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stay the process immediately. The A.I.D. Administrator may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 224.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the A.I.D. Administrator.

(b) No administrative stay is available following a final decision of the A.I.D. Administrator.

§ 224.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the A.I.D. Administrator imposing penalties or assessments under this part and specifies the procedures for such review.

§ 224.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 224.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 224.42 or § 224.43, or any amount agreed upon in a compromise or settlement under § 224.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under the subsection against a refund of an overpayment of Federal taxes, then or later owning by the United States to the defendant.

§ 224.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 224.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The A.I.D. Administrator has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under § 224.42 or during the pendency of any action to collect penalties and assessments under § 224.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 224.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the A.I.D. Administrator, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the A.I.D. Administrator, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 224.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 224.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 224.10(b) shall be deemed notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

PART 225—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b), unless otherwise noted.

SOURCE: 56 FR 28012, 28020, June 18, 1991, unless otherwise noted.

§ 225.101 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 as defined in § 225.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to

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regulation as defined in § 225.102(e) must be reviewed and approved, in compliance with §§ 225.101, 225.102, and §§ 225.107 through 225.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such