

that receives an award directly from a Federal agency.

(Authority: E.O.s 12549 and 12689; 20 U.S.C. 1082, 1094, 1221e-3 and 3474; and Sec. 2455, Pub. L. 103-355, 108 Stat. 3243 at 3327)

#### § 84.665 State.

*State* means any of the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

(Authority: E.O.s 12549 and 12689; 20 U.S.C. 1082, 1094, 1221e-3 and 3474; and Sec. 2455, Pub. L. 103-355, 108 Stat. 3243 at 3327)

#### § 84.670 Suspension.

*Suspension* means an action taken by a Federal agency that immediately prohibits a recipient from participating in Federal Government procurement contracts and covered non-procurement transactions for a temporary period, pending completion of an investigation and any judicial or administrative proceedings that may ensue. A recipient so prohibited is suspended, in accordance with the Federal Acquisition Regulation for procurement contracts (48 CFR part 9, subpart 9.4) and the common rule, Government-wide Debarment and Suspension (Non-procurement), that implements Executive Order 12549 and Executive Order 12689. Suspension of a recipient is a distinct and separate action from suspension of an award or suspension of payments under an award.

(Authority: E.O.s 12549 and 12689; 20 U.S.C. 1082, 1094, 1221e-3 and 3474; and Sec. 2455, Pub. L. 103-355, 108 Stat. 3243 at 3327)

## PART 86—DRUG AND ALCOHOL ABUSE PREVENTION

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## § 86.1

AUTHORITY: 20 U.S.C. 1145g, unless otherwise noted.

SOURCE: 55 FR 33581, Aug. 16, 1990, unless otherwise noted.

### Subpart A—General

#### § 86.1 What is the purpose of the Drug and Alcohol Abuse Prevention regulations?

The purpose of the Drug and Alcohol Abuse Prevention regulations is to implement section 22 of the Drug-Free Schools and Communities Act Amendments of 1989, which added section 1213 to the Higher Education Act. These amendments require that, as a condition of receiving funds or any other form of financial assistance under any Federal program, an institution of higher education (IHE) must certify that it has adopted and implemented a drug prevention program as described in this part.

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

[61 FR 66225, Dec. 17, 1996]

#### § 86.2 What Federal programs are covered by this part?

The Federal programs covered by this part include—

(a) All programs administered by the Department of Education under which an IHE may receive funds or any other form of Federal financial assistance; and

(b) All programs administered by any other Federal agency under which an IHE may receive funds or any other form of Federal financial assistance.

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

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

#### § 86.3 What actions shall an IHE take to comply with the requirements of this part?

(a) An IHE shall adopt and implement a drug prevention program as described in § 86.100 to prevent the unlawful possession, use, or distribution of illicit drugs and alcohol by all students and employees on school premises or as part of any of its activities.

(b) An IHE shall provide a written certification that it has adopted and

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implemented the drug prevention program described in § 86.100.

(Approved by the Office of Management and Budget under control number 1880–0522)

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

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66225, 66226, Dec. 17, 1996]

#### § 86.4 What are the procedures for submitting a drug prevention program certification?

An IHE shall submit to the Secretary the drug prevention program certification required by § 86.3(b).

(Approved by the Office of Management and Budget under control number 1880–0522)

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

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66226, Dec. 17, 1996]

#### § 86.5 What are the consequences if an IHE fails to submit a drug prevention program certification?

(a) An IHE that fails to submit a drug prevention program certification is not eligible to receive funds or any other form of financial assistance under any Federal program.

(b) The effect of loss of eligibility to receive funds or any other form of Federal financial assistance is determined by the statute and regulations governing the Federal programs under which an IHE receives or desires to receive assistance.

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

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

#### § 86.6 When must an IHE submit a drug prevention program certification?

(a) After October 1, 1990, except as provided in paragraph (b) of this section, an IHE is not eligible to receive funds or any other form of financial assistance under any Federal program until the IHE has submitted a drug prevention program certification.

