Guidance for Industry

GUIDELINE FOR THE MONITORING OF CLINICAL INVESTIGATIONS

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Food and Drug Administration
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Comments on the contents of this guideline are invited and should be addressed to the following office and identified with the docket number:

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Purpose

The purpose of this guideline is to present acceptable approaches to monitoring clinical investigations. Existing requirements for sponsors of clinical investigations involving new drugs for human and animal use (including biological products for human use) and medical devices under 21 CFR Parts 312 and 511, and 812 and 813, respectively, require that a sponsor monitor the progress of a clinical investigation. The monitoring functions may be delegated to a contract research organization as defined under 21 CFR 312.3. Proper monitoring is necessary to assure adequate protection of the rights of human subjects and the safety of all subjects involved in clinical investigations and the quality and integrity of the resulting data submitted to the Food and Drug Administration (FDA).

Introduction

This guideline, issued under 21 CFR 10.90, reflects principles recognized by the scientific community as desirable approaches to monitoring clinical research involving human and animal subjects. These principles are not legal requirements but represent a standard of practice that is