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REVIEW ARTICLE

Food and Drug Administration Guidance: Supervisory Responsibilities of Investigators

Carl Anderson,[1] Patti A. Young,[2] and Ann Berenbaum, C.C.R.C.[3]

Abstract

Conducting clinical trials for diabetes can present researchers with a number of regulatory questions. The Food and Drug Administration (FDA) has increased regulatory enforcement at clinical sites, with an increased emphasis on oversight by principal investigators (PIs; referred to by the FDA as the clinical investigator). The FDA has issued a guidance document, "Guidance for Industry: Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects" (2009), to assist investigators and sponsors. This guidance document breaks new ground regarding the FDA's expectations for investigator oversight of subinvestigators and study staff. The guidance document corresponds with a sharp increase in FDA warning letters to PIs for noncompliance with good clinical practice regulatory requirements. For the first time, an FDA guidance document discusses issues such as the delegation of authority, standard operating procedures, and training of study staff. The FDA provides specific examples with particular emphasis given to appropriate delegation of duties by the PI and ensuring that the clinical staff entrusted to carry out the trial has had adequate training and experience in order to allow them to perform the designated tasks.

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Author Affiliations: [1]Carl A. Anderson, LLC, Tacoma, Washington; [2]Kaiser Foundation Research Institute, Oakland, California; and [3]Health Sciences Research Compliance Program, University of California, San Diego, San Diego, California

Abbreviations: (CFR) Code of Federal Regulations, (CRO) contract research organization, (CV) curriculum vitae, (FDA) Food and Drug Administration, (FY) fiscal year, (GCP) good clinical practice, (IRB) Institutional Review Board, (PI) principal investigator, (SOP) standard operating procedure

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Corresponding Author: Carl Anderson, Carl A. Anderson, LLC, 3320 N. 27th St., Tacoma, WA 98407; email address carl11anderson@yahoo.com