TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
GENERAL POWERS AND DUTIES
RESEARCH AND INVESTIGATIONS

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42 USCS § 241

§ 241. Research and investigations generally

(a) Authority of Secretary. The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to--

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or non-profit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under *title 10, United States Code, sections 2353* and *2354*, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services];

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation.

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare [Department of Health and Human Services], engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2) (A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare [Department of Health and Human Services] and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare [Department of Health and Human Services], engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains--

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved--

(I) from a Federal agency outside the Department of Health, Education, and Welfare [Department of Health and Human Services] for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare [Department of Health and Human Services] to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States. The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects. The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local, civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

HISTORY:

(July 1, 1944, ch 373, Title III, Part A, § 301, 58 Stat. 691; July 3, 1946, ch 538, § 7(a), (b), 60 Stat. 423; June 16, 1948, ch 481, § 4(e), (f), 62 Stat. 467, 468; June 24, 1948, ch 621, § 4(e), (f), 62 Stat. 601; June 25, 1948, ch 654, § 1, 62 Stat. 1017; July 3, 1956, ch 510, § 4, 70 Stat. 490; Sept. 15, 1960, P.L. 86-798, 74 Stat. 1053; Oct. 17, 1962, P.L. 87-838, § 2, 76 Stat. 1073; Aug. 9, 1965, P.L. 89-115, § 3, 79 Stat. 448; Dec. 5, 1967, P.L. 90-174, § 9, 81 Stat. 540; Oct. 30, 1970, P.L. 91-515, Title II, Part K, § 292, 84 Stat. 1308; Dec. 23, 1971, P.L. 92-218, § 6(a)(2), 85 Stat. 785; Sept. 19, 1972, P.L. 92-423, § 7(b), 86 Stat. 687; July 12, 1974, P.L. 93-348, Title I, § 104(a)(1), 88 Stat. 346; July 23, 1974, P.L. 93-352, Title I, § 111, 88 Stat. 360; April 22, 1976, P.L. 94-278, Title I, § 111, 90 Stat. 405; Nov. 9, 1978, P.L. 95-622, Title II, Part E, § § 261, 262, 92 Stat. 3434; Nov. 20, 1985, P.L. 99-158, § 3(a)(5), 99 Stat. 879; Oct. 27, 1986, P.L. 99-570, Title IV, Subtitle A, § 4021(b)(2), 100 Stat. 3207-124; Nov. 14, 1986, P.L. 99-660, Title I, § 104, 100 Stat. 3751; Nov. 4, 1988, P.L. 100-607, Title I, Subtitle M, § 163(1)(B), (C), (2), 102 Stat. 3062; June 10, 1993, P.L. 103-43, Title XX, § 2009, 107 Stat. 213.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

The bracketed words "Secretary of Health and Human Services" and "Department of Health and Human Services" have been inserted in this section on authority of § 509(b) of Act Oct. 17, 1979, P.L. 96-88, which appears as *20 USCS § 3508(b)*.

Amendments:

1946. Act July 3, 1946, in subsec. (d), substituted ", or, with respect to mental health, recommended by the National Advisory Mental Health Council;" for a semicolon and, in subsec. (g), inserted, "or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council,".

1948. Act June 16, 1948, in subsec. (d), substituted ", or, with respect to heart diseases, recommended by the National Advisory Heart Council;" for a semicolon; and, in subsec. (g), inserted "or, with respect to heart diseases, upon recommendation of the National Advisory Heart Council,".

Act June 24, 1948, in subsec. (d), substituted ", or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council;" for a semicolon; and, in subsec. (g), inserted "or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council,".

Act June 25, 1948, in subsec. (d), substituted ", and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project;" for a semicolon.

1956. Act July 3, 1956, in subsec. (f), deleted "and" following a semicolon, redesignated former subsec. (g) as subsec. (h), and added new subsec. (g).

1960. Act Sept. 15, 1960, in subsec. (d), inserted the last clause following the semi-colon, and the proviso.

1962. Act Oct. 17, 1962, in subsec. (d), substituted "or research training projects" for "projects" wherever appearing.

1965. Act Aug. 9, 1965, in subsec. (g), deleted "and" following a semicolon, redesignated former subsec. (h) as subsec. (i), and added new subsec. (h).