(b)(1) The Secretary may allow an IHE until not later than April 1, 1991, to submit the drug prevention program certification, only if the IHE establishes that it has a need, other than administrative convenience, for more time to adopt and implement its drug prevention program.

(2) An IHE that wants to receive an extension of time to submit its drug prevention program certification shall submit a written justification to the Secretary that—

(i) Describes each part of its drug prevention program, whether in effect or planned;

(ii) Provides a schedule to complete and implement its drug prevention program; and

(iii) Explains why it has a need, other than administrative convenience, for more time to adopt and implement its drug prevention program.

(3) An IHE shall submit a request for an extension to the Secretary.

(Approved by the Office of Management and Budget under control number 1880-0522)

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

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66226, Dec. 17, 1996]

#### § 86.7 What definitions apply to this part?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR part 77:

Department

EDGAR

Secretary

(b) *Other definitions.* The following terms used in this part are defined as follows:

*Compliance agreement* means an agreement between the Secretary and an IHE that is not in full compliance with its drug prevention program certification. The agreement specifies the steps the IHE will take to comply fully with its drug prevention program certification, and provides a schedule for the accomplishment of those steps. A compliance agreement does not excuse or remedy past violations of this part.

*Institution of higher education* means—

(1) An institution of higher education, as defined in 34 CFR 600.4;

(2) A proprietary institution of higher education, as defined in 34 CFR 600.5;

(3) A postsecondary vocational institution, as defined in 34 CFR 600.6; and

(4) A vocational school, as defined in 34 CFR 600.7.

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

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66226, Dec. 17, 1996]

### Subpart B—Institutions of Higher Education

#### § 86.100 What must the IHE's drug prevention program include?

The IHE's drug prevention program must, at a minimum, include the following:

(a) The annual distribution in writing to each employee, and to each student who is taking one or more classes for any type of academic credit except for continuing education units, regardless of the length of the student's program of study, of—

(1) Standards of conduct that clearly prohibit, at a minimum, the unlawful possession, use, or distribution of illicit drugs and alcohol by students and employees on its property or as part of any of its activities;

(2) A description of the applicable legal sanctions under local, State, or Federal law for the unlawful possession or distribution of illicit drugs and alcohol;

(3) A description of the health risks associated with the use of illicit drugs and the abuse of alcohol;

(4) A description of any drug or alcohol counseling, treatment, or rehabilitation or re-entry programs that are available to employees or students; and

(5) A clear statement that the IHE will impose disciplinary sanctions on students and employees (consistent with local, State, and Federal law), and a description of those sanctions, up to and including expulsion or termination of employment and referral for prosecution, for violations of the standards of conduct required by paragraph (a)(1) of this section. For the purpose of this section, a disciplinary sanction may include the completion of an appropriate rehabilitation program.

(b) A biennial review by the IHE of its program to—

(1) Determine its effectiveness and implement changes to the program if they are needed; and

(2) Ensure that the disciplinary sanctions described in paragraph (a)(5) of this section are consistently enforced.

(Approved by the Office of Management and Budget under control number 1880-0522)

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

## § 86.101

### § 86.101 What review of IHE drug prevention programs does the Secretary conduct?

The Secretary annually reviews a representative sample of IHE drug prevention programs.

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

### § 86.102 What is required of an IHE that the Secretary selects for annual review?

If the Secretary selects an IHE for review under § 86.101, the IHE shall provide the Secretary access to personnel, records, documents and any other necessary information requested by the Secretary to review the IHE's adoption and implementation of its drug prevention program.

(Approved by the Office of Management and Budget under control number 1880-0522)

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

### § 86.103 What records and information must an IHE make available to the Secretary and the public concerning its drug prevention program?

(a) Each IHE that provides the drug prevention program certification required by § 86.3(b) shall, upon request, make available to the Secretary and the public a copy of each item required by § 86.100(a) as well as the results of the biennial review required by § 86.100(b).

(b)(1) An IHE shall retain the following records for three years after the fiscal year in which the record was created:

(i) The items described in paragraph (a) of this section.

(ii) Any other records reasonably related to the IHE's compliance with the drug prevention program certification.

(2) If any litigation, claim, negotiation, audit, review, or other action involving the records has been started before expiration of the three-year period, the IHE shall retain the records until completion of the action and resolution of all issues that arise from it, or until the end of the regular three-year period, whichever is later.

(Approved by the Office of Management and Budget under control number 1880-0522)

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

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### Subpart C [Reserved]

### Subpart D—Responses and Sanctions Issued or Imposed by the Secretary for Violations by an IHE

#### § 86.300 What constitutes a violation of this part by an IHE?

An IHE violates this part by—

(a) Receiving any form of Federal financial assistance after becoming ineligible to receive that assistance because of failure to submit a certification in accordance with § 86.3(b); or

(b) Violating its certification. Violation of a certification includes failure of an IHE to—

(1) Adopt or implement its drug prevention program; or

(2) Consistently enforce its disciplinary sanctions for violations by students and employees of the standards of conduct adopted by an IHE under § 86.100(a)(1).

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

[55 FR 33581, Aug. 16, 1990, as amended at 61 FR 66226, Dec. 17, 1996]

#### § 86.301 What actions may the Secretary take if an IHE violates this part?

(a) If an IHE violates its certification, the Secretary may issue a response to the IHE. A response may include, but is not limited to—

(1) Provision of information and technical assistance; and

(2) Formulation of a compliance agreement designed to bring the IHE into full compliance with this part as soon as feasible.

(b) If an IHE receives any form of Federal financial assistance without having submitted a certification or violates its certification, the Secretary may impose one or more sanctions on the IHE, including—

(1) Repayment of any or all forms of Federal financial assistance received by the IHE when it was in violation of this part; and

(2) The termination of any or all forms of Federal financial assistance that—

(i)(A) Except as specified in paragraph (b)(2)(ii) of this section, ends an IHE's eligibility to receive any or all

forms of Federal financial assistance. The Secretary specifies which forms of Federal financial assistance would be affected; and

(B) Prohibits an IHE from making any new obligations against Federal funds; and

(ii) For purposes of an IHE's participation in the student financial assistance programs authorized by title IV of the Higher Education Act of 1965 as amended, has the same effect as a termination under 34 CFR 668.94.

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

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

**§ 86.302 What are the procedures used by the Secretary for providing information or technical assistance?**

(a) The Secretary provides information or technical assistance to an IHE in writing, through site visits, or by other means.

(b) The IHE shall inform the Secretary of any corrective action it has taken within a period specified by the Secretary.

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

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

**§ 86.303 What are the procedures used by the Secretary for issuing a response other than the formulation of a compliance agreement or the provision of information or technical assistance?**

(a) If the Secretary intends to issue a response other than the formulation of a compliance agreement or the provision of information or technical assistance, the Secretary notifies the IHE in writing of—

(1) The Secretary's determination that there are grounds to issue a response other than the formulation of a compliance agreement or providing information or technical assistance; and

(2) The response the Secretary intends to issue.

(b) An IHE may submit written comments to the Secretary on the determination under paragraph (a)(1) of this section and the intended response under paragraph (a)(2) of this section within 30 days after the date the IHE receives the notification of the Secretary's intent to issue a response.

(c) Based on the initial notification and the written comments of the IHE the Secretary makes a final determination and, if appropriate, issues a final response.

(d) The IHE shall inform the Secretary of the corrective action it has taken in order to comply with the terms of the Secretary's response within a period specified by the Secretary.

(e) If an IHE does not comply with the terms of a response issued by the Secretary, the Secretary may issue an additional response or impose a sanction on the IHE in accordance with the procedures in § 86.304.

