TITLE 42 – The Public Health and Welfare

CHAPTER 6A – PUBLIC HEALTH SERVICE

SUBCHAPTER III – NATIONAL RESEARCH INSTITUTES

Part H – General Provisions

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

Sec. 491. [289](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.

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