Statutory Basis for 45 CFR Part 46

TITLE 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE
SUBCHAPTER III—NATIONAL RESEARCH INSTITUTES
Part H—General Provisions

SEC. 289. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately. (2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, Sec. 491, as added Pub. L. 99-158, Sec. 2, Nov. 20, 1985, 99 Stat. 873.)

SEC. 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 conduct research, the Secretary may not approve or fund any application that is subject to review under section 289(a) of this title by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(July 1, 1944, ch. 373, title IV, Sec. 492A, as added Pub. L. 103-43, Title I, Sec. 101, June 10, 1993, 107 Stat. 126.)

SEC. 289g. FETAL RESEARCH

(a) Conduct or support by Secretary; restrictions

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation--

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be same

In administering the regulations for the protection of human research subjects which--

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations; or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

(July 1, 1944, ch. 373, title IV, Sec. 498, as added Pub. L. 99-158, Sec. 2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 100-607, title I, Secs. 156, 157(b), Nov. 4, 1988, 102 Stat. 3059; Pub. L. 103-43, title I, Sec. 121(b)(1), June 10, 1993, 107 Stat. 133.)

(Note: Section 46.102(g) becomes Section 46.102(i) in Title 45 CFR Part 46 as revised on June 18, 1991.)

Note: 42 U.S.C. 289 is section 491 of The Public Health Service Act,
42 U.S.C. 289a-1 is section 492a of The Public Health Service Act, and
42 U.S.C. 289g is section 498 of The Public Health Service Act