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

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

**§ 86.304 What are the procedures used by the Secretary to demand repayment of Federal financial assistance or terminate an IHE's eligibility for any or all forms of Federal financial assistance?**

(a) A designated Department official begins a proceeding for repayment of Federal financial assistance or termination, or both, of an IHE's eligibility for any or all forms of Federal financial assistance by sending the IHE a notice by certified mail with return receipt requested. This notice—

(1) Informs the IHE of the Secretary's intent to demand repayment of Federal financial assistance or to terminate, describes the consequences of that action, and identifies the alleged violations that constitute the basis for the action;

(2) Specifies, as appropriate—

(i) The amount of Federal financial assistance that must be repaid and the date by which the IHE must repay the funds; and

(ii) The proposed effective date of the termination, which must be at least 30 days after the date of receipt of the notice of intent; and

(3) Informs the IHE that the repayment of Federal financial assistance will not be required or that the termination will not be effective on the date specified in the notice if the designated Department official receives, within a 30-day period beginning on the date the IHE receives the notice of intent described in this paragraph—

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(i) Written material indicating why the repayment of Federal financial assistance or termination should not take place; or

(ii) A request for a hearing that contains a concise statement of disputed issues of law and fact, the IHE's position with respect to these issues, and, if appropriate, a description of which Federal financial assistance the IHE contends need not be repaid.

(b) If the IHE does not request a hearing but submits written material—

(1) The IHE receives no additional opportunity to request or receive a hearing; and

(2) The designated Department official, after considering the written material, notifies the IHE in writing whether—

(i) Any or all of the Federal financial assistance must be repaid; or

(ii) The proposed termination is dismissed or imposed as of a specified date.

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

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

**Subpart E—Appeal Procedures**

**§ 86.400 What is the scope of this subpart?**

(a) The procedures in this subpart are the exclusive procedures governing appeals of decisions by a designated Department official to demand the repayment of Federal financial assistance or terminate the eligibility of an IHE to receive some or all forms of Federal financial assistance for violations of this part.

(b) An Administrative Law Judge (ALJ) hears appeals under this subpart.

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

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

**§ 86.401 What are the authority and responsibility of the ALJ?**

(a) The ALJ regulates the course of the proceeding and conduct of the parties during the hearing and takes all steps necessary to conduct a fair and impartial proceeding.

(b) The ALJ is not authorized to issue subpoenas.

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(c) The ALJ takes whatever measures are appropriate to expedite the proceeding. These measures may include, but are not limited to—

(1) Scheduling of conferences;

(2) Setting time limits for hearings and submission of written documents; and

(3) Terminating the hearing and issuing a decision against a party if that party does not meet those time limits.

(d) The scope of the ALJ's review is limited to determining whether—

(1) The IHE received any form of Federal financial assistance after becoming ineligible to receive that assistance because of failure to submit a certification; or

(2) The IHE violated its certification.

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

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

**§ 86.402 Who may be a party in a hearing under this subpart?**

(a) Only the designated Department official and the IHE that is the subject of the proposed termination or recovery of Federal financial assistance may be parties in a hearing under this subpart.

(b) Except as provided in this subpart, no person or organization other than a party may participate in a hearing under this subpart.

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

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

**§ 86.403 May a party be represented by counsel?**

A party may be represented by counsel.

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

**§ 86.404 How may a party communicate with an ALJ?**

(a) A party may not communicate with an ALJ on any fact at issue in the case or on any matter relevant to the merits of the case unless the other party is given notice and an opportunity to participate.

(b)(1) To obtain an order or ruling from an ALJ, a party shall make a motion to the ALJ.

(2) Except for a request for an extension of time, a motion must be made in writing unless the parties appear in person or participate in a conference telephone call. The ALJ may require a party to reduce an oral motion to writing.

(3) If a party files a written motion, the party shall do so in accordance with § 86.405.

(4) Except for a request for an extension of time, the ALJ may not grant a party's written motion without the consent of the other party unless the other party has had at least 21 days from the date of service of the motion to respond. However, the ALJ may deny a motion without awaiting a response.

