

108TH CONGRESS
1ST SESSION

H. R. 1585

To establish an office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2003

Mr. BUYER (for himself, Mr. SMITH of New Jersey, Mr. EVANS, Mr. EVERETT, Mr. BILIRAKIS, Mr. MICHAUD, Ms. CARSON of Indiana, Mr. FILNER, Mr. BEAUPREZ, Mr. MILLER of Florida, Mr. BOOZMAN, Mr. STEARNS, Mr. QUINN, Mr. SWEENEY, Mr. BROWN of South Carolina, Ms. GINNY BROWN-WAITE of Florida, and Mr. MCHUGH) introduced the following bill; which was referred to the Committee on Veterans' Affairs

A BILL

To establish an office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs.

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. ESTABLISHMENT OF OFFICE OF RESEARCH**
4 **COMPLIANCE AND ASSURANCE.**

5 (a) IN GENERAL.—Section 7303(e) of title 38,
6 United States Code, is amended to read as follows:

7 “(e)(1) There is established within the Veterans
8 Health Administration an office to oversee research com-

1 pliance and assurance, to promote responsible research
2 conduct, and to ensure the ethical treatment and safety
3 of research subjects (hereinafter in this subsection re-
4 ferred to as the ‘Office’). The Office shall be an inde-
5 pendent entity within the Veterans Health Administration.

6 “(2) There is a Director of the Office. The Director
7 shall report directly to the Under Secretary for Health.

8 “(3) The mission of the Office is as follows:

9 “(A) To provide regular counsel to the Under
10 Secretary for Health on all matters related to the
11 protection of human research subjects, research mis-
12 conduct, laboratory animal welfare, and bio-safety.

13 “(B) To promote and enhance the ethical con-
14 duct of research.

15 “(C) To investigate allegations of research im-
16 propriety and misconduct.

17 “(D) To suspend, restrict, or modify research,
18 or take such other actions as the Director deter-
19 mines appropriate—

20 “(i) to ensure the safety and ethical treat-
21 ment of human research subjects;

22 “(ii) to preserve the integrity and validity
23 of research;

24 “(iii) to prevent mistreatment of laboratory
25 animals used in research; and

1 “(iv) to assure compliance with require-
2 ments under law with respect to the conduct of
3 research.

4 “(4) The Director of the Office shall carry out the
5 following duties:

6 “(A) The conduct of periodic inspections and
7 evaluations of research integrity at research facilities
8 of the Department.

9 “(B) The observation of external accreditation
10 site visits for human subjects and animal welfare.

11 “(C) The investigation of allegations of—

12 “(i) research improprieties, endangerment
13 or mistreatment of research subjects,

14 “(ii) research misconduct, and

15 “(iii) non-compliance with applicable re-
16 search policies and regulations.

17 “(D) The immediate notification of the Under
18 Secretary for Health when endangerment of human
19 research subjects is evident or suspected.

20 “(E) The notification of Congress in the case of
21 a finding of impropriety or misconduct with respect
22 to a research project conducted by the Department.

23 “(F) The advancement of research assurance
24 and compliance activities within the Department and
25 with established academic affiliation arrangements.

1 “(G) The negotiation and maintenance of re-
2 search assurances with each medical center of the
3 Department conducting research involving human
4 subjects or laboratory animals.

5 “(5) Amounts for the activities of the Office, includ-
6 ing field offices, shall be derived from amounts appro-
7 priated for the Veterans Health Administration for Med-
8 ical Care, and shall not be derived from amounts appro-
9 priated for the Veterans Health Administration for Med-
10 ical and Prosthetic Research).”.

11 (b) REPORT.—(1) The Comptroller General of the
12 United States shall conduct a study to assess the efficacy
13 of the office established under section 7303(e) of title 38,
14 United States Code, as added by subsection (a).

15 (2) Not later than January 1, 2005, the Comptroller
16 General shall submit to Congress a report on the study
17 conducted paragraph (1), and shall include recommenda-
18 tions for any changes in legislation or administrative ac-
19 tion as the Comptroller General determines appropriate.

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