

§ 86.410

34 CFR Subtitle A (7-1-04 Edition)

(3) A review limited to the written record.

(4) A certification by the parties to facts and legal authorities not in dispute.

(d)(1) The formal rules of evidence and procedures applicable to proceedings in a court of law are not applicable.

(2) The designated Department official has the burden of persuasion in any proceeding under this subpart.

(3)(i) The parties may agree to exchange relevant documents and information.

(ii) The ALJ may not order discovery, as provided for under the Federal Rules of Civil Procedure, or any other exchange between the parties of documents or information.

(4) The ALJ accepts only evidence that is relevant and material to the proceeding and is not unduly repetitious.

(e) The ALJ makes a transcribed record of any evidentiary hearing or oral argument that is held, and makes the record available to—

(1) The designated Department official; and

(2) The IHE on its request and upon payment of a fee comparable to that prescribed under the Department of Education Freedom of Information Act regulations (34 CFR part 5).

(Authority: 20 U.S.C. 1145g)

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66225, Dec. 17, 1996]

**§86.410 What are the procedures for issuance of a decision?**

(a)(1) The ALJ issues a written decision to the IHE, the designated Department official, and the Secretary by certified mail, return receipt requested, within 30 days after—

(i) The last brief is filed;

(ii) The last day of the hearing if one is held; or

(iii) The date on which the ALJ terminates the hearing in accordance with §86.401(c)(3).

(2) The ALJ's decision states whether the violation or violations contained in the Secretary's notification occurred, and articulates the reasons for the ALJ's finding.

(3) The ALJ bases findings of fact only on evidence in the hearing record and on matters given judicial notice.

(b)(1) The ALJ's decision is the final decision of the agency. However, the Secretary reviews the decision on request of either party, and may review the decision on his or her own initiative.

(2) If the Secretary decides to review the decision on his or her own initiative, the Secretary informs the parties of his or her intention to review by written notice sent within 15 days of the Secretary's receipt of the ALJ's decision.

(c)(1) Either party may request review by the Secretary by submitting a brief or written materials to the Secretary within 20 days of the party's receipt of the ALJ's decision. The submission must explain why the decision of the ALJ should be modified, reversed, or remanded. The other party shall respond within 20 days of receipt of the brief or written materials filed by the opposing party.

(2) Neither party may introduce new evidence on review.

(d) The decision of the ALJ ordering the repayment of Federal financial assistance or terminating the eligibility of an IHE does not take effect pending the Secretary's review.

(e)(1) The Secretary reviews the ALJ's decision considering only evidence introduced into the record.

(2) The Secretary's decision may affirm, modify, reverse or remand the ALJ's decision and includes a statement of reasons for the decision.

(Authority: 20 U.S.C. 1145g)

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66225, Dec. 17, 1996]

**§86.411 What are the procedures for requesting reinstatement of eligibility?**

(a)(1) An IHE whose eligibility to receive any or all forms of Federal financial assistance has been terminated may file with the Department a request for reinstatement as an eligible entity no earlier than 18 months after the effective date of the termination.

(2) In order to be reinstated, the IHE must demonstrate that it has corrected the violation or violations on which the termination was based, and that it

has met any repayment obligation imposed upon it under § 86.301(b)(1) of this part.

(b) In addition to the requirements of paragraph (a) of this section, the IHE shall comply with the requirements and procedures for reinstatement of eligibility applicable to any Federal program under which it desires to receive Federal financial assistance.

(Authority: 20 U.S.C. 1145g)

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66225, Dec. 17, 1996]

## PART 97—PROTECTION OF HUMAN SUBJECTS

### Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects)

Sec.

- 97.101 To what does this policy apply?
- 97.102 Definitions.
- 97.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
- 97.104–97.106 [Reserved]
- 97.107 IRB membership.
- 97.108 IRB functions and operations.
- 97.109 IRB review of research.
- 97.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 97.111 Criteria for IRB approval of research.
- 97.112 Review by institution.
- 97.113 Suspension or termination of IRB approval of research.
- 97.114 Cooperative research.
- 97.115 IRB records.
- 97.116 General requirements for informed consent.
- 97.117 Documentation of informed consent.
- 97.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 97.119 Research undertaken without the intention of involving human subjects.
- 97.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
- 97.121 [Reserved]
- 97.122 Use of Federal funds.
- 97.123 Early termination of research support: Evaluation of applications and proposals.
- 97.124 Conditions.

Subparts B–C [Reserved]

### Subpart D—Additional ED Protections for Children Who are Subjects in Research

- 97.401 To what do these regulations apply?
- 97.402 Definitions.
- 97.403 IRB duties.
- 97.404 Research not involving greater than minimal risk.
- 97.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- 97.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- 97.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
- 97.408 Requirements for permission by parents or guardians and for assent by children.
- 97.409 Wards.

AUTHORITY: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; 42 U.S.C. 300v-1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

### Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects)

#### § 97.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated