

“(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child’s research involvement, particularly in terms of research versus therapeutic treatment.

“(3) The definition of ‘minimal risk’ with respect to a healthy child or a child with an illness.

“(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

“(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

“(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

“(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

“(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.”

REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH

Pub. L. 106-310, div. A, title XXVII, §2701, Oct. 17, 2000, 114 Stat. 1167, as amended by Pub. L. 106-505, title X, §1001(a), Nov. 13, 2000, 114 Stat. 2350, provided that: “Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act [Oct. 17, 2000], the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations.”

[Pub. L. 106-505, title X, §1001(b), Nov. 13, 2000, 114 Stat. 2350, provided that: “The amendment made by subsection (a) [amending section 2701 of Pub. L. 106-310, set out above] takes effect on the date of the enactment of the Children’s Health Act of 2000 [Oct. 17, 2000].”]

§ 289a. Peer review requirements

(a) Applications for biomedical and behavioral research grants, cooperative agreements, and contracts; regulations

(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this chapter for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on November 20, 1985, to grants under this chapter for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before November 20, 1985,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(16) and 284(c)(3) of this title.

(b) Periodic review of research at National Institutes of Health

The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(6)¹ and 284(c)(3) of this title.

(c) Compliance with requirements for inclusion of women and minorities in clinical research

(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 289a-2 of this title.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 289a-2 of this title, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

(July 1, 1944, ch. 373, title IV, §492, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103-43, title I, §132, June 10, 1993, 107 Stat. 135; Pub. L. 109-482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685.)

REFERENCES IN TEXT

Section 282(b)(6) of this title, referred to in subsec. (b), was redesignated section 282(b)(16) by Pub. L. 109-482, title I, §102(a)(3), Jan. 15, 2007, 120 Stat. 3681.

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109-482 substituted “sections 282(b)(16)” for “sections 282(b)(6)” in concluding provisions.

1993—Subsec. (c). Pub. L. 103-43 added subsec. (c).

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

§ 289a-1. Certain provisions regarding review and approval of proposals for research

(a) Review as precondition to research

(1) Protection of human research subjects

(A) In the case of any application submitted to the Secretary for financial assistance to

¹ See References in Text note below.