1967. Act Dec. 5, 1967, in subsec. (h), substituted "five" for "two".

1970. Act Oct. 30, 1970, in subsec. (h), substituted "eight" for "five".

1971. Act Dec. 23, 1971 (effective as provided by § 7 of such Act, which appears as *42 USCS § 218* note), in subsecs. (d) and (i), substituted "National Cancer Advisory Board" for "National Advisory Cancer Board".

1972. Act Sept. 19, 1972 (effective as provided by § 9 of such Act, which appears as *42 USCS § 218* note), in subsecs. (d) and (i), substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

1974. Act July 12, 1974 (effective as provided by § 104(b) of such Act, which appears as a note to this section), struck out para. (c) which read: "Establish and maintain research fellowships in the Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad;"; and in paragraph (d), struck out "or research training", "and research training programs", and "and research training program"; and redesignated paragraphs (d)-(i) as paragraphs (c)-(h), respectively.

Act July 23, 1974, in redesignated paragraph (g), deleted "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" before ", including contracts for research".

1976. Act April 22, 1976, substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and substituted "National Heart, Lung, and Blood Advisory Council" for "National Heart and Lung Advisory Council" in paragraphs (c) and (h).

1978. Act Nov. 9, 1978 (effective Oct. 1, 1978, as provided by § § 261, 261 of such Act), redesignated existing matter as subsec. (a); redesignated subsecs. (a)-(h), as paras. (1)-(8), respectively; added new subsec. (b); in subsec. (a), as redesignated, substituted "Secretary" for "Surgeon General", wherever appearing, in para. (1), as redesignated, substituted "collect" for "Collect", in para. (2), (3), and (6), as redesignated, substituted "make" for "Make", in para. (4), as redesignated, substituted "secure" for "Secure", in para. (5), as redesignated, substituted "for" for "For", in para. (7), as redesignated, substituted "enter" for "Enter", in para. (8), as redesignated, substituted "adopt" for "Adopt", in para. (6), as redesignated, deleted "and", which appeared at the end thereof (see Explanatory note); in subsec. (a), as redesignated, added: "The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.".

Act Nov. 9, 1978, § 262(8), purported to delete "and" which appeared at the end of subsec. (f), redesignated as (6); however, this deletion was made from the end of subsec. (g), redesignated as (7), as the probable intent of Congress.

1985. Act Nov. 20, 1985, in subsec. (a), in para. (3), substituted "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research" for "as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council, and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided*, That such uniform per-

centage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year" and, in para. (8), purported to substitute "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendations of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems"; however, to conform to the probable intent of Congress, such amendment was executed by substituting "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

1986. Act Oct. 27, 1986, in subsec. (a)(3), deleted "or, in the case of mental health projects, by the National Advisory Mental Health Council;" following "Department supporting such projects", and deleted "or the National Advisory Mental Health Council" following "entity of the Department".

Act Nov. 14, 1986 added subsec. (c).

1988. Act Nov. 4, 1988 transferred the concluding matter of *42 USCS § 242a(a)* to this section and designated it as subsec. (d), and in such subsec., substituted "biomedical, behavioral, clinical, or other research (including research on mental health, including" for "research on mental health, including", and substituted "drugs)" for "drugs".

1993. Act June 10, 1993 (effective on enactment as provided by § 2101 of such Act, which appears as *42 USCS § 201* note), in subsec. (b)(4), in the introductory matter, substituted "a biennial" for "an annual".

Transfer of functions:

The functions of the Surgeon General of the Public Health Service were transferred to the Secretary of Health, Education and Welfare, and the agency designated as the Office of the Surgeon General was abolished by Reorg. Plan No. 3 of 1966, § § 1, 3, which appears as *42 USCS § 202* note. Act Oct. 17, 1979, P.L. 96-88, Title V, § 509, 93 Stat. 695, which appears as *20 USCS § 3508*, redesignated the Department of Health, Education, and Welfare as the Department of Health and Human Services and provided that any reference to the Department of Health, Education, and Welfare, in any law in force on the effective date of such Act [effective Oct. 17, 1979], shall be deemed to refer and apply to the Department of Health and Human Services, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under such Act Oct. 17, 1979.

