Statutory Basis for

TITLE 45 CODE OF FEDERAL REGULATIONS PART 46 PROTECTION OF HUMAN SUBJECTS

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45 CFR 46 IMPLEMENTS THE FOLLOWING SECTIONS OF THE PUBLIC HEALTH SERVICE ACT

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AS AMENDED BY THE HEALTH RESEARCH EXTENSION ACT OF 1985
PUBLIC LAW 99-158 NOVEMBER 20, 1985

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

Sec. 491.

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act 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 and 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 Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

FETAL RESEARCH

Sec. 498.

(a) The Secretary may not conduct or support any research or experimentation, in the United States of 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) 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.*

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

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AS AMENDED BY THE NATIONAL INSTITUTES OF HEALTH
REVITALIZATION ACT OF 1993
PUBLIC LAW 103-43 JUNE 10, 1993
CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF
PROPOSALS FOR RESEARCH

Sec. 492A.

(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 491(a) 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.