

and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009, and the Omnibus Appropriations Act, 2009, and not as part of the Public Health Service Act which comprises this chapter.

§ 282d. Transferred

CODIFICATION

Section, act July 1, 1944, ch. 373, title IV, §402C, as added Pub. L. 111-148, title X, §10409(d), Mar. 23, 2010, 124 Stat. 978, which related to the Cures Acceleration Network, was renumbered section 480 of act July 1, 1944, by Pub. L. 112-74, div. F, title II, §221(c)(1)(A), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a of this title.

§ 283. Biennial reports of Director of NIH

(a) In general

The Director of NIH shall submit to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after January 15, 2007. Each such report shall include the following information:

(1) An assessment of the state of biomedical and behavioral research.

(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

(3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 282(b)(7) of this title through the Division of Program Coordination, Planning, and Strategic Initiatives.

(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

(A) The catalog shall, for each such activity—

(i) identify the agency or agencies involved;

(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

(iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on minority health and health disparities.

(C) Research activities listed in the catalog shall include, where applicable, the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clearinghouses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including—

(I) National Research Service Awards and Clinical Transformation Science Awards;

(II) graduate medical education programs, including information on the

number and type of graduate degrees awarded during the period in which the programs received funding under this subchapter;

(III) investigator-initiated awards for postdoctoral training and postdoctoral training funded through research grants;

(IV) a breakdown by demographic variables and other appropriate categories; and

(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 289a-2 of this title (regarding inclusion of women and minorities in clinical research).

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

(A) Cancer.

(B) Neurosciences.

(C) Life stages, human development, and rehabilitation.

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

(I) Chronic diseases, including pain and palliative care.

(J) Infectious diseases and bioterrorism.

(K) Minority health and health disparities.

(L) Such additional categories as the Director determines to be appropriate.

(6) A review of each entity receiving funding under this subchapter in its capacity as a center of excellence (in this paragraph referred to as a "center of excellence"), including the following:

(A) An evaluation of the performance and research outcomes of each center of excellence.

(B) Recommendations for promoting coordination of information among the centers of excellence.

(C) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(D) If no additional centers of excellence have been funded under this subchapter since the previous report under this section, an explanation of the reasons for not funding any additional centers.

(b) Requirement regarding disease-specific research activities

In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

(1) present information in a standardized format;

(2) identify the actual dollar amounts obligated for such activities; and

(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

(c) Additional reports

In addition to reports required by subsections (a) and (b), the Director of NIH or the head of a national research institute or national center may submit to the Congress such additional reports as the Director or the head of such institute or center determines to be appropriate.

(July 1, 1944, ch. 373, title IV, § 403, as added Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3689; amended Pub. L. 110-85, title XI, § 1104(3), Sept. 27, 2007, 121 Stat. 975.)

PRIOR PROVISIONS

A prior section 283, act July 1, 1944, ch. 373, title IV, § 403, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100-607, title I, § 112, Nov. 4, 1988, 102 Stat. 3052, required a biennial report by the Director to the President and Congress, prior to repeal by Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3689.

AMENDMENTS

2007—Subsec. (a)(4)(C)(iv)(III). Pub. L. 110-85 inserted “and postdoctoral training funded through research grants” before semicolon at end.

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§ 283a. Annual reporting to increase interagency collaboration and coordination

(a) Collaboration with other HHS agencies

On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

(b) Clinical trials

Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 282(i) of this title.

(c) Human tissue samples

On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

(d) First report

The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, § 403A, as added Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3691.)

PRIOR PROVISIONS

A prior section 403A of act July 1, 1944, was renumbered section 403D and is classified to section 283a-3 of this title.

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§ 283a-1. Annual reporting to prevent fraud and abuse

(a) Whistleblower complaints

(1) In general

On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

(2) Contents

For each whistleblower complaint pending during the year for which a report is submitted under this subsection, the report shall identify the following:

- (A) Each agency of the National Institutes of Health involved.
- (B) The status of the complaint.
- (C) The resolution of the complaint to date.

(b) Experts and consultants

On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report that—

- (1) identifies the number of experts and consultants, including any special consultants, whose services are obtained by the National Institutes of Health or its agencies;
- (2) specifies whether such services were obtained under section 209(f) of this title, section 282(d) of this title, or other authority;
- (3) describes the qualifications of such experts and consultants;
- (4) describes the need for hiring such experts and consultants; and
- (5) if such experts and consultants make financial disclosures to the National Institutes of Health or any of its agencies, specifies the income, gifts, assets, and liabilities so disclosed.

(c) First report

The first report under subsections (a) and (b) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, § 403B, as added Pub. L. 109-482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3691.)