, or designee, should identify a project manager, who will serve as the institutional contact and provide administrative oversight throughout the course of the inspection.
4. The clinical investigator, or designee, must promptly retrieve and provide access to records and other relevant documentation to the UCI inspection team.
5. The clinical investigator and all UCI inspection team members should attend training for FDA inspection readiness, provided by the Compliance and Privacy Office.
6. The clinical investigator, or designee, must secure appropriate access to paper records and electronic systems prior to the FDA inspection (e.g., electronic health record, research pharmacy system, USB).

B. **During the Inspection:**

1. Upon arrival to UCI, the FDA inspector must display their credentials, issue the original, properly executed, and signed Form FDA 482 Notice of Inspection, and explain the purpose of their visit.
2. The clinical investigator must be available in person to receive the Form FDA 482 prior to allowing the FDA inspection to commence. In the instance the clinical investigator is unavailable (e.g., left UCI, out of the country, on leave, etc.), the Department or clinical trial unit should identify an appropriate designee.
3. The clinical investigator, or designee, should provide a copy of the Form FDA 482 to the Compliance and Privacy Office.
4. The clinical investigator, or designee, should be available to answer questions daily

throughout the inspection and maintain proactive communication with the UCI inspection team and the Compliance and Privacy Office.

5. If there are inspectional findings, the FDA inspector must provide a Form FDA 483 Inspectional Observations to the clinical investigator upon completion of the inspection and before leaving the premises. The clinical investigator, or designee, must provide a copy of the Form FDA 483 to the individuals listed in the notification section above.

C. **After the Inspection:**

1. If the inspection results in discussion items and/or inspectional observations, the clinical investigator must prepare a written response to all items and submit it to the FDA within 15 working days. A draft written response should be provided to the Compliance and Privacy Office for feedback within 7 working days of receiving the Form FDA 483, or other timeframe agreed upon by the Compliance and Privacy Office and clinical investigator.
2. The clinical investigator must provide copies of the final written response, any follow up responses, and any official correspondence from the FDA regarding the inspection to the Compliance and Privacy Office.
3. The Compliance and Privacy Office shall notify the Executive Compliance Committee (ECC) of FDA inspections and observations, as appropriate.
4. Upon receipt of the Establishment Inspection Report (EIR), the clinical investigator, or designee, should provide a copy to the Compliance and Privacy Office, HRP, IAS, and other appropriate stakeholders. In the instance the clinical investigator is unavailable (e.g., left UCI, out of the country, on leave, etc.), the Department or clinical trial unitshould request the EIR through a Freedom of Information Act request.

Approval Signatures

Step Description	Approver	Date
Governing Body	Governing Body [JL]	09/2024
Medical Executive Committee	Medical Executive Committee [AR]	09/2024
Policy & Communications Committee	Policy & Communications Cte [JL]	08/2024
Executive Compliance Board	Nazeli Khodabakhsh: Principal Compliance & Privacy Analyst	08/2024

Applicability

UCI Health - Orange