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H. R. 7724

729034

IN THE SENATE OF THE UNITED STATES

MARCH 21, 1974

Ordered to be printed with the amendments of the Senate

[Strike out all after the enacting clause and insert the part printed in italic]

AN ACT

To amend the Public Health Service Act to establish a national program of biomedical research fellowships, traineeships, and training to assure the continued excellence of biomedical research in the United States, 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 ~~SHORT TITLE~~

4 ~~SECTION 1. This Act may be cited as the "National~~
5 ~~Biomedical Research Fellowship, Traineeship, and Training~~
6 ~~Act of 1973".~~

7 ~~FINDINGS AND DECLARATION OF PURPOSE~~

8 ~~SEC. 2. (a) Congress finds and declares that—~~

9 ~~(1) the success and continued viability of the~~

1 ~~Federal biomedical research effort depends on the avail-~~
2 ~~ability of excellent scientists and a network of institu-~~
3 ~~tions of excellence capable of producing superior research~~
4 ~~personnel;~~

5 ~~(2) direct support of the training of scientists for~~
6 ~~careers in biomedical research is an appropriate and~~
7 ~~necessary role for the Federal Government; and~~

8 ~~(3) graduate training and research fellowship pro-~~
9 ~~grams should be the key elements in the training pro-~~
10 ~~grams of the National Institutes of Health, the National~~
11 ~~Institute of Mental Health, and their respective research~~
12 ~~institutes.~~

13 ~~(b) It is the purpose of this Act to increase the capa-~~
14 ~~bility of the National Institutes of Health, the National Insti-~~
15 ~~tute of Mental Health, and their respective research institutes~~
16 ~~to carry out their statutory responsibility of maintaining a~~
17 ~~superior national program of biomedical research into the~~
18 ~~basic biological processes and mechanisms involved in the~~
19 ~~physical and mental diseases and impairments of man.~~

20 ~~BIOMEDICAL RESEARCH FELLOWSHIPS, TRAINEESHIPS, AND~~

21 ~~TRAINING~~

22 ~~SEC. 3. (a) Part G of title IV of the Public Health~~
23 ~~Service Act is amended by adding after section 454 the~~
24 ~~following new section:~~

1 ~~“BIOMEDICAL RESEARCH FELLOWSHIPS, TRAINEESHIPS,~~
2 ~~AND TRAINING~~

3 ~~“SEC. 455. (a) The Secretary shall provide biomedical~~
4 ~~research fellowships, traineeships, and training in the follow-~~
5 ~~ing manner:~~

6 ~~“(1) The Secretary shall establish and maintain~~
7 ~~fellowships for (A) biomedical research at the National~~
8 ~~Institutes of Health and the National Institute of Mental~~
9 ~~Health, and (B) training at such Institutes of individuals~~
10 ~~to undertake such research. Any reference in this section~~
11 ~~to the National Institutes of Health and the National~~
12 ~~Institute of Mental Health shall be considered a refer-~~
13 ~~ence to the Institutes and their respective research in-~~
14 ~~stitutes, divisions, and bureaus.~~

15 ~~“(2) The Secretary shall establish and maintain~~
16 ~~fellowships for (A) biomedical research at non-Federal~~
17 ~~public institutions and at nonprofit private institutions,~~
18 ~~and (B) training at such public and private institutions~~
19 ~~of individuals to undertake such research.~~

20 ~~“(3) The Secretary shall (A) provide training, and~~
21 ~~establish and maintain traineeships, in the Institutes (re-~~
22 ~~ferred to in paragraph (1)) in matters relating to the~~
23 ~~cause, diagnosis, prevention, and treatment of the disease~~
24 ~~(or diseases) to which the activities of such Institutes are~~

1 ~~directed; and (B) make grants to public or nonprofit~~
2 ~~private institutions for traineeships in such matters.~~
3 ~~Training and traineeships provided under this paragraph~~
4 ~~(or under grants made thereunder) may not include~~
5 ~~residency training or traineeships.~~

