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.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 26.117.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Subparts E–J [Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

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

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (c) of this section, this subpart applies to all research initiated on or after April 15, 2013 involving intentional exposure of a human subject to:

(1) Any substance if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136–136y) or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a), or to hold the results of the research for later inspection by EPA under FIFRA or section 408 of FFDCA; or

(2) A pesticide if, at any time prior to initiating such research, any person who conducted or supported such research intended either to submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section, or to hold the results of the research for later inspection by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section.

(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available and relevant information. EPA must rebuttably presume the existence of intent if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the research was initiated, the results of such research would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

(c) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d) The EPA Administrator retains final judgment as to whether a particular activity is covered by this subpart.

(e) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(g) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]