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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-

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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;

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(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the Agency under § 26.1502(a) and the EPA Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and inves-

tigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in § 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in § 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are disclosable to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 26.1502(c).

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

[71 FR 6168, Feb. 6, 2006, as amended at 72 FR 2427, Jan. 19, 2007]