6 ~~“(b) (1) No fellowship or traineeship may be awarded~~
7 ~~under subsection (a) (or under any grant made thereunder)~~
8 ~~to, and no training may be provided under such subsection~~
9 ~~for, any individual unless such individual provides, in such~~
10 ~~form and manner as the Secretary shall by regulation pre-~~
11 ~~scribe, assurances satisfactory to the Secretary that the indi-~~
12 ~~vidual will meet the requirement of subsection (c) (1).~~

13 ~~“(2) The award of fellowships and traineeships by the~~
14 ~~Secretary under subsection (a), the making of grants for~~
15 ~~traineeships under such subsection, and the number of per-~~
16 ~~sons receiving training under such subsection, shall each be~~
17 ~~subject to review and approval by the appropriate advisory~~
18 ~~councils to the Institutes referred to in subsection (a) (1)~~
19 ~~(A) whose activities relate to the research or training under~~
20 ~~such fellowships, traineeships, or traineeship grants or (B)~~
21 ~~at which such training will be conducted.~~

22 ~~“(3) The period of any fellowship, traineeship, or~~
23 ~~training (or any combination thereof) provided any indi-~~
24 ~~vidual under subsection (a) (or under any grant made~~
25 ~~thereunder) may not exceed three years in the aggregate~~

1 ~~unless the Secretary for good cause shown waives the appli-~~
2 ~~cation of the three-year limit to such individual.~~

3 ~~“(4) (A) No fellowship or traineeship may be awarded~~
4 ~~by the Secretary under paragraph (1), (2), or (3) (A) of~~
5 ~~subsection (a) to any individual unless the individual has~~
6 ~~submitted to the Secretary an application therefor and the~~
7 ~~Secretary has approved the application. The application shall~~
8 ~~be in such form, submitted in such manner, and contain such~~
9 ~~information, as the Secretary may by regulation prescribe.~~

10 ~~“(B) Fellowships and traineeships awarded under sub-~~
11 ~~section (a) shall provide for such stipends and allowances~~
12 ~~(including travel and subsistence expenses and dependency~~
13 ~~allowances) for the fellows and trainees as the Secretary~~
14 ~~may deem necessary. A fellowship awarded under subsec-~~
15 ~~tion (a) (2) may also provide for payments (in such amount~~
16 ~~as the Secretary determines is appropriate) to be made to~~
17 ~~the institution at which the research or training, for which~~
18 ~~the fellowship is awarded, is conducted for support services~~
19 ~~provided such individual by such institution.~~

20 ~~“(5) No grant for traineeships may be made under~~
21 ~~subsection (a) (3) (B) unless an application therefor has~~
22 ~~been submitted to, and approved by, the Secretary. Such~~
23 ~~application shall be in such form, submitted in such manner,~~
24 ~~and contain such information, as the Secretary may by reg-~~
25 ~~ulation prescribe. Traineeships under a grant under subsec-~~

1 ~~tion (a) (3) (B) shall be awarded in accordance with such~~
2 ~~regulations as the Secretary shall prescribe.~~

3 ~~“(c) (1) (A) Each individual who receives a fellowship~~
4 ~~or traineeship, or receives training, provided under subsec-~~
5 ~~tion (a) (or under a grant made thereunder) shall, in ac-~~
6 ~~cordance with paragraph (2), engage in health research~~
7 ~~or teaching, or if authorized under paragraph (B), serve~~
8 ~~as a member of the National Health Service Corps (estab-~~
9 ~~lished under section 329), for a period computed as follows:~~
10 ~~For each year during which the individual receives such a~~
11 ~~fellowship or traineeship and for each year of such training~~
12 ~~the individual received, the individual shall (i) engage in~~
13 ~~twenty-four months of health research or teaching, or (ii)~~
14 ~~(if so authorized) serve as a member of such Corps for a pe-~~
15 ~~riod of twenty-four months.~~

