

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.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2015

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

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## 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.

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