(5) The date of service of a motion is determined by the standards for determining a filing date in § 86.405(d).

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

**§ 86.405 What are the requirements for filing written submissions?**

(a) Any written submission under this subpart must be filed by hand-delivery, by mail, or by facsimile transmission. The Secretary discourages the use of facsimile transmission for documents longer than five pages.

(b) If a party files a brief or other document, the party shall serve a copy of the filed material on the other party on the filing date by hand-delivery or by mail. If agreed upon by the parties, service of a document may be made upon the other party by facsimile transmission.

(c) Any written submission must be accompanied by a statement certifying the date that the filed material was filed and served on the other party.

(d)(1) The filing date for a written submission is the date the document is—

- (i) Hand-delivered;
- (ii) Mailed; or
- (iii) Sent by facsimile transmission.

(2) If a scheduled filing date falls on a Saturday, Sunday, or Federal holiday, the filing deadline is the next Federal business day.

(e) A party filing by facsimile transmission is responsible for confirming that a complete and legible copy of the document was received by the Department.

(f) If a document is filed by facsimile transmission, the Secretary or the designated Department official, as applicable, may require the filing of a follow-up hard copy by hand-delivery or by mail within a reasonable period of time.

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

[57 FR 56795, Nov. 30, 1992]

**§ 86.406 What must the ALJ do if the parties enter settlement negotiations?**

(a) If the parties to a case file a joint motion requesting a stay of the proceedings for settlement negotiations or for the parties to obtain approval of a settlement agreement, the ALJ grants the stay.

(b) The following are not admissible in any proceeding under this part:

- (1) Evidence of conduct during settlement negotiations.
- (2) Statements made during settlement negotiations.
- (3) Terms of settlement offers.

(c) The parties may not disclose the contents of settlement negotiations to the ALJ. If the parties enter into a settlement agreement and file a joint motion to dismiss the case, the ALJ grants the motion.

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

**§ 86.407 What are the procedures for scheduling a hearing?**

(a) If the IHE requests a hearing by the time specified in § 86.304(a)(3), the designated Department official sets the date and the place.

(b)(1) The date is at least 15 days after the designated Department official receives the request and no later than 45 days after the request for hearing is received by the Department.

(2) On the motion of either or both parties, the ALJ may extend the period before the hearing is scheduled beyond the 45 days specified in paragraph (b)(1) of this section.

(c) No termination takes effect until after a hearing is held and a decision is issued by the Department.

(d) With the approval of the ALJ and the consent of the designated Department official and the IHE, any time

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schedule specified in this section may be shortened.

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

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

### § 86.408 What are the procedures for conducting a pre-hearing conference?

(a)(1) A pre-hearing conference may be convened by the ALJ if the ALJ thinks that such a conference would be useful, or if requested by—

(i) The designated Department official; or

(ii) The IHE.

(2) The purpose of a pre-hearing conference is to allow the parties to settle, narrow, or clarify the dispute.

(b) A pre-hearing conference may consist of—

(1) A conference telephone call;

(2) An informal meeting; or

(3) The submission and exchange of written material.

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

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

### § 86.409 What are the procedures for conducting a hearing on the record?

(a) A hearing on the record is an orderly presentation of arguments and evidence conducted by an ALJ.

(b) An ALJ conducts the hearing entirely on the basis of briefs and other written submissions unless—

(1) The ALJ determines, after reviewing all appropriate submissions, that an evidentiary hearing is needed to resolve a material factual issue in dispute; or

(2) The ALJ determines, after reviewing all appropriate submissions, that oral argument is needed to clarify the issues in the case.

(c) The hearing process may be expedited as agreed by the ALJ, the designated Department official, and the IHE. Procedures to expedite may include, but are not limited to, the following:

(1) A restriction on the number or length of submissions.

(2) The conduct of the hearing by telephone conference call.

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(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)**

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- 97.102 Definitions for purposes of this policy.
- 97.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
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- 97.107 IRB membership.
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- 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.