

114TH CONGRESS
2D SESSION

S. _____

To amend the Public Health Service Act to protect the privacy of individuals who are research subjects, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN (for herself and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to protect the privacy of individuals who are research subjects, 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 “Genetic Research Pri-
5 vacy Protection Act”.

6 **SEC. 2. PROTECTION OF PRIVACY OF INDIVIDUALS WHO**
7 **ARE RESEARCH SUBJECTS.**

8 (a) IN GENERAL.—Subsection (d) of section 301 of
9 the Public Health Service Act (42 U.S.C. 241) is amended
10 to read as follows:

1 “(d) PROTECTION OF PRIVACY OF INDIVIDUALS WHO
2 ARE RESEARCH SUBJECTS.—

3 “(1) ISSUANCE OF CERTIFICATE.—

4 “(A) IN GENERAL.—If a person is engaged
5 in biomedical, behavioral, clinical, or other re-
6 search, in which identifiable, sensitive informa-
7 tion is collected (including research on mental
8 health and research on the use and effect of al-
9 cohool and other psychoactive drugs), the Sec-
10 retary, in coordination with other Departments,
11 as applicable—

12 “(i) shall issue to such person a cer-
13 tificate of confidentiality to protect the pri-
14 vacy of individuals who are the subjects of
15 such research if the research is funded
16 wholly or in part by the Federal Govern-
17 ment; and

18 “(ii) may, upon application by a per-
19 son engaged in research, issue to such per-
20 son a certificate of confidentiality to pro-
21 tect the privacy of such individuals if the
22 research is not so funded.

23 “(B) RESULT OF CERTIFICATE.—Except
24 as provided in subparagraph (C), any person to
25 whom a certificate is issued under subpara-

1 graph (A) to protect the privacy of individuals
2 described in such subparagraph shall not dis-
3 close or provide to any other person not con-
4 nected with the research the name of such an
5 individual or any information, document, or bio
6 specimen that contains identifiable, sensitive in-
7 formation about such an individual and that
8 was created or compiled for purposes of the re-
9 search.

10 “(C) EXCEPTIONS.—The disclosure prohi-
11 bition in subparagraph (B) shall not apply to
12 disclosure or use that is—

13 “(i) required by Federal, State, or
14 local laws, excluding instances described in
15 subparagraph (D);

16 “(ii) necessary for the medical treat-
17 ment of the individual to whom the infor-
18 mation, document, or biospecimen pertains;

19 “(iii) made with the consent of the in-
20 dividual to whom the information, docu-
21 ment, or biospecimen pertains; or

22 “(iv) made for the purposes of other
23 scientific research that is in compliance
24 with applicable Federal regulations gov-

1 erning the protection of human subjects in
2 research.

3 “(D) PROHIBITION ON COMPELLING DIS-
4 CLOSURE.—Any person to whom a certificate is
5 issued under subparagraph (A) to protect the
6 privacy of an individual described in such sub-
7 paragraph shall not, in any Federal, State, or
8 local civil, criminal, administrative, legislative,
9 or other proceeding, disclose or provide the
10 name of such individual or any such informa-
11 tion, document, or biospecimen that contains
12 identifiable, sensitive information about the in-
13 dividual and that was created or compiled for
14 purposes of the research.

15 “(E) IMMUNITY.—Identifiable, sensitive in-
16 formation protected under subparagraph (A),
17 and all copies thereof, shall be immune from
18 the legal process, and shall not, without the
19 consent of the individual to whom the informa-
20 tion pertains, be admissible as evidence or used
21 for any purpose in any action, suit, or other ju-
22 dicial, legislative, or administrative proceeding.

23 “(F) TERMS OF PROTECTION.—Identifi-
24 able, sensitive information collected by a person
25 to whom a certificate has been issued under

1 subparagraph (A), and all copies thereof, shall
2 be subject to the protections afforded by this
3 section for perpetuity.

4 “(G) MINIMIZING ADMINISTRATIVE BUR-
5 DEN.—The Secretary shall take steps to mini-
6 mize the burden to researchers, streamline the
7 process, and reduce the time it takes to comply
8 with the requirements of this subsection.

9 “(2) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed to limit the access
11 of an individual who is a subject of research to infor-
12 mation about himself or herself collected during such
13 individual’s participation in the research.

14 “(3) DEFINITIONS.—For purposes of this sub-
15 section, the term ‘identifiable, sensitive information’
16 means information that is about an individual and
17 that is gathered or used during the course of re-
18 search described in paragraph (1)(A) and—

19 “(A) through which an individual is identi-
20 fied; or

21 “(B) for which there is a risk, as deter-
22 mined by current scientific practices or statis-
23 tical methods, that some combination of the in-
24 formation, the request, and other available data

1 sources could be used to deduce the identity of
2 an individual.”.

3 (b) APPLICABILITY.—Beginning on the date of enact-
4 ment of this Act, all persons engaged in research and au-
5 thorized by the Secretary of Health and Human Services
6 to protect information under section 301(d) of the Public
7 Health Service Act (42 U.S.C. 241(d)) prior to the date
8 of enactment of this Act shall be subject to the require-
9 ments of such section (as amended by this Act).

10 **SEC. 3. PROTECTION OF IDENTIFIABLE, SENSITIVE INFOR-**
11 **MATION.**

12 Section 301 of the Public Health Service Act (42
13 U.S.C. 241) is amended by adding at the end the fol-
14 lowing:

15 “(f)(1) The Secretary may exempt from disclosure
16 under section 552(b)(3) of title 5, United States Code,
17 biomedical information that is about an individual and
18 that is gathered or used during the course of biomedical
19 research if—

20 “(A) an individual is identified; or

21 “(B) there is a risk, as determined by current
22 scientific practices or statistical methods, that some
23 combination of the information, the request, and
24 other available data sources could be used to deduce
25 the identity of an individual.

1 “(2)(A) Each determination of the Secretary under
2 paragraph (1) to exempt information from disclosure shall
3 be made in writing and accompanied by a statement of
4 the basis for the determination.

5 “(B) Each such determination and statement of basis
6 shall be available to the public, upon request, through the
7 Office of the Chief FOIA Officer of the Department of
8 Health and Human Services.

9 “(3) Nothing in this subsection shall be construed to
10 limit a research participant’s access to information about
11 such participant collected during the participant’s partici-
12 pation in the research.”.