

116TH CONGRESS
2D SESSION

S. 3224

To require the Secretary of Veterans Affairs to allow for the use of commercial institutional review boards for research, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 21, 2020

Mr. CASSIDY (for himself and Mr. TESTER) introduced the following bill;
which was read twice and referred to the Committee on Veterans' Affairs

A BILL

To require the Secretary of Veterans Affairs to allow for the use of commercial institutional review boards for research, and for other purposes.

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 “VA Research Approval
5 Efficiency Act of 2020”.

6 **SEC. 2. USE BY DEPARTMENT OF VETERANS AFFAIRS OF**
7 **COMMERCIAL INSTITUTIONAL REVIEW**
8 **BOARDS IN SPONSORED RESEARCH TRIALS.**

9 (a) IN GENERAL.—Not later than 90 days after the
10 date of the enactment of this Act, the Secretary of Vet-

1 erans Affairs shall complete all necessary policy revisions
 2 within the directive of the Veterans Health Administration
 3 numbered 1200.05 and titled “Requirements for the Pro-
 4 tection of Human Subjects in Research”, to allow spon-
 5 sored clinical research of the Department of Veterans Af-
 6 fairs to use accredited commercial institutional review
 7 boards to review research proposal protocols of the De-
 8 partment.

9 (b) IDENTIFICATION OF REVIEW BOARDS.—Not later
 10 than 90 days after the completion of the policy revisions
 11 under subsection (a), the Secretary shall—

12 (1) identify accredited commercial institutional
 13 review boards for use in connection with sponsored
 14 clinical research of the Department; and

15 (2) establish a process to modify existing ap-
 16 provals in the event that a commercial institutional
 17 review board loses its accreditation during an ongo-
 18 ing clinical trial.

19 (c) REPORT.—

20 (1) IN GENERAL.—Not later than 90 days after
 21 the completion of the policy revisions under sub-
 22 section (a), and annually thereafter, the Secretary
 23 shall submit to the Committee on Veterans’ Affairs
 24 of the Senate and the Committee on Veterans’ Af-
 25 fairs of the House of Representatives a report on all

1 approvals of institutional review boards, including
 2 central institutional review boards and commercial
 3 institutional review boards.

4 (2) ELEMENTS.—The report required by para-
 5 graph (1) shall include, at a minimum, the following:

6 (A) The name of each clinical trial with re-
 7 spect to which the use of an institutional review
 8 board has been approved.

9 (B) The institutional review board or insti-
 10 tutional review boards used in the approval
 11 process for each clinical trial.

12 (C) The amount of time between submis-
 13 sion and approval.

14 **SEC. 3. CREATION OF OFFICE OF RESEARCH REVIEWS**
 15 **WITHIN THE OFFICE OF INFORMATION AND**
 16 **TECHNOLOGY OF THE DEPARTMENT OF VET-**
 17 **ERANS AFFAIRS.**

18 (a) IN GENERAL.—Not later than one year after the
 19 date of the enactment of this Act, the Secretary of Vet-
 20 erans Affairs shall establish within the Office of Informa-
 21 tion and Technology of the Department of Veterans Af-
 22 fairs an Office of Research Reviews (in this section re-
 23 ferred to as the “Office”).

24 (b) ELEMENTS.—The Office shall do the following:

1 (1) Perform centralized security reviews and
2 complete security processes for approved research
3 sponsored outside the Department, with a focus on
4 multi-site clinical trials.

5 (2) Develop and maintain a list of commercially
6 available software preferred for use in sponsored
7 clinical trials of the Department and ensure such list
8 is maintained as part of the official approved soft-
9 ware products list of the Department.

10 (3) Develop benchmarks for appropriate
11 timelines for security reviews conducted by the Of-
12 fice.

13 (c) REPORT.—

14 (1) IN GENERAL.—Not later than one year
15 after the establishment of the Office, the Office shall
16 submit to the Committee on Veterans' Affairs of the
17 Senate and the Committee on Veterans' Affairs of
18 the House of Representatives a report on the activity
19 of the Office.

20 (2) ELEMENTS.—The report required by para-
21 graph (1) shall include the following:

22 (A) The number of security reviews com-
23 pleted.

- 1 (B) The number of personnel assigned for
- 2 performing the functions described in sub-
- 3 section (b).