16 ~~“(B) Any individual who~~

17 ~~“(i) received a fellowship or traineeship, or re-~~
18 ~~ceived training, provided under subsection (a) (or un-~~
19 ~~der a grant made thereunder), and~~

20 ~~“(ii) is a physician, dentist, nurse, or other person~~
21 ~~trained to provide health care directly to individual~~
22 ~~patients,~~

23 ~~may, upon application to the Secretary, be authorized by~~
24 ~~the Secretary to serve as a member of the National Health~~
25 ~~Service Corps in lieu of engaging in health research or~~

1 ~~teaching if the Secretary determines that there are no suit-~~
2 ~~able health research or teaching positions available to such~~
3 ~~individual to enable him to comply with the research or~~
4 ~~teaching requirement of this paragraph.~~

5 ~~“(2) The requirement of paragraph (1) shall be com-~~
6 ~~plied with by any individual to whom it applies within such~~
7 ~~reasonable period of time, after the completion of such in-~~
8 ~~dividual’s fellowship, traineeship, or training (as the case~~
9 ~~may be), as the Secretary shall by regulation prescribe. The~~
10 ~~Secretary shall (A) by regulation prescribe (i) the type of~~
11 ~~research and teaching which an individual may engage in to~~
12 ~~comply with such requirement, and (ii) such other require-~~
13 ~~ments respecting such research and teaching as he deems~~
14 ~~necessary; and (B) to the extent feasible, provide that the~~
15 ~~members of the National Health Service Corps who are~~
16 ~~serving in the Corps to meet the requirement of paragraph~~
17 ~~(1) shall be assigned to patient care.~~

18 ~~“(3) (A) If any individual to whom the requirement of~~
19 ~~paragraph (1) is applicable fails, within the period pre-~~
20 ~~scribed by paragraph (2), to comply with such requirement,~~
21 ~~the United States shall be entitled to recover from such~~
22 ~~individual an amount equal to the product of—~~

23 ~~“(i) the aggregate of (I) the amount of assistance~~
24 ~~provided to such individual under subsection (a), and~~
25 ~~(II) the sums of the interest which would be payable~~

1 ~~on such assistance if, at the time such assistance was~~
2 ~~provided, such assistance were a loan bearing interest~~
3 ~~at a rate fixed by the Secretary of the Treasury, after~~
4 ~~taking into consideration private consumer rates of in-~~
5 ~~terest prevailing at the time such assistance was provided~~
6 ~~and if the interest on each such assistance had been com-~~
7 ~~pounded annually, and~~

8 ~~“(ii) a fraction (I) the numerator of which is the~~
9 ~~number obtained by subtracting the number of months~~
10 ~~equal to one half the number of months of research or~~
11 ~~teaching performed by the individual in compliance with~~
12 ~~paragraph (1) from the total number of months in the~~
13 ~~period of research or teaching required to be performed~~
14 ~~by such individual by such paragraph, and (II) the~~
15 ~~denominator of which is a number equal to such total~~
16 ~~number of months.~~

17 ~~Any amount which the United States is entitled to recover~~
18 ~~under this subparagraph shall, within the three-year period~~
19 ~~beginning on the date the United States becomes entitled to~~
20 ~~recover such amount, be paid to the United States. Until any~~
21 ~~amount due the United States under this subparagraph on~~
22 ~~account of any assistance provided under this section is paid,~~
23 ~~there shall accrue to the United States interest on such~~
24 ~~amount at the same rate as that fixed by the Secretary of the~~

1 ~~Treasury pursuant to clause (i) with respect to the assistance~~
2 ~~on account of which such amount is due the United States.~~

3 ~~“(B) For purposes of subparagraph (A)—~~

4 ~~“(i) in determining the amount of assistance pro-~~
5 ~~vided an individual the Secretary shall include amounts~~
6 ~~paid to the individual (or to any institution on his be-~~
7 ~~half) under a fellowship or traineeship and the cost (as~~
8 ~~determined in accordance with regulations of the Secre-~~
9 ~~tary) of any training provided such individual; and~~

