

Environmental Protection Agency

§ 26.202

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.

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

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.

§ 26.121 [Reserved]

§ 26.122 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.

§ 26.123 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).

§ 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.

§ 26.203

(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

40 CFR Ch. I (7–1–07 Edition)

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