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has submitted a marketing application containing covered clinical studies shall keep on file certain information pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:

(1) Complete records showing any financial interest or arrangement as described in §54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.

(2) Complete records showing significant payments of other sorts, as described in §54.4(a)(3)(ii), made by the sponsor of the covered clinical study to the clinical investigator.

(3) Complete records showing any financial interests held by clinical investigators as set forth in §54.4(a)(3)(iii) and (a)(3)(iv).

(b) *Requirements for maintenance of clinical investigators' financial records.*

(1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.

(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

Sec.
56.101 Scope.
56.102 Definitions.
56.103 Circumstances in which IRB review is required.
56.104 Exemptions from IRB requirement.
56.105 Waiver of IRB requirement.

Subpart B—Organization and Personnel

56.107 IRB membership.

Subpart C—IRB Functions and Operations

56.108 IRB functions and operations.
56.109 IRB review of research.
56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
56.111 Criteria for IRB approval of research.
56.112 Review by institution.
56.113 Suspension or termination of IRB approval of research.
56.114 Cooperative research.

Subpart D—Records and Reports

56.115 IRB records.

Subpart E—Administrative Action for Noncompliance

56.120 Lesser administrative actions.
56.121 Disqualification of an IRB or an institution.
56.122 Public disclosure of information regarding revocation.
56.123 Reinstatement of an IRB or an institution.
56.124 Actions alternative or additional to disqualification.

AUTHORITY: 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 46 FR 8975, Jan. 27, 1981, unless otherwise noted.

Subpart A—General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§56.102 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–392)).