Other provisions:

Application of July 12, 1974 amendments. Act July 12, 1974, P.L. 93-348, Title I, § 104(b), 88 Stat. 347, provided that "The amendments made by subsection (a) shall not apply with respect to commitments made before the date of the enactment of this Act by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a).".

Termination of advisory committees. Act Jan. 4, 1975, P.L. 93-641, § 6, 88 Stat. 2275, which appears as *42 USCS § 217a* note, provided that an advisory committee establish pursuant to the Publi Health Service Act [for full classifica-

tion, see USCS Tables volumes] shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

Analysis of thyroid cancer. Act Jan. 4, 1983, P.L. 97-414, § 7, 96 Stat. 2059, provides:

"(a) In carrying out section 301 of the Public Health Service Act [this section], the Secretary of Health and Human Services shall--

"(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

"(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

"(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

"(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

"(b)

(1) Within one year after the date of enactment of this Act, the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

"(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish--

"(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

"(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

"(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.".

Provision of continuing care for certain psychiatric patients. Act Oct. 7, 1985, P.L. 99-117, § 10, 99 Stat. 494 provides: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [this section] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations.".

Study of thyroid morbidity for Hanford, Washington. Act Nov. 4, 1988, P.L. 100-607, Title I, Subtitle M, § 161, 102 Stat. 3059; Oct. 27, 1992, P.L. 102-531, Title III, § 312(e)(1), 106 Stat. 3506, provides:

"(a) In general. In carrying out the purposes of section 301 of the Public Health Service Act (*42 U.S.C. 241*), the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention (hereafter referred to in this section as the 'Director'), shall conduct a study of thyroid morbidity of the population (including Indian tribes and tribal organizations) in the vicinity of Hanford, in the State of Washington, during the years 1944 through 1957.

"(b) Peer review. As soon as is practicable after the date of the enactment of this Act, the Director shall establish a peer review committee that shall, along with the Centers for Disease Control and Prevention, make any determinations as to the conduct of the study required under this section.

"(c) Contract.

(1) In general. Except as provided in paragraph (2), the Director may contract out any portion of the study required under this section if the Director considers such appropriate, except that such contractor shall not have any direct or indirect interest in the outcome of such study including, contracts with the Department of Energy.

"(2) Relationships. Contractors that currently are parties to contracts with the Department of Energy (or who have previously been parties to such) shall be given consideration pursuant to paragraph (1), except that the Director shall make a determination in each such circumstance that the relationship of the contractor with the Department of Energy does not represent a conflict of interest or the appearance of such a conflict regarding the conduct of the study required under this section.

"(d) Report. Not later than 42 months after the date of enactment of this section, the Director shall transmit a report including such study to the Congress, the chief executive officers of the States of Oregon and Washington, and the governing officials of the Indian tribes in the vicinity of Hanford, Washington.".

National Commission on Sleep Disorders Research. Act Nov. 4, 1988, P.L. 100-607, Title I, Subtitle M, § 162, 102 Stat. 3060, provides:

"(a) Establishment. Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (hereafter in this section referred to as the 'Secretary'), after consultation with the Director of the National Institutes of Health, shall establish a National Commission on Sleep Disorders Research (hereafter in this section referred to as the 'Commission').

"(b) Composition.

(1) Appointed members. The Commission shall be composed of 10 members to be appointed as follows:

"(A) Six members shall be appointed by the Secretary from among scientists, physicians, and other health professionals who are not in the employment of the Federal Government, and who have primary expertise in sleep disorders research or medicine.

"(B) Two members shall be appointed by the Secretary from the general public, of whom one of which shall have personal or close family experience with sleep disorders.

"(C) Two members shall be appointed by the Secretary from among the personnel of the National Institutes of Health, and such members interest shall be in the field of sleep disorders research.

"(2) Ex officio members. The Director of the National Institutes of Health, the Director of the National Institute of Neurological and Communicative Disorders and Stroke, the Directors of the National Heart, Lung and Blood Institute, the National Institute on Mental Health, the National Institute on Aging, the National Institute on Child Health and Human Development, the Director of the Center for Disease Control, the Chief Medical Director of the Veterans' Administration, and the Secretary of Defense shall be ex officio members of the Commission, or their designees.

