Subsec. (c). Pub. L. 102–96, § 3(2), substituted '', schools of medicine and primary providers'' for ''and schools of medicine'' in heading and substituted ''schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome'' for ''schools of medicine and osteopathic medicine''.

Subsec. (e). Pub. L. 102–96, § 3(3), substituted ''1996'' for ''1991'' in pars. (1) and (2).

1989—Subsec. (c). Pub. L. 101–93 inserted ''and osteopathic medicine'' after ''schools of medicine''.

1988—Subsec. (a). Pub. L. 100–690, § 2617(b)(1), which directed substitution of ''through the Director of the National Institute of Allergy'' for ''through the National Institutes of Allergy'', was executed by making substitution for ''through the National Institute of Allergy'' as the probable intent of Congress.

Subsec. (b)(2)(B)(iii). Pub. L. 100–690, § 2617(b)(2), which directed substitution of ''Institute'' for ''Institutes'', could not be executed because ''Institute'' was singular in original.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

FINDINGS AND SENSE OF CONGRESS

Pub. L. 102–96, § 2, Aug. 14, 1991, 105 Stat. 481, provided that:

''(a) FINDINGS.—Congress finds that—

''(1) community-based clinical trials complement the National Institute of Allergy and Infectious Diseases' university-based research in order to provide increased access to experimental therapies;

''(2) community-based clinical trials provide an efficient and cost-effective means to develop new HIV-related treatments, benefiting all people living with HIV disease and other illnesses; and

''(3) because the community-based clinical trials model has a proven ability to conduct rapid trials that meet the very highest standards of scientific inquiry, this program should be reauthorized and significantly expanded.

''(b) SENSE OF CONGRESS.—It is the sense of Congress that, because of Terry Beirn's tireless efforts to foster a partnership among all parties invested in AIDS research (including the National Institutes of Health university-based research system, primary care physicians practicing in the community, and patients), the community-based clinical trials program should be renamed as the 'Terry Beirn Community-Based AIDS Research Initiative' in his honor.''

§ 300cc–14. Evaluation of certain treatments

(a) Establishment of program

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title, the Secretary shall establish a program for the evaluation of drugs that—

(A) are not approved by the Commissioner of Food and Drugs for the purpose of treatments with respect to acquired immune deficiency syndrome; and

(B) are being utilized for such purpose by individuals infected with the etiologic agent for such syndrome.

(2) The program established under paragraph (1) shall include evaluations of the effectiveness and the risks of the treatment involved, including the risks of foregoing treatments with respect to acquired immune deficiency syndrome that are approved by the Commissioner of Food and Drugs.

(b) Authority with respect to grants and contracts

(1) For the purpose of conducting evaluations required in subsection (a), the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) Nonprofit private entities under paragraph (1) may include nonprofit private organizations that—

(A) are established for the purpose of evaluating treatments with respect to acquired immune deficiency syndrome; and

(B) consist primarily of individuals infected with the etiologic agent for such syndrome.

(c) Scientific and ethical guidelines

(1) The Secretary shall establish appropriate scientific and ethical guidelines for the conduct of evaluations carried out pursuant to this section. The Secretary may not provide financial assistance under subsection (b)(1) unless the applicant for such assistance agrees to comply with such guidelines.

(2) The Secretary may establish the guidelines described in paragraph (1) only after consulting with—

(A) physicians whose clinical practice includes a significant number of individuals with acquired immune deficiency syndrome;

(B) individuals who are infected with the etiologic agent for such syndrome; and

(C) other individuals with appropriate expertise or experience.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, § 2314, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3069; amended Pub. L. 103–43, title XX, § 2008(d)(3), June 10, 1993, 107 Stat. 212.)

Editorial Notes

PRIOR PROVISIONS

A prior section 300cc–14, act July 1, 1944, § 2315, was successively renumbered by subsequent acts and transferred, see section 238*l* of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 substituted ''AIDS Research Advisory Committee'' for ''Clinical Research Review Committee'' in introductory provisions.

§ 300cc–15. Support of international efforts

(a) Grants and contracts for research

(1) Under section 242*l* of this title, the Secretary, acting through the Director of the National Institutes of Health—

(A) shall, for the purpose described in paragraph (2), make grants to, enter into cooperative agreements and contracts with, and provide technical assistance to, international organizations concerned with public health; and

(B) may, for such purpose, provide technical assistance to foreign governments.

(2) The purpose referred to in paragraph (1) is promoting and expediting international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.

(b) Grants and contracts for additional purposes

After consultation with the Administrator of the Agency for International Development, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall under section 242*l* of this title make grants to, enter into contracts with, and provide technical assistance to, international organizations concerned with public health and may provide technical assistance to foreign governments, in order to support—

(1) projects for training individuals with respect to developing skills and technical expertise for use in the prevention, diagnosis, and treatment of acquired immune deficiency syndrome; and

(2) epidemiological research relating to acquired immune deficiency syndrome.

(c) Special Programme of World Health Organization

Support provided by the Secretary pursuant to this section shall be in furtherance of the global strategy of the World Health Organization Special Programme on Acquired Immunodeficiency Syndrome.

(d) Preferences

In providing grants, cooperative agreements, contracts, and technical assistance under subsections (a) and (b), the Secretary shall—

(1) give preference to activities under such subsections conducted by, or in cooperation with, the World Health Organization; and

(2) with respect to activities carried out under such subsections in the Western Hemisphere, give preference to activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

(e) Requirement of application

The Secretary may not make a grant or enter into a cooperative agreement or contract under this section unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which such assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(July 1, 1944, ch. 373, title XXIII, § 2315, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3070; amended Pub. L. 102–531, title III, § 312(d)(18), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XVIII, § 1811(3), June 10, 1993, 107 Stat. 199.)

Editorial Notes

PRIOR PROVISIONS

A prior section 300cc–15, act July 1, 1944, § 2316, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

1993—Subsec. (a)(2). Pub. L. 103–43, § 1811(3)(A), substituted ''international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections'' for ''international research concerning the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome''.

Subsec. (f). Pub. L. 103–43, § 1811(3)(B), substituted ''such sums as may be necessary for each fiscal year'' for ''there are authorized to be appropriated $40,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991''.

1992—Subsec. (b). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

§ 300cc–16. Research centers

(a) In general

(1) The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to, and enter into contracts with, public and nonprofit private entities to assist such entities in planning, establishing, or strengthening, and providing basic operating support for, centers for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immune deficiency syndrome.

(2) A grant or contract under paragraph (1) shall be provided in accordance with policies established by the Secretary, acting through the Director of the National Institutes of Health, and after consultation with the advisory council for the National Institute of Allergy and Infectious Diseases.

(3) The Secretary shall ensure that, as appropriate, clinical research programs carried out under paragraph (1) include as research subjects women, children, hemophiliacs, and minorities.

(b) Use of financial assistance

(1) Financial assistance under subsection (a) may be expended for—

(A) the renovation or leasing of space;

(B) staffing and other basic operating costs, including such patient care costs as are required for clinical research;

(C) clinical training with respect to acquired immune deficiency syndrome (including such training for allied health professionals); and

(D) demonstration purposes, including projects in the long-term monitoring and out-