(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.)

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 outpatient treatment of individuals infected with the etiologic agent for such syndrome.

(2) Financial assistance under subsection (a) may not be expended to provide research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(c) Duration of support

Support of a center under subsection (a) may be for not more than five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(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, § 2316, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3071; amended Pub. L. 107–206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874.)

AMENDMENTS

2002—Subsec. (b)(2). Pub. L. 107–206 substituted ''Ruth L. Kirschstein National Research Service Awards'' for ''National Research Service Awards''.

§ 300cc–17. Information services

(a) Establishment of program

The Secretary shall establish, maintain, and operate a program with respect to information on research, treatment, and prevention activities relating to infection with the etiologic agent for acquired immune deficiency syndrome. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated.

(b) Toll-free telephone communications for health care entities

(1) After consultation with the Director of the Office of AIDS Research, the Administrator of the Health Resources and Services Administration, and the Director of the Centers for Disease Control and Prevention, the Secretary shall provide for toll-free telephone communications to provide medical and technical information with respect to acquired immune deficiency syndrome to health care professionals, allied health care providers, and to professionals providing emergency health services.

(2) Information provided pursuant to paragraph (1) shall include—

(A) information on prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome; and

(B) information contained in the data banks established in subsections (c) and (d).

(c) Data bank on research information

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physicians, and other appropriate individuals, of countries other than the United States.

(d) Data bank on clinical trials and treatments

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 300cc–3 of this title, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the ''Data Bank'').

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) Requirements with respect to data bank on clinical trials and treatments

The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 355 of title 21 that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

(July 1, 1944, ch. 373, title XXIII, § 2317, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3071; amended Pub. L. 100–690, title II, § 2617(c), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 102–531, title III, § 312(d)(19), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XX, § 2008(d)(4), June 10, 1993, 107 Stat. 212.)

AMENDMENTS

1993—Subsec. (d)(1). Pub. L. 103–43 substituted ''AIDS Research Advisory Committee established under section 300cc–3 of this title'' for ''Clinical Research Review Committee''.

1992—Subsecs. (b)(1), (c)(1). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

1988—Subsec. (e). Pub. L. 100–690 substituted ''data bank on clinical trials and treatments'' for ''data bank'' in heading.

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.

§ 300cc–18. Development of model protocols for clinical care of infected individuals

(a) In general

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Director of the Agency for Healthcare Research and Quality, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph (1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) Requirement of provision of certain services

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the