"(c) Chairperson. The members of the Commission shall select a Chairperson from among the appointed members of the Commission.

"(d) Meetings. Not later than 60 days after the establishment of the Commission, the Commission shall meet as directed by the Secretary, and thereafter shall meet at the call of the Chairperson of the Commission, but in no event shall the Commission meet less often than three times during the life of the Commission. The Commission may hold such hearings, take such testimony, and sit and act at such time and places as the Commission considers appropriate.

"(e) Personnel.

(1) Executive secretary.

(A) Appointment. The Commission may appoint and fix the compensation of an executive secretary to effectively carry out the functions of the Commission.

(B) Compensation. The executive secretary shall be appointed subject to title 5, United States Code, governing appointments in the competitive service, and shall receive compensation in accordance with chapter 51 and subchapter III of chapter 53 of such *title [5 USCS § § 5101* et seq. and *5331* et seq.] relating to classification and General Schedule pay rates.

"(2) Additional personnel. The Secretary shall, to the extent practicable, provide the Commission with such additional professional and clerical staff, such information, and the services of such consultants as the Commission determines to be necessary to carry out its functions effectively.

"(f) Compensation.

(1) Officers or employees of the Federal government. Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment.

"(2) Non-federal Government members. Members of the Commission who are not officers or employees of the Federal Government shall receive compensation at a rate not to exceed the daily equivalent of the annual rate in effect for Grade GS-18 of the General Schedule for each day (including traveltime) that such members are engaged in the performance of their duties as members of the Commission.

"(3) Expenses. All members of the Commission, while serving away from their homes or regular places of business in the performance of services for the Commission, shall be allowed travel expenses, including per diem in lieu of sub-

sistence, in the same manner as such expenses are authorized by *section 5703 of title 5, United States Code*, for persons in Government Service employed intermittently.

"(g) Duties.

(1) Study. The Commission shall--

"(A) conduct a comprehensive study of the present state of knowledge of the incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of the social and economic impact of such disorders;

"(B) evaluate the public and private facilities and resources (including trained personnel and research activities) available for the diagnosis, prevention, and treatment of, and research into, such disorders; and

"(C) identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in the management and research into sleep disorders can be accomplished.

"(2) Development of plan. Based on the study conducted under paragraph (1), the Commission shall develop a long-range plan for the use and organization of national resources to effectively deal with sleep disorders research and medicine.

"(3) Cooperation. Each Federal entity administering programs and activities related to sleep disorders shall, on request, assist the Commission in carrying out its duties under this subsection.

"(h) Development of estimates. The Commission shall recommend, for each of the Institutes of the National Institutes of Health whose activities are to be affected by the long-range plan, estimates of the expenditures needed to carry out each Institute's part of the overall program. Such estimates shall be prepared for the fiscal year beginning immediately after completion of the plan under subsection (g)(2) and for each of the next 2 fiscal years.

"(i) Report. Not later than 18 months after the initial meeting of the Commission (as prescribed by subsection (d)), the Commission shall prepare and submit to the appropriate Committees of Congress, a final report describing--

"(1) the long-range plan developed under subsection (g);

"(2) the expenditure estimates required under subsection (h); and

"(3) any recommendations of the Commission for legislation.

"(j) Termination. The Commission shall cease to exist on the 30th day following the date of the submission of the final report under subsection (i).".

Sentinel disease survey. Act June 10, 1993, P.L. 103-43, Title XIX, § 1910, 107 Stat. 205 (effective on enactment as provided by § 2101 of such Act, which appears as *42 USCS § 201* note), provides:

"(a) In general. The Secretary of Health and Human Services, in cooperation with the Agency for Toxic Substances and Disease Registry and the Centers for Disease Control and Prevention, shall design and implement a pilot sentinel disease surveillance system, and as appropriate, a follow-up system.

"(b) Purpose. The purpose of the study conducted under subsection (a) shall be to determine the applicability of and the difficulties associated with the implementation of the sentinel disease concept for identifying the relationship between the occupation of household members and the incidence of subsequent conditions or diseases in other members of the household.

"(c) Report. Not later than 4 years after the date of enactment of this Act, the Director of the National Institutes of Health shall prepare and submit to the appropriate committees of Congress, a report concerning the results of the study conducted under subsection (a).".

