

institution determined to be responsible for formal designation of the IRB.

§ 56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under § 56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in § 56.123.

§ 56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20.

§ 56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 56.121(c).

§ 56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Subpart A—General Provisions

- Sec.
- 58.1 Scope.
- 58.3 Definitions.
- 58.10 Applicability to studies performed under grants and contracts.
- 58.15 Inspection of a testing facility.

Subpart B—Organization and Personnel

- 58.29 Personnel.

Food and Drug Administration, HHS

§ 58.3

- 58.31 Testing facility management.
- 58.33 Study director.
- 58.35 Quality assurance unit.

Subpart C—Facilities

- 58.41 General.
- 58.43 Animal care facilities.
- 58.45 Animal supply facilities.
- 58.47 Facilities for handling test and control articles.
- 58.49 Laboratory operation areas.
- 58.51 Specimen and data storage facilities.

Subpart D—Equipment

- 58.61 Equipment design.
- 58.63 Maintenance and calibration of equipment.

Subpart E—Testing Facilities Operation

- 58.81 Standard operating procedures.
- 58.83 Reagents and solutions.
- 58.90 Animal care.

Subpart F—Test and Control Articles

- 58.105 Test and control article characterization.
- 58.107 Test and control article handling.
- 58.113 Mixture of articles with carriers.

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

- 58.120 Protocol.
- 58.130 Conduct of a nonclinical laboratory study.

Subparts H–I [Reserved]

Subpart J—Records and Reports

- 58.185 Reporting of nonclinical laboratory study results.
- 58.190 Storage and retrieval of records and data.
- 58.195 Retention of records.

Subpart K—Disqualification of Testing Facilities

- 58.200 Purpose.
- 58.202 Grounds for disqualification.
- 58.204 Notice of and opportunity for hearing on proposed disqualification.
- 58.206 Final order on disqualification.
- 58.210 Actions upon disqualification.
- 58.213 Public disclosure of information regarding disqualification.
- 58.215 Alternative or additional actions to disqualification.
- 58.217 Suspension or termination of a testing facility by a sponsor.
- 58.219 Reinstatement of a disqualified testing facility.

AUTHORITY: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

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

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987]

§ 58.3 Definitions.

As used in this part, the following terms shall have the meanings specified:

(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)).

(b) *Test article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354–360F of the Public Health Service Act.

(c) *Control article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system