

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 § 1028.101 (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.

**§ 1028.119 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.

**§ 1028.120 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.

**§ 1028.121 [Reserved]**

**§ 1028.122 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.

**§ 1028.123 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 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).

**§ 1028.124 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 1030—EMPLOYEE STANDARDS OF CONDUCT**

**Subpart A—General**

**Sec.**

1030.101 Cross-references to employee ethical conduct standards and financial disclosure regulations.

## Consumer Product Safety Commission

## § 1031.2

### Subparts B–D [Reserved]

AUTHORITY: 5 U.S.C. 552a, 7301; 15 U.S.C. 2053(c).

SOURCE: 61 FR 65458, Dec. 13, 1996, unless otherwise noted.

### Subpart A—General

#### **§ 1030.101 Cross-references to employee ethical conduct standards and financial disclosure regulations.**

Employees of the Consumer Product Safety Commission are subject to the Standards of Ethical Conduct, 5 CFR part 2635, which are applicable to all executive branch personnel; the CPSC regulations at 5 CFR part 8101, which supplement the executive branch standards; the Office of Personnel Management regulations on employee conduct at 5 CFR part 735; and the financial disclosure regulations at 5 CFR part 2634, which are applicable to all executive branch personnel. In addition, the Commissioners of the CPSC are subject to the statutory provisions of 15 U.S.C. 2053(c).

### Subparts B–D [Reserved]

## **PART 1031—COMMISSION PARTICIPATION AND COMMISSION EMPLOYEE INVOLVEMENT IN VOLUNTARY STANDARDS ACTIVITIES**

### Subpart A—General Policies

Sec.

1031.1 Purpose and scope.

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1031.10 Definitions.

1031.11 Procedural safeguards.

1031.12 Membership criteria.

1031.13 Participation and monitoring criteria.

1031.14 Observation criteria.

1031.15 Communication criteria.

AUTHORITY: 15 U.S.C. 2051–2083, 15 U.S.C. 1261–1276, 15 U.S.C. 1191–1204.

SOURCE: 54 FR 6652, Feb. 14, 1989, unless otherwise noted.

### Subpart A—General Policies

#### **§ 1031.1 Purpose and scope.**

(a) This part 1031 sets forth the Consumer Product Safety Commission's guidelines and requirements on participating in the activities of voluntary standards bodies. Subpart A sets forth general policies on Commission participation, and subpart B sets forth policies and guidelines on employee involvement in voluntary standards activities.

(b) For purposes of both subpart A and subpart B of this part 1031, voluntary standards bodies are private sector domestic or multinational organizations or groups, or combinations thereof, such as, but not limited to, all non-profit organizations, industry associations, professional and technical societies, institutes, and test laboratories, that are involved in the planning, development, establishment, revision, review or coordination of voluntary standards. Voluntary standards development bodies are voluntary standards bodies, or their sub-groups, that are devoted to developing or establishing voluntary standards.

#### **§ 1031.2 Background.**

(a) Congress enacted the Consumer Product Safety Act in 1972 to protect consumers against unreasonable risks of injury associated with consumer products. In order to achieve that goal, Congress established the Consumer Product Safety Commission as an independent regulatory agency and granted it broad authority to promulgate mandatory safety standards for consumer products as a necessary alternative to industry self regulation.