(c) Coordination of clinical trials networks; reports

The Director may, as appropriate, provide for the coordination of information among networks funded through this section and ensure regular communication among members of the networks, and may require the periodic preparation of reports on the activities of the networks and submission of reports to the Director.

(Pub. L. 111–11, title XIV, §14201, Mar. 30, 2009, 123 Stat. 1453.)

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

DEFINITION OF ''DIRECTOR''

''Director'' as meaning the Director of the National Institutes of Health, see section 284*o*(a) of this title.

§ 284q. Pain research

(a) Research initiatives

(1) In general

The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

(2) Annual recommendations

Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 282a(c)(1) of this title for the Common Fund or otherwise available for such initiatives.

(3) Definition

In this subsection, the term ''Pain Consortium'' means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) Interagency Pain Research Coordinating Committee

(1) Establishment

The Secretary shall establish not later than 1 year after March 23, 2010, and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the ''Committee''), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

(2) Membership

(A) In general

The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives appoint[1] by the Secretary from agencies that conduct pain care research and treatment.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) Additional members

The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.

(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

(C) Nonvoting members

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(3) Chairperson

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(4) Meetings

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(5) Duties

The Committee shall—

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(D) make recommendations on how best to disseminate information on pain care; and

(E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

(6) Review

The Secretary shall review the necessity of the Committee at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §409J, as added Pub. L. 111–148, title IV, §4305(b), Mar. 23, 2010, 124 Stat. 585.)

§ 284q–1. NIH opioid research

(a) In general

The Director of the National Institutes of Health (referred to in this section as the ''NIH'') may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to—

(1) the understanding of pain;

(2) the discovery and development of therapies for chronic pain; and

[1] So in original. Probably should be ''appointed''.

(3) the development of alternatives to opioids for effective pain treatments.

(b) Priority and direction

The prioritization and direction of the Federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016–2020, the latter of which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

(Pub. L. 114–198, title I, § 108, July 22, 2016, 130 Stat. 705.)

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

§ 284r. Basic research

(1) Developing policies

Not later than 2 years after December 13, 2016, the Director of the National Institutes of Health (referred to in this section as the ''Director of the National Institutes of Health''), taking into consideration the recommendations developed under section 2039,[1] shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) Revising policies

The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) Consultation and outreach

In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) Additional requirements

The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(Pub. L. 114–255, div. A, title II, § 2038(g), Dec. 13, 2016, 130 Stat. 1066.)

REFERENCES IN TEXT

Section 2039, referred to in par. (1), is section 2039 of Pub. L. 114–255, which is set out as a note under section 282 of this title.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 284s. Tick-borne diseases

(a) In general

The Secretary of Health and Human Services (referred to in this section as ''the Secretary'') shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) Reports

The Secretary shall ensure that each triennial report under section 283 of this title (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) Tick-Borne Diseases Working Group

(1) Establishment

The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the ''Working Group''), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) Responsibilities

The working group shall—

(A) not later than 2 years after December 13, 2016, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to

[1] See References in Text note below.