

## Environmental Protection Agency

## § 26.301

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).

### § 26.124 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.

### Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

#### § 26.201 To what does this subpart apply?

(a) This subpart applies to all research involving intentional exposure of any human subject who is a pregnant woman (and her fetus) or a child conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

#### § 26.202 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart.

(a) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(b) A *child* is a person who has not attained the age of 18 years.

#### § 26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

### Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

#### § 26.301 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all observational research involving human subjects who are pregnant women (and therefore their fetuses) conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The exemptions at § 26.101(b)(1) through (b)(6) are applicable to this subpart.

(c) The provisions of § 26.101(c) through (i) are applicable to this subpart. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally

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recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

### § 26.302 Definitions.

The definitions in §§ 26.102 and 26.202 shall be applicable to this subpart as well. In addition, *observational research* means any human research that does not meet the definition of *research involving intentional exposure of a human subject* in § 26.202(a).

### § 26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.

The provisions of 45 CFR 46.203 are applicable to this section.

### § 26.304 Additional protections for pregnant women and fetuses involved in observational research.

The provisions of 45 CFR 46.204 are applicable to this section.

### § 26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

The provisions of 45 CFR 46.206 are applicable to this section.

## Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

### § 26.401 To what does this subpart apply?

(a) This subpart applies to all observational research involving children as subjects, conducted or supported by EPA. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) Exemptions at § 26.101(b)(1) and (b)(3) through (b)(6) are applicable to

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this subpart. The exemption at § 26.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 26.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 26.101(c) through (i) are applicable to this subpart.

### § 26.402 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the following terms are defined:

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency and any other officer or employee of the Environmental Protection Agency to whom authority has been delegated by the Administrator.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State, Tribal, or local law to consent on behalf of a child to general medical care.

(f) *Observational research* means any research with human subjects that does not meet the definition of research involving intentional exposure of a human subject in § 26.202(a).

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

### § 26.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each