

118TH CONGRESS
1ST SESSION

S. _____

To improve national security at the National Institutes of Health, to address national security issues in the licensure of biological products, to address national security considerations in research at the Department of Health and Human Services, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. RUBIO introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve national security at the National Institutes of Health, to address national security issues in the licensure of biological products, to address national security considerations in research at the Department of Health and Human Services, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genomics Data Secu-
5 rity Act”.

1 **SEC. 2. MODERNIZING THE NATIONAL INSTITUTES OF**
2 **HEALTH'S APPROACH TO NATIONAL SECU-**
3 **RITY.**

4 Section 402(m)(2) of the Public Health Service Act
5 (42 U.S.C. 282(m)(2)) is amended—

6 (1) in subparagraph (E), by striking “; and”
7 and inserting a semicolon;

8 (2) by redesignating subparagraph (F) as sub-
9 paragraph (G); and

10 (3) by inserting after subparagraph (E) the fol-
11 lowing:

12 “(F) address national security issues, in-
13 cluding ways in which the National Institutes of
14 Health can engage with other Federal agencies
15 to modernize the national security strategy of
16 the National Institutes of Health; and”.

17 **SEC. 3. UTILIZATION OF GENOMIC SEQUENCING SERVICES**
18 **BY THE NATIONAL INSTITUTES OF HEALTH.**

19 Notwithstanding any other provision of law, no
20 amounts made available to the National Institutes of
21 Health may be used with respect to activities carried out
22 by any company or its subcontractors or subsidiaries—

23 (1) over which control is exercised or exer-
24 cisable by the Government of the People's Republic
25 of China, a national of the People's Republic of

1 China, or an entity organized under the laws of the
2 People’s Republic of China; or

3 (2) in which the Government of the People’s
4 Republic of China has a substantial interest.

5 **SEC. 4. NATIONAL SECURITY CONSIDERATIONS THROUGH**
6 **LICENSURE.**

7 Section 353 of the Public Health Service Act (42
8 U.S.C. 263a) is amended—

9 (1) by redesignating subsection (q) as sub-
10 section (r); and

11 (2) by inserting after subsection (p) the fol-
12 lowing:

13 “(q) TIES TO THE PEOPLE’S REPUBLIC OF CHINA.—

14 “(1) IN GENERAL.—Each certificate issued by
15 the Secretary under this section shall state wheth-
16 er—

17 “(A) the laboratory;

18 “(B) the company that owns or manages
19 the laboratory; or

20 “(C) any subcontractors or subsidiaries of
21 such a laboratory or company,

22 is an entity described in paragraph (2).

23 “(2) ENTITY DESCRIBED.—An entity described
24 in this paragraph is an entity—

1 “(A)(i) that is engaged in the biological,
2 microbiological, serological, chemical, immuno-
3 hematological, hematological, biophysical,
4 cytological, pathological, or other examination
5 of materials derived from the human body for
6 the purpose of providing information for the di-
7 agnosis, prevention, or treatment of any disease
8 or impairment of, or the assessment of the
9 health of, people of the United States; or

10 “(ii) that handles or has access to any
11 data related to people of the United States that
12 is derived from any activity described in clause
13 (i); and

14 “(B)(i) over which control is exercised or
15 exercisable by the Government of the People’s
16 Republic of China, a national of the People’s
17 Republic of China, or an entity organized under
18 the laws of the People’s Republic of China; or

19 “(ii) in which the Government of the Peo-
20 ple’s Republic of China has a substantial inter-
21 est.”.

22 **SEC. 5. NIH GRANTEE TIES TO FOREIGN GOVERNMENTS.**

23 Title IV of the Public Health Service Act is amended
24 by inserting after section 403C (42 U.S.C. 283a–2) the
25 following:

1 **“SEC. 403C-1. ANNUAL REPORTING REGARDING GRANTEE**
2 **TIES TO FOREIGN GOVERNMENTS.**

3 “(a) IN GENERAL.—On an annual basis, the Director
4 of NIH shall submit to the Committee on Health, Edu-
5 cation, Labor, and Pensions, the Committee on Foreign
6 Relations, and the Select Committee on Intelligence of the
7 Senate, and to the Committee on Energy and Commerce,
8 the Committee on Foreign Affairs, and the Permanent Se-
9 lect Committee on Intelligence of the House of Represent-
10 atives, a report on any ties to foreign governments that
11 researchers funded by grants from the National Institutes
12 of Health have and that are not properly disclosed, vetted,
13 and approved by the National Institutes of Health, includ-
14 ing the status of any ongoing National Institutes of
15 Health compliance reviews related to such ties and all ad-
16 ministrative actions taken to address such concerns.

17 “(b) REQUIREMENT.—The Committees receiving the
18 reports under subsection (a) shall keep confidential, and
19 shall not release, any provision of such a report that is
20 related to an ongoing National Institutes of Health com-
21 pliance review.”.

22 **SEC. 6. NATIONAL SECURITY CONSIDERATIONS IN RE-**
23 **SEARCH.**

24 (a) ESTABLISHMENT OF WORKING GROUP.—Not
25 later than 120 days after the date of enactment of this
26 Act, the Secretary of Health and Human Services (re-

1 referred to in this section as the “Secretary”) shall establish
2 a working group (in this Act referred to as the “Working
3 Group”) in the Department of Health and Human Serv-
4 ices to make recommended updates to the National Insti-
5 tute of Health’s Genomic Data Sharing Policy and to that
6 end, develop and disseminate best practices on data shar-
7 ing for use by entities engaged in biomedical research and
8 international collaboration to enable both academic, pub-
9 lic, and private institutions to—

10 (1) protect intellectual property;

11 (2) weigh the national security risks of poten-
12 tial partnerships where sensitive health information
13 (for purposes of this Act, as defined by the Health
14 IT Policy Committee), of the people of the United
15 States is exchanged; and

16 (3) protect the sensitive health information of
17 the people of the United States.