10 ~~“(ii) the time at which assistance shall be con-~~
11 ~~sidered as having been provided under subsection (a)~~
12 ~~to an individual shall, in the case of a traineeship or~~
13 ~~fellowship, be the date on which the traineeship or fel-~~
14 ~~lowship is awarded and shall, in the case of training, be~~
15 ~~the date on which such training was begun.~~

16 ~~“(4) (A) Any obligation of any individual under para-~~
17 ~~graph (3) shall be canceled upon the death of such indi-~~
18 ~~vidual.~~

19 ~~“(B) The Secretary shall by regulation provide for the~~
20 ~~waiver or suspension of any such obligation applicable to~~
21 ~~any individual whenever compliance by such individual is~~
22 ~~impossible or would involve extreme hardship to such indi-~~
23 ~~vidual and if enforcement of such obligation with respect to~~
24 ~~any individual would be against equity and good conscience.~~

1 ~~“(d) (1) There are authorized to be appropriated to~~
 2 ~~make payments under fellowships awarded under subsection~~
 3 ~~(a) (2), \$54,599,000 for each of the fiscal years ending~~
 4 ~~June 30, 1974, and June 30, 1975.~~

5 ~~“(2) There are authorized to be appropriated to make~~
 6 ~~payments under grants under subsection (a) (3) (B), \$153,~~
 7 ~~348,000 for each of the fiscal years ending June 30, 1974,~~
 8 ~~and June 30, 1975.”~~

9 ~~(b) Section 433 (a) of such Act is amended by striking~~
 10 ~~out the last two sentences.~~

11 ~~(c) The heading for such part G is amended by striking~~
 12 ~~out “ADMINISTRATIVE” and inserting in lieu thereof~~
 13 ~~“GENERAL”.~~

14 ~~LIMITATIONS ON RESEARCH~~

15 ~~SEC. 4. Part G of title IV of the Public Health Service~~
 16 ~~Act is further amended by adding after section 455 (as~~
 17 ~~added by section 3 of this Act) the following new section:~~

18 ~~LIMITATIONS ON RESEARCH~~

19 ~~“SEC. 456. (a) The Secretary may not conduct or sup-~~
 20 ~~port research in the United States or abroad which violates~~
 21 ~~any ethical standard respecting research adopted by the~~
 22 ~~National Institutes of Health, the National Institute of Men-~~
 23 ~~tal Health, or their respective research institutes.~~

24 ~~“(b) The Secretary may not conduct or support re-~~
 25 ~~search in the United States or abroad on a human fetus~~

1 ~~which is outside the uterus of its mother and which has a~~
2 ~~beating heart."~~

3 ~~STUDIES RESPECTING BIOMEDICAL RESEARCH PERSONNEL~~

4 ~~SEC. 5. (a) The Secretary of Health, Education, and~~
5 ~~Welfare shall, in accordance with subsection (b), arrange for~~
6 ~~the conduct of studies to—~~

7 ~~(1) establish (A) the Nation's overall need for bio-~~
8 ~~medical research personnel, (B) the subject areas in~~
9 ~~which such personnel are needed and the number of~~
10 ~~such personnel needed in each such area, and (C) the~~
11 ~~kinds and extent of training which should be provided~~
12 ~~such personnel;~~

13 ~~(2) assess (A) current training programs avail-~~
14 ~~able for the training of biomedical research personnel~~
15 ~~which are conducted under the Public Health Act at~~
16 ~~or through the National Institutes of Health, the Na-~~
17 ~~tional Institute of Mental Health, and their respective~~
18 ~~research institutes, and (B) other current training pro-~~
19 ~~grams available for the training of such personnel;~~

20 ~~(3) identify the kinds of research positions avail-~~
21 ~~able to and held by individuals completing such pro-~~
22 ~~grams;~~

