

114TH CONGRESS
1ST SESSION

H. R. 965

To require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2015

Mr. PASCARELL (for himself and Mr. BOUSTANY) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries.

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 “Facilitating Participa-
5 tion in Clinical Data Registries Act of 2015”.

6 **SEC. 2. GUIDANCE ON APPLICATION OF COMMON RULE TO**
7 **CLINICAL DATA REGISTRIES.**

8 Not later than one year after the date of the enact-
9 ment of this Act, the Secretary of Health and Human
10 Services, through the Office for Human Research Protec-

1 tions of the Department of Health and Human Services,
2 shall issue guidance on the application with respect to clin-
3 ical data registries of the provisions of subpart A of part
4 46 of title 45, Code of Federal Regulations, or equivalent
5 Federal regulations for the protection of human subjects
6 in research.