18 (b) MEMBERSHIP.—

19 (1) COMPOSITION.—The Secretary shall, after
20 consultation with the Director of the National
21 Science Foundation and the Attorney General, ap-
22 point to the Working Group—

23 (A) individuals with knowledge and exper-
24 tise in data privacy or security, data-sharing,
25 national security, or the uses of genomic tech-

1 nology and information in clinical or non-clin-
2 ical research;

3 (B) representatives of national associations
4 representing biomedical research institutions
5 and academic societies;

6 (C) representatives of at least 2 major
7 genomics research organizations from the pri-
8 vate sector; and

9 (D) representatives of any other entities
10 the Secretary determines appropriate and nec-
11 essary to develop the best practices described in
12 subsection (a).

13 (2) REPRESENTATION.—In addition to the
14 members described in paragraph (1), the Working
15 Group shall include not less than one representative
16 of each of the following:

17 (A) The National Institutes of Health.

18 (B) The Bureau of Industry and Security
19 of the Department of Commerce.

20 (C) The National Academies of Science,
21 Engineering, and Medicine.

22 (D) The Department of State.

23 (E) The Department of Justice.

24 (F) The Federal Health IT Coordinating
25 Council.

1 (G) The Office of the National Coordinator
2 for Health Information Technology.

3 (H) The Defense Advanced Research
4 Projects Agency.

5 (I) The Department of Energy.

6 (3) DATE.—The appointments of the members
7 of the Working Group shall be made not later than
8 90 days after the date of enactment of this Act.

9 (c) DUTIES OF WORKING GROUP.—

10 (1) STUDY.—The Working Group shall study—

11 (A) the transfer of data between private,
12 public, and academic institutions that partake
13 in science and technology research and their re-
14 search partners, with a focus on entities of the
15 People’s Republic of China and other foreign
16 entities of concern, including a review of what
17 circumstances would constitute a transfer of
18 data;

19 (B) best practices regarding data protec-
20 tion to help private, public, and academic insti-
21 tutions that partake in biomedical research de-
22 cide how to weigh and factor national security
23 into their partnership decisions and, through
24 research collaborations, what steps the institu-

1 tions can take to safeguard data, particularly
2 genomic data;

3 (C) recommendations regarding areas
4 where Federal agencies can coordinate to in-
5 crease education to such private and academic
6 research institutions that partake in science
7 and technology research to ensure the institu-
8 tions can better protect themselves from eco-
9 nomic threats with a strengthened under-
10 standing of intellectual property rights, re-
11 search ethics, and the risk of intellectual prop-
12 erty theft, as well as education on how to recog-
13 nize and report such threats; and

14 (D) other risks and best practices related
15 to information and data sharing, as identified
16 by the Working Group, including any gaps in
17 current practice that could be addressed by con-
18 gressional action.

19 (2) REPORT.—

20 (A) IN GENERAL.—Not later than 1 year
21 after the date of enactment of this Act, the
22 Working Group shall submit a report that con-
23 tains a detailed statement of the findings and
24 conclusions of the Working Group, together
25 with recommendations to update the National

1 Institute of Health's Genomic Data Sharing
2 Policy and subsequent nonbinding guidance re-
3 garding risks and safeguards for data sharing
4 with foreign entities for research institutions in
5 the field, to—

6 (i) the Secretary of Health and
7 Human Services;

8 (ii) the President;

9 (iii) the Committee on Health, Edu-
10 cation, Labor, and Pensions, the Com-
11 mittee on Foreign Relations, and the Se-
12 lect Committee on Intelligence of the Sen-
13 ate; and

14 (iv) the Committee on Energy and
15 Commerce, the Committee on Foreign Af-
16 fairs, and the Permanent Select Committee
17 on Intelligence of the House of Represent-
18 atives.

19 (B) GUIDANCE.—The guidance provided
20 under subparagraph (A) shall include non-bind-
21 ing guidance for entities that utilize genomic
22 technologies, such as whole genomic sequencing,
23 for use in research or other types of sensitive
24 health information, as defined by the Secretary.

1 (3) REQUIREMENTS.—In carrying out the du-
2 ties of this subsection, the Working Group shall con-
3 sider all existing Federal guidance and grant re-
4 quirements (as of the date of consideration), particu-
5 larly with regard to foreign influences and research
6 integrity, and ensure that all recommended updates
7 to the Genomic Data Sharing Policy and subsequent
8 best practices put forward by the working group not
9 duplicate or conflict with existing guidance, as of the
10 date of publication.

11 (d) POWERS OF WORKING GROUP.—

12 (1) HEARINGS.—The Working Group may hold
13 such hearings, sit and act at such times and places,
14 take such testimony, and receive such evidence as
15 the Working Group considers advisable to carry out
16 this Act.

17 (2) INFORMATION FROM FEDERAL AGENCIES.—

18 (A) IN GENERAL.—The Working Group
19 may secure directly from a Federal department
20 or agency such information as the Working
21 Group considers necessary to carry out this Act.

22 (B) FURNISHING INFORMATION.—On re-
23 quest of a majority of the members of the
24 Working Group, the head of the department or

1 agency shall furnish the information to the
2 Working Group.

3 (3) **POSTAL SERVICES.**—The Working Group
4 may use the United States mails in the same man-
5 ner and under the same conditions as other depart-
6 ments and agencies of the Federal Government.

7 (e) **TERMINATION OF WORKING GROUP.**—The Work-
8 ing Group shall terminate 90 days after the date on which
9 the Working Group submits the report required under
10 subsection (c)(2).