

Pub. L. 100-553, §2(3), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100-607, title I, §101(3), Nov. 4, 1988, 102 Stat. 3049; Pub. L. 100-690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101-93, §5(a), Aug. 16, 1989, 103 Stat. 611.)

#### AMENDMENTS

1989—Pub. L. 101-93 substituted “disease and” for “disease and and”.

1988—Pub. L. 100-553 and Pub. L. 100-607 made identical amendments, substituting “Neurological Disorders” for “Neurological and Communicative Disorders” and “and disorder and stroke” for “disorder, stroke, and disorders of human communication”. Pub. L. 100-690 amended this section to read as if the amendments by Pub. L. 100-607 had not been enacted.

#### EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100-690, see section 2613(b)(1) of Pub. L. 100-690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

### § 285j-1. Spinal cord regeneration research

The Director of the Institute shall conduct and support research into spinal cord regeneration.

(July 1, 1944, ch. 373, title IV, §458, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 857.)

#### INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

Section 7 of Pub. L. 99-158 provided that:

“(a) ESTABLISHMENT.—Within 90 days after the date of enactment of this Act [Nov. 20, 1985], the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the ‘Interagency Committee’). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

“(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Interagency Committee shall consist of representatives from—

“(A) the National Institute on Neurological and Communicative Disorders and Stroke;

“(B) the Department of Defense;

“(C) the Department of Education;

“(D) the Veterans’ Administration;

“(E) the Office of Science and Technology Policy;

and  
“(F) the National Science Foundation;

designated by the heads of such entities.  
“(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

“(c) REPORT.—Within the 18 months after the date of enactment of this Act [Nov. 20, 1985], the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

“(d) TERMINATION.—The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress.”

### § 285j-2. Bioengineering research

The Director of the Institute shall make grants or enter into contracts for research on

the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

(July 1, 1944, ch. 373, title IV, §459, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 857.)

### § 285j-3. Research on multiple sclerosis

The Director of the Institute shall conduct and support research on multiple sclerosis, especially 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. Purpose of Institute

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.

(July 1, 1944, ch. 373, title IV, §461, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 857.)

#### 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.