

Environmental Protection Agency

§ 26.1203

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

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

§ 26.1201 To what does this subpart apply?

Subpart L applies to any person who, after April 7, 2006, conducts or supports research with a human subject intended:

(1) For submission 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 be held 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) 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.

§ 26.1202 Definitions.

The definitions in § 26.1102 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. In addition, a child is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

Notwithstanding any other provision of this part, under no circumstances

§ 26.1301

shall a person conduct or support research covered by § 26.1201 that involves 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 M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

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

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits a report containing the results of any human research if:

(a) The report is submitted after April 7, 2006, and

(b) The report is submitted 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).

§ 26.1302 Definitions.

The definitions in § 26.102 shall apply to this subpart as well.

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by § 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in § 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as speci-

40 CFR Ch. I (7–1–07 Edition)

fied by § 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O—Administrative Actions for Noncompliance

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

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection. EPA may send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the Agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;