Female genital mutilation. Act April 26, 1996, P.L. 104-134, Title I [Title V, § 520], 110 Stat. 1321-250; May 2, 1996, P.L. 104-140, § 1(a), 110 Stat. 1327, provides:

"(a) Congress finds that--

"(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

"(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

"(b) The Secretary of Health and Human Services shall do the following:

"(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

"(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

"(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

"(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

"(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act.".

Coordination of data surveys and reports. Act Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536 (enacting into law § 703(e) of Title VII of H.R. 3426 (113 Stat. 1501A-402), as introduced on Nov. 17, 1999), provides: "The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health.".

Transfer of provision regarding placement of automatic external defibrillators in Federal buildings. Act Dec. 6, 1999, P.L. 106-129, § 7, 113 Stat. 1676, which formerly appeared as a note to this section, has been transferred to *42 USCS § 238p* note.

NOTES:

Code of Federal Regulations:

Food and Drug Administration, Department of Health and Human Services--Enforcement policy, 21 CFR Part 7.

Food and Drug Administration, Department of Health and Human Services--Public information, 21 CFR Part 20.

Food and Drug Administration, Department of Health and Human Services--Mutual recognition of pharmaceutical good manufacturing practice reports, medical device quality system audit reports, and certain medical device product evaluation reports: United States and the European Community, 21 CFR Part 26.

Food and Drug Administration, Department of Health and Human Services--Protection of human subjects, 21 CFR Part 50.

Food and Drug Administration, Department of Health and Human Services--Institutional review boards, 21 CFR Part 56.

Food and Drug Administration, Department of Health and Human Services--Hazard analysis and critical control point (HACCP) systems, 21 CFR Part 120.

Food and Drug Administration, Department of Health and Human Services--Fish and fishery products, 21 CFR Part 123.

Food and Drug Administration, Department of Health and Human Services--Food additives, 21 CFR Part 170.

Food and Drug Administration, Department of Health and Human Services--Food additive petitions, 21 CFR Part 171.

Food and Drug Administration, Department of Health and Human Services--Food additives permitted in food or in contact with food on an interim basis pending additional study, 21 CFR Part 180.

Food and Drug Administration, Department of Health and Human Services--Labeling, 21 CFR Part 201.

Food and Drug Administration, Department of Health and Human Services--New drugs, 21 CFR Part 310.

Food and Drug Administration, Department of Health and Human Services--Applications for FDA approval to market a new drug, 21 CFR Part 314.

Food and Drug Administration, Department of Health and Human Services--Prescription drugs for human use generally recognized as safe and effective and not misbranded: drugs used in research, 21 CFR Part 361.

Food and Drug Administration, Department of Health and Human Services--Food additives, 21 CFR Part 570.

Food and Drug Administration, Department of Health and Human Services--Food additive petitions, 21 CFR Part 571.

Food and Drug Administration, Department of Health and Human Services--Investigational device exemptions, 21 CFR Part 812.

Environmental Protection Agency--OMB approvals under the Paperwork Reduction Act, 40 CFR Part 9.

Environmental Protection Agency--Uniform administrative requirements for grants and agreements with institutions of higher education, hospitals, and other non-profit organizations, 40 CFR Part 30.

Environmental Protection Agency--Research and demonstration grants, 40 CFR Part 40.

Environmental Protection Agency--Concentrated aquatic animal production point source category, 40 CFR Part 451.

Public Health Service, Department of Health and Human Services--Minority biomedical research support program, 42 CFR Part 52c.

Public Health Service, Department of Health and Human Services--Fellowships, 42 CFR Part 61.

Public Health Service, Department of Health and Human Services--Public Health Service policies on research misconduct, 42 CFR Part 93.

Related Statutes & Rules:
This section is referred to in *42 USCS § § 242, 254c, 254c-8, 254c-14, 263, 282, 284, 284f* 7610.

Research Guide:

Federal Procedure:
17 Fed Proc L Ed, Health, Education, and Welfare § 42:191.

