

103D CONGRESS
1ST SESSION

S. 1042

To amend the Public Health Service Act to establish an Ethical Advisory Board, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 27 (legislative day, APRIL 19), 1993

Mr. HATFIELD introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Public Health Service Act to establish an Ethical Advisory Board, 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. ESTABLISHMENT OF ETHICAL ADVISORY**

4 **BOARD.**

5 Part G of title IV of the Public Health Service Act
6 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
7 tion 492 the following new section:

1 “CERTAIN PROVISIONS REGARDING REVIEW AND
2 APPROVAL OF PROPOSALS FOR RESEARCH

3 “SEC. 492A. (a) REVIEW AS PRECONDITION TO RE-
4 SEARCH.—

5 “(1) PROTECTION OF HUMAN RESEARCH SUB-
6 JECTS.—

7 “(A) In the case of any application submit-
8 ted to the Secretary for financial assistance to
9 conduct research, the Secretary may not ap-
10 prove or fund any application that is subject to
11 review under section 491(a) by an Institutional
12 Review Board unless the application has under-
13 gone review in accordance with such section and
14 has been recommended for approval by a major-
15 ity of the members of the Board conducting
16 such review.

17 “(B) In the case of research that is subject
18 to review under procedures established by the
19 Secretary for the protection of human subjects
20 in clinical research conducted by the National
21 Institutes of Health, the Secretary may not au-
22 thorize the conduct of the research unless the
23 research has, pursuant to such procedures, been
24 recommended for approval.

1 “(2) PEER REVIEW.—In the case of any appli-
2 cation submitted to the Secretary for financial as-
3 sistance to conduct research, the Secretary may not
4 approve or fund any application that is subject to
5 technical and scientific peer review under section
6 492(a) unless the application has undergone peer re-
7 view in accordance with such section and has been
8 recommended for approval by a majority of the
9 members of the entity conducting such review.

10 “(b) ETHICAL REVIEW OF RESEARCH.—

11 “(1) ESTABLISHMENT OF A STANDING ETHICAL
12 ADVISORY BOARD.—

13 “(A) Not later than 180 days after the
14 date of enactment of this Act, the Secretary, in
15 accordance with subpart B of part 46 of title
16 45, Code of Federal Regulations, and with the
17 recommendations of the National Commission
18 for the Protection of Human Subjects of Bio-
19 medical and Behavioral Research, shall estab-
20 lish a standing Ethical Advisory Board (here-
21 after referred to in this section as the ‘Board’).

22 “(B) The Board shall advise, report on,
23 and make recommendations to the Secretary
24 and the Congress regarding the ethical, legal,
25 and social acceptability of supporting specific

1 biomedical and behavioral research designs, ap-
2 plications, or proposals submitted to it by the
3 Secretary or any Agency Head within the De-
4 partment, and shall prepare reports and make
5 recommendations concerning ethical policies re-
6 lating to biomedical and behavioral research re-
7 ferred to it by the Secretary, Agency Heads, or
8 Congressional Committees. With the approval of
9 the Secretary, the Board may develop reports
10 and make recommendations concerning other
11 matters that it considers of major importance
12 to the general public.

13 “(C)(i) The Board shall be composed of 15
14 individuals who are not officers or employees of
15 the United States to be appointed as follows:

16 “(I) Five individuals shall be ap-
17 pointed by the President.

18 “(II) Five individuals shall be ap-
19 pointed by the Speaker of the House of
20 Representatives in consultation with the
21 Minority Leader.

22 “(III) Five individuals shall be ap-
23 pointed by the Majority Leader of the
24 Senate in consultation with the Minority
25 Leader.

1 “(ii) In appointing individuals under clause
2 (i), the appointing authority shall ensure that
3 such individuals possess special qualifications
4 and competence to provide advice and rec-
5 ommendations regarding ethical matters in bio-
6 medical and behavioral research. Of the mem-
7 bers of the Board—

8 “(I) at least one shall be an attorney;

9 “(II) at least one shall be a profes-
10 sional ethicist;

11 “(III) at least one shall be a practic-
12 ing physician;

13 “(IV) at least one shall be a theolo-
14 gian; and

15 “(V) at least one-third, and no more
16 than one-half, of all such members shall be
17 scientists who have made significant con-
18 tributions to the advancement of bio-
19 medical or behavioral science.

