

In the Senate of the United States,

December 8, 2014.

Resolved, That the bill from the House of Representatives (H.R. 1281) entitled “An Act to amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.”, do pass with the following

AMENDMENT:

At the end, add the following:

1 **SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING**

2 **RESEARCH.**

3 *(a) IN GENERAL.—Research on newborn dried blood*
4 *spots shall be considered research carried out on human*
5 *subjects meeting the definition of section 46.102(f)(2) of title*
6 *45, Code of Federal Regulations, for purposes of Federally*
7 *funded research conducted pursuant to the Public Health*
8 *Service Act until such time as updates to the Federal Policy*
9 *for the Protection of Human Subjects (the Common Rule)*
10 *are promulgated pursuant to subsection (c). For purposes*

1 *of this subsection, sections 46.116(c) and 46.116(d) of title*
2 *45, Code of Federal Regulations, shall not apply.*

3 *(b) EFFECTIVE DATE.—Subsection (a) shall apply*
4 *only to newborn dried blood spots used for purposes of Fed-*
5 *erally funded research that were collected not earlier than*
6 *90 days after the date of enactment of this Act.*

7 *(c) REGULATIONS.—Not later than 6 months after the*
8 *date of enactment of this Act, the Secretary of Health and*
9 *Human Services shall promulgate proposed regulations re-*
10 *lated to the updating of the Federal Policy for the Protec-*
11 *tion of Human Subjects (the Common Rule), particularly*
12 *with respect to informed consent. Not later than 2 years*
13 *after such date of enactment, the Secretary shall promulgate*
14 *final regulations based on such proposed regulations.*

Attest:

Secretary.

113TH CONGRESS
2^D SESSION

H.R. 1281

AMENDMENT