

international exchanges, partnerships, or programs, for which such participation has been approved by the National Institutes of Health. In such circumstances, the National Institutes of Health shall ensure appropriate training is provided to the participant on how to respond to overtures from individuals associated with foreign talent recruitment programs.

(b) Extramural research

The Secretary shall require disclosure of participation in foreign talent recruitment programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded through the Department of Health and Human Services.

(c) Consistency

The Secretary shall ensure that the policies developed, updated, or issued pursuant to subsections (a) and (b) are, to the greatest extent practicable, consistent with the requirements of subtitle D of title VI of division B of Public Law 117-167 (42 U.S.C. 19231 et seq.) related to foreign talent recruitment programs.

(Pub. L. 117-328, div. FF, title II, §2321, Dec. 29, 2022, 136 Stat. 5765.)

Editorial Notes

REFERENCES IN TEXT

Sections 242v to 242v-3 of this title, referred to in subsec. (a)(1), was in the original “this chapter”, meaning chapter 3 (§§2321-2326) of title II of div. FF of Pub. L. 117-328, 136 Stat. 5765, which enacted this section and sections 242v-1 to 242v-3 of this title and amended section 282 of this title.

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

§ 242v-1. Securing identifiable, sensitive information and addressing other national security risks related to research

(a) In general

The Secretary of Health and Human Services, in consultation with the Director of National Intelligence, the Secretary of State, the Secretary of Defense, and other national security experts, as appropriate, shall ensure that biomedical research conducted or supported by the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services is conducted or supported in a manner that appropriately considers national security risks, including national security implications related to research involving the sequencing of human genomic information, and collection, analysis, or storage of identifiable, sensitive information, as defined in section 241(d)(4) of this title, and the potential misuse of such data. Not later than 2 years after December

29, 2022, the Secretary shall ensure that the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services, in consultation with the heads of agencies and national security experts, including the Office of the National Security within the Department of Health and Human Services—

(1) develop a comprehensive framework and policies for assessing and managing such national security risks that includes, or review and update, as appropriate, the current (as of the date of review) such framework and policies to include—

(A) criteria for how and when to conduct risk assessments for projects that may have national security implications;

(B) security controls and training for researchers or entities, including peer reviewers, that manage or have access to such data that may present national security risks; and

(C) methods to incorporate risk mitigation in the process for funding such projects that may have national security implications and monitor associated research activities following issuance of an award, including changes in the terms and conditions related to the use of such funds, as appropriate;

(2) not later than 1 year after the framework and policies are developed or reviewed and updated, as applicable, under paragraph (1), develop and implement controls to ensure that—

(A) researchers or entities involved in projects reviewed under the framework and relevant policies, including such projects that manage or have access to sensitive, identifiable information, have complied with the requirements of paragraph (1) and ongoing requirements with such paragraph;

(B) consideration of funding for projects that may have national security implications takes into account the extent to which the country in which the proposed research will be conducted or supported poses a risk to the integrity of the United States biomedical research enterprise; and

(C) data access committees reviewing data access requests for projects that may have national security risks, as appropriate, include members with expertise in current and emerging national security threats, in order to make appropriate decisions, including related to access to such identifiable, sensitive information; and

(3) not later than 2 years after the framework and relevant policies are developed or reviewed and updated, as applicable, under paragraph (1), update data access and sharing policies related to human genomic data, as applicable, based on current and emerging national security threats.

(b) Congressional briefing

Not later than 1 year after December 29, 2022, the Secretary shall provide a briefing to the Committee on Health, Education, Labor, and Pensions and the Select Committee on Intelligence of the Senate and the Committee on Energy and Commerce and the Permanent Select

Committee on Intelligence of the House of Representatives on the activities required under subsection (a).

(Pub. L. 117-328, div. FF, title II, § 2322, Dec. 29, 2022, 136 Stat. 5765.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

§ 242v-2. Protecting America's biomedical research enterprise

(a) In general

The Secretary, in consultation with the Assistant to the President for National Security Affairs, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other relevant departments and agencies, and in consultation with research institutions and research advocacy organizations or other relevant experts, as appropriate, shall—

(1) identify ways to improve the protection of intellectual property and other proprietary information, as well as identifiable, sensitive information of participants in biomedical research and development, from national security risks and other applicable threats, including the identification of gaps in policies and procedures in such areas related to biomedical research and development supported by the Department of Health and Human Services, and make recommendations to institutions of higher education or other entities that have traditionally received Federal funding for biomedical research to protect such information;

(2) identify or develop strategies to prevent, mitigate, and address national security risks and threats in biomedical research and development supported by the Federal Government, including such threats associated with foreign talent programs, by countries seeking to exploit United States technology and other proprietary information as it relates to such biomedical research and development, and make recommendations for additional policies and procedures to protect such information;

(3) identify national security risks and potential misuse of proprietary information, and identifiable, sensitive information of biomedical research participants and other applicable risks, including with respect to peer review, and make recommendations for additional policies and procedures to protect such information;

(4) develop a framework to identify areas of biomedical research and development supported by the Federal Government that are emerging areas of interest for state actors and would compromise national security if they were to be subjected to undue foreign influence; and

(5) regularly review recommendations or policies developed under this section and make

additional recommendations or updates, as appropriate.

(b) Report to President and to Congress

Not later than 1 year after December 29, 2022, the Secretary shall prepare and submit, in a manner that does not compromise national security, to the President and the Committee on Health, Education, Labor, and Pensions and the Select Committee on Intelligence of the Senate, the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the House of Representatives, and other congressional committees as appropriate, a report on the findings and recommendations pursuant to subsection (a).

(Pub. L. 117-328, div. FF, title II, § 2324, Dec. 29, 2022, 136 Stat. 5767.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

DEFINITION OF “SECRETARY”

“Secretary” means the Secretary of Health and Human Services, see section 242v(a)(1) of this title.

§ 242v-3. Report on progress to address undue foreign influence

Not later than 1 year after December 29, 2022, and annually thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce in the House of Representatives, in a manner that does not compromise national security, a report on actions taken by the Secretary—

(1) to address cases of noncompliance with disclosure requirements or research misconduct related to foreign influence, including—

(A) the number of potential noncompliance cases investigated by the National Institutes of Health or reported to the National Institutes of Health by a research institution, including relating to undisclosed research support, undisclosed conflicts of interest or other conflicts of commitment, and peer review violations;

(B) the number of cases referred to the Office of Inspector General of the Department of Health and Human Services, the Office of National Security of the Department of Health and Human Services, the Federal Bureau of Investigation, or other law enforcement agencies;

(C) a description of enforcement actions taken for noncompliance related to undue foreign influence; and

(D) any other relevant information; and

(2) to prevent, address, and mitigate instances of noncompliance with disclosure re-