

from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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[56 FR 28012, 28018, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

**§ 1c.118 Applications and proposals lacking definite plans for involvement of human subjects.**

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 1c.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

**§ 1c.119 Research undertaken without the intention of involving human subjects.**

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the

research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

**§ 1c.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.**

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

**§ 1c.121 [Reserved]**

**§ 1c.122 Use of Federal funds.**

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

**§ 1c.123 Early termination of research support: Evaluation of applications and proposals.**

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other

## § 1c.124

eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

### § 1c.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

## PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

### Subpart A—General

Sec.

- 2.1 Establishment of the Department.
- 2.2 Authority of the Secretary to prescribe regulations.
- 2.3 Authority of the Secretary to delegate authority.
- 2.4 General officers.
- 2.5 Order in which officers of the Department shall act as Secretary.

### Subpart B—General Delegations of Authority by the Secretary of Agriculture

- 2.7 Authority to supervise and direct.
- 2.8 Delegations of authority to agency heads to order that the United States flag be flown at half-staff.
- 2.9 Additional delegations.
- 2.10 Limitations.
- 2.11 New principles and periodic reviews.
- 2.12 Secretary and general officers not precluded from exercising delegated powers.
- 2.13 Status of prior delegations.

### Subpart C—Delegations of Authority to the Deputy Secretary, Under Secretaries, and Assistant Secretaries

- 2.15 Deputy Secretary.

## 7 CFR Subtitle A (1–1–13 Edition)

- 2.16 Under Secretary for Farm and Foreign Agricultural Services.
- 2.17 Under Secretary for Rural Development.
- 2.18 Under Secretary for Food Safety.
- 2.19 Under Secretary for Food, Nutrition, and Consumer Services.
- 2.20 Under Secretary for Natural Resources and Environment.
- 2.21 Under Secretary for Research, Education, and Economics.
- 2.22 Under Secretary for Marketing and Regulatory Programs.
- 2.23 Assistant Secretary for Congressional Relations.
- 2.24 Assistant Secretary for Administration.
- 2.25 Assistant Secretary for Civil Rights.

### Subpart D—Delegations of Authority to Other General Officers and Agency Heads

- 2.27 Office of Administrative Law Judges.
- 2.29 Chief Economist.
- 2.31 General Counsel.
- 2.33 Inspector General.
- 2.34 Director, National Appeals Division.
- 2.35 Judicial Officer.
- 2.36 Director, Office of Communications.

### Subpart E [Reserved]

### Subpart F—Delegations of Authority by the Under Secretary for Farm and Foreign Agricultural Services

- 2.40 Deputy Under Secretary for Farm and Foreign Agricultural Services.
- 2.42 Administrator, Farm Service Agency.
- 2.43 Administrator, Foreign Agricultural Service.
- 2.44 Administrator, Risk Management Agency and Manager, Federal Crop Insurance Corporation.

### Subpart G—Delegations of Authority by the Under Secretary for Rural Development

- 2.45 Deputy Under Secretary for Rural Development.
- 2.47 Administrator, Rural Utilities Service.
- 2.48 Administrator, Rural Business-Cooperative Service.
- 2.49 Administrator, Rural Housing Service.

### Subpart H—Delegations of Authority by the Under Secretary for Food Safety

- 2.51 Deputy Under Secretary for Food Safety.