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

APRIL 5, 2016

Ms. WARREN (for herself and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Genetic Research Privacy Protection Act”.
SEC. 2. PROTECTION OF PRIVACY OF INDIVIDUALS WHO ARE RESEARCH SUBJECTS.

(a) In General.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

“(d) Protection of Privacy of Individuals Who Are Research Subjects.—

“(1) Issuance of Certificate.—

“(A) In General.—If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other Departments, as applicable—

“(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

“(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to pro-
tect the privacy of such individuals if the research is not so funded.

“(B) RESULT OF CERTIFICATE.—Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

“(C) EXCEPTIONS.—The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

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

“(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains;
“(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

“(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

“(D) PROHIBITION ON COMPELLING DISCLOSURE.—Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research.

“(E) IMMUNITY.—Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the informa-
tion pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

“(F) TERMS OF PROTECTION.—Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

“(G) MINIMIZING ADMINISTRATIVE BURDEN.—The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

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

“(3) DEFINITIONS.—For purposes of this subsection, the term ‘identifiable, sensitive information’ means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—
“(A) through which an individual is identified; or

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

(b) APPLICABILITY.—Beginning on the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 3. PROTECTION OF IDENTIFIABLE, SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

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

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

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

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

“(3) Nothing in this subsection shall be construed to limit a research participant’s access to information about such participant collected during the participant’s participation in the research.”.