

cially research on effects of genetics and hormonal changes on the progress of the disease.

(July 1, 1944, ch. 373, title IV, § 460, as added Pub. L. 103-43, title XII, § 1201, June 10, 1993, 107 Stat. 169.)

SUBPART 11—NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

§ 285k. National Institute of General Medical Sciences

(a) General purpose

The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

(b) Institutional development award program

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Institute of General Medical Sciences, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

- (i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;
- (ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and
- (iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

(July 1, 1944, ch. 373, title IV, § 461, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 112-74, div. F, title II, § 221(b)(5), Dec. 23, 2011, 125 Stat. 1088.)

CODIFICATION

Section 282(g) of this title, which was transferred and redesignated as subsec. (b) of this section by Pub. L. 112-74, div. F, title II, § 221(b)(5)(B), Dec. 23, 2011, 125 Stat. 1088, was based on act July 1, 1944, ch. 373, title

IV, § 402(g), as added Pub. L. 103-43, title II, § 202, June 10, 1993, 107 Stat. 144.

AMENDMENTS

2011—Pub. L. 112-74, § 221(b)(5)(A), substituted “National Institute of General Medical Sciences” for “Purpose of Institute” in section catchline, designated existing provisions as subsec. (a), and inserted subsec. heading.

Subsec. (b). Pub. L. 112-74, § 221(b)(5)(C)(i), (ii), inserted heading and realigned margins.

Pub. L. 112-74, § 221(b)(5)(B), transferred subsec. (g) of section 282 of this title and redesignated it as subsec. (b) of this section. See Codification note above.

Subsec. (b)(1)(A). Pub. L. 112-74, § 221(b)(5)(C)(iii), substituted “acting through the Director of the National Institute of General Medical Sciences” for “acting through the Director of the National Center for Research Resources”.

SUBPART 12—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

§ 285l. Purpose of Institute

The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the “Institute”) is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

(July 1, 1944, ch. 373, title IV, § 463, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 103-43, title XIII, § 1301(b), June 10, 1993, 107 Stat. 170.)

AMENDMENTS

1993—Pub. L. 103-43 inserted “(in this subpart referred to as the ‘Institute’)” after “Sciences”.

§ 285l-1. Applied Toxicological Research and Testing Program

(a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a) of this section, the Director of the Institute shall, with respect to toxicology, carry out activities—

- (1) to expand knowledge of the health effects of environmental agents;
- (2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;
- (3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;
- (4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;
- (5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and
- (6) to integrate related activities of the Department of Health and Human Services.

(July 1, 1944, ch. 373, title IV, § 463A, as added Pub. L. 103-43, title XIII, § 1301(a), June 10, 1993, 107 Stat. 169.)

§ 2851-2. Definitions

In sections 2851-2 to 2851-5 of this title:

(1) Alternative test method

The term “alternative test method” means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

(2) ICCVAM test recommendation

The term “ICCVAM test recommendation” means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

(Pub. L. 106-545, §2, Dec. 19, 2000, 114 Stat. 2721.)

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 2851-3. Interagency Coordinating Committee on the Validation of Alternative Methods**(a) In general**

With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in sections 2851-2 to 2851-5 of this title as “ICCVAM”) and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 2851-1(b) of this title, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Sections 2851-2 to 2851-5 of this title may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before December 19, 2000, except to the extent inconsistent with sections 2851-2 to 2851-5 of this title.

(b) Purposes

The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

(c) Composition

The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) Scientific Advisory Committee**(1) Establishment**

The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in sections 2851-2 to 2851-5 of this title as the “SAC”) to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

(2) Membership**(A) In general**

The SAC shall be composed of the following voting members:

(i) At least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c) of this section; and

(III) a national animal protection organization established under section 501(c)(3) of title 26.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

(B) Nonvoting ex officio members

The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agency heads specified in subsection (c) of this section (or their designees).