

§ 26.302

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