CHAPTER 307
FORMERLY
SENATE BILL NO. 44
AS AMENDED BY
SENATE AMENDMENT NO. 1

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend §1230 of Title 16 of the Delaware code by inserting a new paragraph "(5)" to read as follows:

"(5) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Section 2. Amend § 1232(d)(7) of Title 16 of the Delaware Code by deleting the word "or" at the end of the sentence.

Section 3. Amend § 1232(d)(8) of Title 16 of the Delaware Code by deleting the period (.) at the end of the paragraph and inserting the punctuation and word, "; or".

Section 4. Amend § 1232(d) of Title 16 of the Delaware Code by inserting thereto a new subsection "(9)" to read as follows:

"(9) For research, regardless of the source of funding of the research, provided that:

(i) The researcher provides documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by subsection (a) of this section for use or disclosure of protected health information has been approved by the applicable privacy board in accordance with HIPAA regulations. Said approval shall not be granted until the Board has determined all of the following:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

Approved June 28, 2010