Law Review Articles:
Federal support of research projects through contracts and grants: A rationale. *19 Am U L Rev 423, 1970.*

Interpretive Notes and Decisions:
1. Generally 2. Awarding of grants-in-aid 3. --Transfer of grants 4. Judicial review of agency grant decisions 5. --Standing 6. --Pleadings 7. Designation of carcinogens 8. Public access to information

1. Generally

Legislative purpose underlying Public Health Service Act (*42 USCS § 241*) can be fulfilled only by protecting interest of medical research personnel and medical faculties in fair and objective distribution of government grants. *Apter v Richardson (1975, CA7 Ill) 510 F2d 351.*

2. Awarding of grants-in-aid

While Secretary, Health, Education and Welfare [now Secretary of Health and Human Services], is authorized to make grants-in-aid (*42 USCS § 241*), Director, National Cancer Institute may approve such grants (*42 USCS § 282(b)*). *Grassetti v Weinberger (1976, ND Cal) 408 F Supp 142.*

3. --Transfer of grants

Regulation providing for continuation of project under new grantee was validly promulgated, and transfer of funding in accord therewith did not violate any rights of original grantee. *Rubinstein v Baltimore (1969, DC Md) 295 F Supp 108.*

4. Judicial review of agency grant decisions

Public Health Service Act confers broad discretion in funding of training programs (*42 USCS § § 241* and *289c*), and this consideration leads to conclusion that medical merits of National Institute of Health decisions on training grants may be committed to unreviewable discretion of agency; however, that does not mean that National Institute of Health actions wholly escape judicial scrutiny, and where it is alleged that agency has transgressed constitutional guaranty or violated express statutory or procedural directive, otherwise nonreviewable agency action should be examined to extent necessary to determine merits of allegation. *Apter v Richardson (1975, CA7 Ill) 510 F2d 351.*

5. --Standing

Prospective program director of medical training program who alleged grant was denied because of her exercise of First Amendment rights in testifying before senate subcommittee and participation in feminist associations, sufficiently harmed and has standing to challenge denial of grant despite fact that medical center at which she was employed did not join suit. *Apter v Richardson (1975, CA7 Ill) 510 F2d 351.*

Power to transfer ongoing grant is vested exclusively in Surgeon General; regulations do not purport to establish any rights in principal investigator or any staff member; consequently principal investigator of grant project had no legal right which was violated when grant to hospital was terminated and transferred to another. *Rubinstein v Baltimore (1969, DC Md) 295 F Supp 108.*

6. --Pleadings

In suit by professor of surgery at medical center appealing dismissal of her complaint challenging denial of medical training grant by department of Health, Education and Welfare and National Institute of Health, in which District Court held that professor was not applicant for grant and therefore lacked standing to bring action, although there were ambiguous references in complaint to effect that she rather than medical center was applicant, District Court did not err in treating complaint as if application was merely filed by her on behalf of medical center. *Apter v Richardson (1975, CA7 Ill) 510 F2d 351.*

7. Designation of carcinogens

Injunction against government's listing of chlorobenzenes as carcinogens is denied under *42 USCS § 241(b)(4),* where government relied on animal testing and there is broad consensus in scientific community that animal evidence can and should be used to predict human carcinogenicity. *Synthetic Organic Chemical Mfrs. Asso. v Secretary, Dep't of Health & Human Services (1989, WD La) 720 F Supp 1244.*

Designation of sulfuric acid mist as known carcinogen on 9th Report of Carcinogens by National Toxicology Program (NTP) was proper because NTP supported its findings by substantial evidence through peer reviewed studies that sulfuric acid mist was carcinogenic and that there were significant number of people in U.S. that were exposed to it; listing was not substantive ruling and NTP was not required to go through notice and comment period as required by *5 USCS § 553,* part of Administrative Procedure Act before making listing. *Fertilizer Inst. v United States HHS (2004, DC Dist Col) 355 F Supp 2d 123.*

8. Public access to information

Public at large does not have right under Freedom of Information Act to underlying raw data in hands of investigators in university groups who conducted the study program under *42 USCS § 241* grant from Federal Government. *Forsham v Califano (1978, App DC) 190 US App DC 231, 587 F2d 1128, 4 Media L R 1122,* affd *(1980) 445 US 169, 63 L Ed 2d 293, 100 S Ct 977, 5 Media L R 2473.*

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