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 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

IRB shall review observational research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§ 26.404 Observational research not involving greater than minimal risk.

EPA will conduct or fund observational research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 26.406.

§ 26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that an intervention or procedure presents more than minimal risk to children, EPA will not conduct or fund observational research that includes such an intervention or procedure unless the IRB finds and documents that:

(a) The intervention or procedure holds out the prospect of direct benefit to the individual subject or is likely to contribute to the subject's well-being;

(b) The risk is justified by the anticipated benefit to the subjects;

(c) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 26.406.

§ 26.406 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the observational research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the observational research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 26.116(d).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 26.116, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 26.404 or § 26.405.

(c) In addition to the provisions for waiver contained in § 26.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may replace the consent requirements in subpart A of this part and paragraph (b) of this section with provided an appropriate, equivalent mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate, equivalent mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.