§ 26.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution’s responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 26.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 26.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

§ 26.121 [Reserved]

§ 26.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 26.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other
(a) Research involving intentional exposure of a human subject means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject’s participation in the study.

(b) A child is a person who has not attained the age of 18 years.

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

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving 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 C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

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

§ 26.301 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all observational research involving human subjects who are pregnant women (and therefore their fetuses) conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The exemptions at §26.101(b)(1) through (b)(6) are applicable to this subpart.

(c) The provisions of §26.101(c) through (f) are applicable to this subpart. References to State or local laws in this subpart and in §26.101(f) are intended to include the laws of federally