

§ 1b.4 Exclusion of agencies.

(a) The USDA agencies and agency units listed in paragraph (b) of this section conduct programs and activities that have been found to have no individual or cumulative effect on the human environment. The USDA agencies and agency units listed in paragraph (b) of this section are excluded from the requirements of preparing procedures to implement NEPA. Actions of USDA agencies and agency units listed in paragraph (b) of this section are categorically excluded from the preparation of an EA or EIS unless the agency head determines that an action may have a significant environmental effect.

- (b)(1) Agricultural Marketing Service
- (2) Economic Research Service
- (3) [Reserved]
- (4) Federal Corp Insurance Corporation
- (5) Food and Consumer Service
- (6) Food Safety and Inspection Service
- (7) Foreign Agricultural Service
- (8) Grain Inspection, Packers and Stockyards Administration
- (9) National Agricultural Library
- (10) National Agricultural Statistics Service
- (11) Office of the General Counsel
- (12) Office of the Inspector General

[60 FR 66481, Dec. 22, 1995, as amended at 76 FR 4802, Jan. 27, 2011]

PART 1c—PROTECTION OF HUMAN SUBJECTS

Sec.

- 1c.101 To what does this policy apply?
- 1c.102 Definitions.
- 1c.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
- 1c.104–1c.106 [Reserved]
- 1c.107 IRB membership.
- 1c.108 IRB functions and operations.
- 1c.109 IRB review of research.
- 1c.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 1c.111 Criteria for IRB approval of research.
- 1c.112 Review by institution.
- 1c.113 Suspension or termination of IRB approval of research.
- 1c.114 Cooperative research.
- 1c.115 IRB records.

- 1c.116 General requirements for informed consent.
- 1c.117 Documentation of informed consent.
- 1c.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 1c.119 Research undertaken without the intention of involving human subjects.
- 1c.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
- 1c.121 [Reserved]
- 1c.122 Use of Federal funds.
- 1c.123 Early termination of research support: Evaluation of applications and proposals.
- 1c.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28018, June 18, 1991, unless otherwise noted.

§ 1c.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 § 1c.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 regulation as defined in § 1c.102(e) must be reviewed and approved, in compliance with §§ 1c.101, 1c.102, and 1c.107 through 1c.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