

UNITED STATES CODE

TITLE 42. THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A. THE PUBLIC HEALTH SERVICE

PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

42 USCS § 300v-1 (2002)

CURRENT THROUGH P.L. 107-151, APPROVED 3/13/02

§ 300v-1. Duties of Commission

(a) Studies and investigations; priority and order; report to President and Congress.

(1) The Commission shall undertake studies of the ethical and legal implications of--

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained [contained] in such records, [;] and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this title [42 USCS § 300v et seq.] on its own initiative or at the request of the head of a Federal agency.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) Recommendations to agencies; subsequent administrative requirements.

(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that--

(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

(c) Report on protection of human subjects; scope; submission to President, etc. The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) Annual report; scope; submission to President, etc. Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) made to Federal agencies by the Commission during the fiscal year and the actions taken, pursuant [pursuant] to subsection (b)(2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(e) Publication and dissemination of reports. The Commission may at any time publish and disseminate to the public reports respecting its activities.

(f) Definitions. For purposes of this section:

(1) The term "Federal agency" means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

(2) The term "protection of human subjects" includes the protection of the health, safety, and privacy of individuals.