§ 282c. Public access to funded investigators' final manuscripts

The Director of the National Institutes of Health (''NIH'') shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.

(Pub. L. 111–8, div. F, title II, § 217, Mar. 11, 2009, 123 Stat. 782.)

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2009, 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. Triennial reports of Director of NIH

(a) In general

The Director of NIH shall submit to the Congress on a triennial 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) A description of intra-National Institutes of Health activities, including—

(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

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

(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, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health, 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, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a–2(f) of this title, and such other information as may be necessary to demonstrate compliance with section 289a–2 of this title and other applicable requirements regarding inclusion of demographic groups.

(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; and

(B) recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(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; Pub. L. 114–255, div. A, title II, § 2032, Dec. 13, 2016, 130 Stat. 1056.)

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

2016—Pub. L. 114–255, § 2032(1), substituted ''Triennial'' for ''Biennial'' in section catchline.

Subsec. (a). Pub. L. 114–255, § 2032(2)(A), substituted ''triennial'' for ''biennial'' in introductory provisions.

Subsec. (a)(3). Pub. L. 114–255, § 2032(2)(B), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''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.''

Subsec. (a)(4)(B). Pub. L. 114–255, § 2032(2)(C)(i), substituted ''demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health,'' for ''demographic variables and other variables''.

Subsec. (a)(4)(C)(v). Pub. L. 114–255, § 2032(2)(C)(ii), substituted ''demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a–2(f) of this title, and such'' for ''demographic variables and such'' and ''and other applicable requirements regarding inclusion of demographic groups'' for ''(regarding inclusion of women and minorities in clinical research)''.

Subsec. (a)(6). Pub. L. 114–255, § 2032(2)(D), substituted ''the following—'' for ''the following:'' in introductory provisions, ''an evaluation'' for ''An evaluation'' and ''; and'' for the period in subpar. (A), redesignated subpar. (C) as (B) and substituted ''recommendations'' for ''Recommendations'', and struck out former subpars. (B) and (D), which read as follows:

''(B) Recommendations for promoting coordination of information among 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.''

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