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Owner: Arash Naeim: Prof In Res-Hcomp

Policy Area: Compliance

Reference Tags:

Applicability: Ronald Reagan UCLA Medical Center
 Ambulatory Care - UCLA
 Resnick Neuropsychiatric Hospital
 Santa Monica UCLA Medical & Orthopaedic
 UCLA Health

Ronald Reagan UCLA Medical Center

FDA Inspection Notifications Related to Research Studies, HS 9441

PURPOSE

Since the Investigational New Drug (IND) Regulations went into effect in 1963, the Food and Drug Administration (FDA) has exercised oversight of the conduct of clinical studies involving FDA regulated products. The Bioresearch Monitoring Program (BIMO) was established in 1977 by a task force that included representatives from the drug, biologic, device, animal drug, and food areas.

Compliance programs were developed to provide uniform guidance and specific instructions for inspections of Clinical Investigators (CP 7348.811), Sponsors (CP 7348.810), In-Vivo Bioequivalence facilities (CP 7348.001), Institutional Review Boards (CP 7348.809), and Non-Clinical Laboratories (CP 7348.808).

This policy outlines the processes for an FDA inspection. This policy applies to all UCLA faculty and staff involved in the implementation, conduct, and coordination of FDA-regulated clinical studies.

SCOPE

This Hospital System Policy applies to the Ronald Reagan UCLA Medical Center, Santa Monica UCLA Medical Center and Orthopaedic Hospital and Resnick Neuropsychiatric Hospital at UCLA and the licensed clinics.

DEFINITIONS

For the purposes of this Policy, the following definitions apply:

Principal Investigator: A Principal Investigator (PI) is the individual who is responsible and accountable for conducting the clinical investigation. The PI assumes full responsibility for the evaluation and treatment of human subjects, and for the collection, integrity and maintenance of the research data and results in accordance with the protocol (investigational plan), FDA regulations, and other applicable regulatory requirements. When the investigation is conducted by a team, the Principal Investigator is the leader of the team." The PI may also be the sponsor of the study, i.e., the sponsor-investigator.

Sponsor-Investigators: A sponsor-investigator is an individual who initiates and also conducts the clinical

investigation. A sponsor-investigator must comply with regulatory requirements applicable to both sponsors and clinical investigators.

POLICY

When a Principal Investigator is informed that their study will be subject to an FDA inspection, it is important that the appropriate University Offices and Personnel are notified of the inspection and inspection outcomes. This policy identifies the Offices and Individuals that should be notified of an FDA inspection.

I. NOTIFICATION

- A. Upon receipt of notification from the FDA of an inspection, the Principal Investigator/Sponsor-Investigator (P/SI) will immediately notify the following UCLA Officials, Offices, and Sponsors:
 - i. The CAO, Division Chief and/or Chair, and other appropriate representative of Department;
 - ii. The Director of the UCLA Office of the Human Research Protection Program (OHRPP);
 - iii. fdainspection@mednet.ucla.edu, which will notify the following offices:
 - a. For Non-Cancer Studies: The Clinical and Translational Science Institute Office of Regulatory Affairs (CTSI-ORA);
 - b. For Cancer Studies: The Jonsson Comprehensive Cancer Center (JCCC) Office of Regulatory Compliance (ORC);
 - c. The Office of Compliance Services
 - iv. The sponsor, if applicable.

II. POST-INSPECTION

- A. If the PI/SI receives a summary of Inspectional Observations (FDA Form 483) after the inspection, the PI/SI should provide a copy of the 483 to the individuals outlined in the notification section above.
- B. The PI/SI will prepare a written response related to any and all observations included in the FDA Form 483. The PI/SI will then send the response to those specified by the Inspector, which may include the FDA local field office and the FDA central office, within the time frame specified by FDA. Investigators typically have 15 calendar days from the conclusion of inspection to respond to the FDA. A copy of the response should be sent to the individuals outlined in the notification section above. The CTSI ORA or JCCC ORC, Office of Compliance Services, and other appropriate persons and offices can provide input and assistance in the drafting of this response including assistance with any corrective action plan (CAPA) if needed.
- C. If an FDA Form 483 is not issued, the PI should summarize the discussion, including observations made by the inspector and provide the information to the individuals outlined in the notification section above.

III. MONITORING AND SUPPORT

Two offices at UCLA will perform monitoring of this policy: The Clinical Translational Science Institute for non-cancer studies and the Jonsson Comprehensive Cancer Center for cancer studies. Support staff is available from both entities to assist and advise the PI/SI with preparation for an FDA inspection and advise the PI/SI regarding their obligations with respect to this Policy.

Contact Information is as follows:

- A. Office of Regulatory Affairs, Clinical and Translational Science Institute: ctsiora@mednet.ucla.edu

B. Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center: jccorc@mednet.ucla.edu

C. UCLA Researchgo website, www.researchgo.ucla.edu

REFERENCES

Title 21 CFR part 11 - Electronic Records; Electronic Signatures

Title 21 CFR parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards)

Title 21 CFR part 312 (Investigational New Drug Application), part 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials

Title 21 CFR part 812 (Investigational Device Exemptions), part 812.140 - Investigator Record Keeping and Record Retention for Device Trials

ICH GCP Consolidated Guideline - Part 4.9 Records and Reports

ICH GCP Consolidated Guideline - Part 5.15 Record Access

FDA Compliance Program Guidance Manuals 7348.811 – Investigators and 7348.810 – Sponsors/CROs/ Monitors

FDA Investigations Operations Manual

CONTACT

Chief Medical Officer for Clinical Research

REVISION HISTORY

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APPROVAL

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Attachments:

No Attachments

Approval Signatures

Step Description	Approver	Date
Administration Approval	Laurie Casaus: Hs Assoc Clin Prof-Hcomp [JM]	7/27/2017
Administration Approval	Roger Lee: Hs Clin Prof-Hcomp [MA]	7/27/2017
Administration Approval	Christopher Tarnay: Hs Assoc Clin Prof-Hcomp [MA]	7/27/2017
Administration Approval	Johnese Spisso: Ceo Med Ctr [MA]	7/27/2017
Executive Medical Boards - MSEC, RNPH PSEC, SMEMB	James Morva: Admin Anl Prn 1	7/27/2017
Hospital System Policy Committee Chair	Margaret Armbruster: Dir	6/30/2017
Hospital System Policy Committee	James Morva: Admin Anl Prn 1	6/28/2017
	Arash Naeim: Prof In Res-Hcomp	6/21/2017

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