20 “(D) The terms of service of members of
21 the Board shall be for 3 years. The initial mem-
22 bers of the Board shall be appointed to serve
23 staggered terms of 1, 2 or 3 years. If a member
24 does not complete a full term of service, the in-
25 dividual appointed to fill the resulting vacancy

1 shall be appointed for the remainder of the
2 term of the predecessor of the individual. A
3 member may be reappointed to serve no more
4 than two consecutive full terms.

5 “(E) A member of the Board shall be sub-
6 ject to removal from the Board by the Secretary
7 for neglect of duty, malfeasance, or for other
8 good cause as demonstrated by the Secretary.

9 “(F) The members of the Board shall se-
10 lect one member to serve as the chairperson of
11 the Board. The chairperson shall serve not
12 more than one consecutive 3-year term.

13 “(G) In carrying out its responsibilities as
14 described in subparagraph (B), the Board shall
15 hold such inquiries, hold public hearings, enter
16 into contracts the aggregate of which shall not
17 exceed \$300,000 per year, and report to the
18 Secretary and to the Congress the results and
19 recommendations that result from its delibera-
20 tions.

21 “(H) With respect to information relevant
22 to the duties described in subparagraph (B),
23 the Board shall have access to all such informa-
24 tion possessed by the Department of Health

1 and Human Services, or available to the Sec-
2 retary from other sources.

3 “(I) With respect to the duties described in
4 subparagraph (B), the members of the Board
5 shall receive compensation for each day they are
6 engaged in carrying out the purposes of the
7 Board, including time engaged in traveling for
8 such purposes. Such compensation may not be
9 provided in an amount in excess of the maxi-
10 mum rate of basic pay accorded for individuals
11 GS-18 of the General Schedule.

12 “(J) The Secretary, acting through the Di-
13 rector of the National Institutes of Health,
14 shall provide the Board with staff and such
15 other assistance necessary to carrying out the
16 duties of the Board.

17 “(K) Prior to reconstituting the Board, the
18 Secretary shall, through a statement published
19 in the Federal Register, announce the intention
20 of the Secretary to constitute the Board.

21 “(L) A statement issued under subpara-
22 graph (K) shall include a request that inter-
23 ested parties submit to the Secretary rec-
24 ommendations specifying the particular individ-
25 uals who should be appointed to the Board. The

1 Secretary shall consider such recommendations
2 in making appointments to the Board.

3 “(M) The appointments to the Board
4 under subparagraph (C) shall not take effect
5 until the expiration of the 30-day period begin-
6 ning with the date on which the statement re-
7 quired in subparagraph (K) is made with re-
8 spect to the Board.

9 “(2) PROCEDURES REGARDING THE WITHHOLD-
10 ING OF FUNDS.—

11 “(A) If research has been recommended
12 for approval for purposes of subsection (a), the
13 Secretary may not withhold funding for the re-
14 search on ethical grounds unless—

15 “(i) the Secretary refers the proposal
16 within 30 days to the Board in accordance
17 with paragraph (1) to study the ethical im-
18 plications of the research; and

19 “(ii) (I) the majority of the Board rec-
20 ommends that, on ethical grounds, the Sec-
21 retary withhold funds for the research; or

22 “(II) the majority of the Board rec-
23 ommends that the Secretary not withhold
24 funds for the research on ethical grounds,
25 but the Secretary determines, on the basis

1 of the report submitted under subpara-
2 graph (D) that there is a reasonable basis
3 for overruling the Board's recommenda-
4 tions.

5 "(B) The limitation established in subpara-
6 graph (A) regarding the authority to withhold
7 funds on ethical grounds shall apply without re-
8 gard to whether the withholding such funds is
9 characterized as a disapproval, a moratorium, a
10 prohibition, or other description.

11 "(C) Not later than 180 days after the
12 date on which the matter is referred under sub-
13 paragraph (A) to the Board, the Board shall
14 submit to the Secretary, and to the Committee
15 on Energy and Commerce of the House of Rep-
16 resentatives and the Committee on Labor and
17 Human Resources of the Senate, a report de-
18 scribing the findings of the Board regarding the
19 project of research involved and making a rec-
20 ommendation under subparagraph (A)(ii) of
21 whether the Secretary should or should not
22 withhold funds for the project. The report shall
23 include the information considered in making
24 the findings."

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