deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) Personnel and administrative support

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) 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, § 2311, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XVIII, § 1811(2), June 10, 1993,107 Stat. 199.)

PRIOR PROVISIONS

A prior section 300cc–11, act July 1, 1944, § 2312, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 inserted before semicolon at end ‘‘, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases’’.

§ 300cc–12. Use of investigational new drugs with respect to acquired immune deficiency syndrome

(a) Encouragement of applications with respect to clinical trials

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 355(i) of title 21.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) Encouragement of applications with respect to treatment use in circumstances other than clinical trials

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 355(i) of title 21, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) Technical assistance with respect to treatment use

In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a), the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b); and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) “New drug” defined

For purposes of this section, the term ‘‘new drug’’ has the meaning given such term in section 321 of title 21.

(July 1, 1944, ch. 373, title XXIII, § 2312, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XX, § 2008(d)(2), June 10, 1993, 107 Stat. 212.)

PRIOR PROVISIONS

A prior section 300cc–12, act July 1, 1944, § 2313, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1993—Subsec. (a)(2)(A). Pub. L. 103–43 substituted ''AIDS Research Advisory Committee'' for ''AIDS Clinical Research Review Committee''.

§ 300cc–13. Terry Beirn Community-Based AIDS Research Initiative

(a) In general

After consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to public entities and nonprofit private entities concerned with acquired immune deficiency syndrome, and may enter into contracts with public and private such[1] entities, for the purpose of planning and conducting, in the community involved, clinical trials of experimental treatments for infection with the etiologic agent for such syndrome that are approved by the Commissioner of Food and Drugs for investigational use under regulations issued under section 355 of title 21.

(b) Requirement of certain projects

(1) Financial assistance under subsection (a) shall include such assistance to community-based organizations and community health centers for the purpose of—

(A) retaining appropriate medical supervision;

(B) assisting with administration, data collection and record management; and

(C) conducting training of community physicians, nurse practitioners, physicians' assistants and other health professionals for the purpose of conducting clinical trials.

(2)(A) Financial assistance under subsection (a) shall include such assistance for demonstration projects designed to implement and conduct community-based clinical trials in order to provide access to the entire scope of communities affected by infections with the etiologic agent for acquired immune deficiency syndrome, including minorities, hemophiliacs and transfusion-exposed individuals, women, children, users of intravenous drugs, and individuals who are asymptomatic with respect to such infection.

(B) The Director of the National Institutes of Health may not provide financial assistance under this paragraph unless the application for such assistance is approved—

(i) by the Commissioner of Food and Drugs;

(ii) by a duly constituted Institutional Review Board that meets the requirements of part 56 of title 21, Code of Federal Regulations; and

(iii) by the Director of the National Institute of Allergy and Infectious Diseases.

[1] So in original.

(c) Participation of private industry, schools of medicine and primary providers

Programs carried out with financial assistance provided under subsection (a) shall be designed to encourage private industry and schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome to participate in, and to support, the clinical trials conducted pursuant to the programs.

(d) Requirement of application

The Secretary may not provide financial assistance under subsection (a) unless—

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

(2) with respect to carrying out the purpose for which the assistance is to be made, 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.

(e) Authorization of appropriations

(1) For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(2) For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(July 1, 1944, ch. 373, title XXIII, § 2313, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3068; amended Pub. L. 100–690, title II, § 2617(b), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 101–93, § 6, Aug. 16, 1989, 103 Stat. 615; Pub. L. 102–96, § 3, Aug. 14, 1991, 105 Stat. 481.)

PRIOR PROVISIONS

A prior section 300cc–13, act July 1, 1944, § 2314, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

1991—Pub. L. 102–96, § 3(1), substituted ''Terry Beirn Community-Based AIDS Research Initiative'' for ''Community-based evaluations of experimental therapies'' in section catchline.

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.