(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 (b) of this section, subpart K of this part applies to all research initiated after April 7, 2006 involving intentional exposure of a human subject if, at any time prior to initiating such research, any person who conducted or supported such research intended:

(1) 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 (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or

(2) To hold the results of the research for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 346a).

(b) 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.

(c) The Administrator retains final judgment as to whether a particular activity within the scope of paragraphs (a) and (b) of this section is covered by this subpart.

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

(e) 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.

(f) 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.

(g) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available information relevant to determining the intent of a person who conducts or supports research with human subjects after the effective date of the rule. EPA shall rebuttably presume such intent existed 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 under FIFRA or the FFDCA and, at the time the research was initiated, the results of the research would be relevant to EPA's exercise of its authority under FIFRA or the FFDCA with respect to that class of people, products, or activities.

§ 26.1102 Definitions.

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

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).