§ 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.

§ 26.1203 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 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 specified 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.