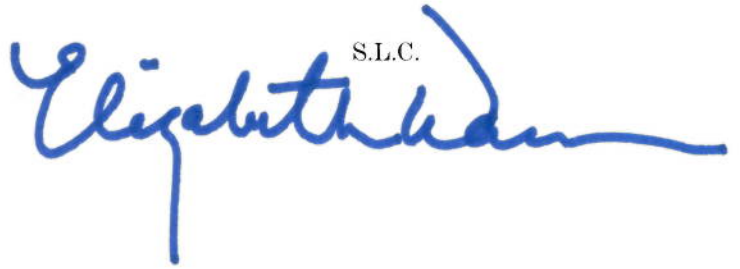


S.L.C.  


AMENDMENT NO. 1 Calendar No. \_\_\_\_\_

Purpose: To improve the protection of privacy of individuals who are research subjects.

**IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.**

**S. 2713**

To provide for the implementation of a Precision Medicine Initiative.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. WARREN (for herself and Mr. ENZI)

Viz:

1 On page 3, between lines 19 and 20, insert the following:  
2

3 **SEC. 3. PROTECTION OF PRIVACY OF INDIVIDUALS WHO**  
4 **ARE RESEARCH SUBJECTS.**

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

8 “(d) PROTECTION OF PRIVACY OF INDIVIDUALS WHO  
9 ARE RESEARCH SUBJECTS.—

10 “(1) ISSUANCE OF CERTIFICATE.—

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

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

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

20                  “(B) RESULT OF CERTIFICATE.—Except  
21                  as provided in subparagraph (C), any person to  
22                  whom a certificate is issued under subpara-  
23                  graph (A) to protect the privacy of individuals  
24                  described in such subparagraph shall not dis-  
25                  close or provide to any other person not con-

1           needed with the research the name of such an  
2           individual or any information, document, or bio  
3           specimen that contains identifiable, sensitive in-  
4           formation about such an individual and that  
5           was created or compiled for purposes of the re-  
6           search.

7           “(C) EXCEPTIONS.—The disclosure prohi-  
8           bition in subparagraph (B) shall not apply to  
9           disclosure or use that is—

10                   “(i) required by Federal, State, or  
11                   local laws, excluding instances described in  
12                   subparagraph (D);

13                   “(ii) necessary for the medical treat-  
14                   ment of the individual to whom the infor-  
15                   mation, document, or biospecimen pertains;

16                   “(iii) made with the consent of the in-  
17                   dividual to whom the information, docu-  
18                   ment, or biospecimen pertains; or

19                   “(iv) made for the purposes of other  
20                   scientific research that is in compliance  
21                   with applicable Federal regulations gov-  
22                   erning the protection of human subjects in  
23                   research.

24           “(D) PROHIBITION ON COMPELLING DIS-  
25           CLOSURE.—Any person to whom a certificate is

1 issued under subparagraph (A) to protect the  
2 privacy of an individual described in such sub-  
3 paragraph shall not, in any Federal, State, or  
4 local civil, criminal, administrative, legislative,  
5 or other proceeding, disclose or provide the  
6 name of such individual or any such informa-  
7 tion, document, or biospecimen that contains  
8 identifiable, sensitive information about the in-  
9 dividual and that was created or compiled for  
10 purposes of the research.

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

19 “(F) TERMS OF PROTECTION.—Identifi-  
20 able, sensitive information collected by a person  
21 to whom a certificate has been issued under  
22 subparagraph (A), and all copies thereof, shall  
23 be subject to the protections afforded by this  
24 section for perpetuity.

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

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

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

16                 “(A) through which an individual is identi-  
17                 fied; or

18                 “(B) for which there is a risk, as deter-  
19                 mined by current scientific practices or statis-  
20                 tical methods, that some combination of the in-  
21                 formation, the request, and other available data  
22                 sources could be used to deduce the identity of  
23                 an individual.”.

24          (b) APPLICABILITY.—Beginning on the date of enact-  
25          ment of this Act, all persons engaged in research and au-

1 thORIZED by the Secretary of Health and Human Services  
2 to protect information under section 301(d) of the Public  
3 Health Service Act (42 U.S.C. 241(d)) prior to the date  
4 of enactment of this Act shall be subject to the require-  
5 ments of such section (as amended by this Act).