23 ~~(4) determine, to the extent feasible, whether the~~
24 ~~programs referred to in clause (B) of paragraph (2)~~
25 ~~would be adequate to meet the needs established under~~

1 ~~paragraph (1) if the programs referred to in clause (A)~~
2 ~~of paragraph (2) were terminated; and~~

3 ~~(5) determine what modifications in the programs~~
4 ~~referred to in paragraph (2) are required to meet the~~
5 ~~needs established under paragraph (1).~~

6 ~~(b) (1) The Secretary shall request the National~~
7 ~~Academy of Sciences to conduct such studies under an ar-~~
8 ~~rangement under which the actual expenses incurred by such~~
9 ~~Academy in conducting such studies will be paid by the~~
10 ~~Secretary. If the National Academy of Sciences is willing~~
11 ~~to do so, the Secretary shall enter into such an arrangement~~
12 ~~with such Academy for the conduct of such studies.~~

13 ~~(2) If the National Academy of Sciences is unwilling~~
14 ~~to conduct one or more such studies under such an arrange-~~
15 ~~ment, then the Secretary shall enter into a similar arrange-~~
16 ~~ment with other appropriate nonprofit private groups or~~
17 ~~associations under which such groups or associations will con-~~
18 ~~duct such studies and prepare and submit the reports thereon~~
19 ~~as provided in subsection (c).~~

1 ~~(c) The studies required by subsection (a) shall be com-~~
2 ~~pleted within the one-year period beginning on the date of~~
3 ~~the enactment of this Act; and a report on the results of~~
4 ~~such study shall be submitted by the Secretary to the Com-~~
5 ~~mittee on Interstate and Foreign Commerce of the House~~
6 ~~of Representatives and the Committee on Labor and Public~~
7 ~~Welfare of the Senate before the expiration of such period.~~
8 *That this Act may be cited as the "National Research Serv-*
9 *ice Awards and Protection of Human Subjects Act".*

10 **TITLE I—NATIONAL RESEARCH SERVICE**

11 **AWARDS**

12 **SHORT TITLE**

13 *SEC. 101. This title may be cited as the "National Re-*
14 *search Service Award Act".*

15 **FINDINGS AND DECLARATION OF PURPOSE**

16 *SEC. 102. (a) Congress finds and declares that—*

17 *(1) the success and continued viability of the Fed-*
18 *eral biomedical and behavioral research effort depends on*
19 *the availability of excellent scientists and a network of*

1 *institutions of excellence capable of producing superior*
2 *research personnel;*

3 (2) *direct support of the training of scientists for*
4 *careers in biomedical and behavioral research is an*
5 *appropriate and necessary role for the Federal Gov-*
6 *ernment;*

7 (3) *National Research Service Awards should be*
8 *the key element in the training programs of the National*
9 *Institutes of Health and the National Institute of Mental*
10 *Health.*

11 (b) *It is the purpose of this title, by consolidating exist-*
12 *ing research training and fellowship authorities into a single*
13 *National Research Service Awards authority, to increase the*
14 *capability of the National Institutes of Health and the Na-*
15 *tional Institute of Mental Health to carry out their statutory*
16 *responsibility of maintaining a superior national program of*
17 *research into physical and mental diseases and impairments*
18 *of man.*

19 NATIONAL RESEARCH SERVICE AWARDS

20 SEC. 103. (a) *Except as amended by this Act, the au-*
21 *thorities of the Secretary of Health, Education, and Welfare*
22 *to establish and maintain fellowships and traineeships for*
23 *training in biomedical and behavioral research pursuant to*
24 *sections 301 and 303 of title IV of the Public Health Service*

1 *Act are repealed effective upon the date of the enactment*
2 *of this Act.*

3 *(b) Part G of title IV of the Public Health Service*
4 *Act (42 U.S.C. 201) is amended by adding after section*
5 *454 the following new sections:*

6 ***“NATIONAL RESEARCH SERVICE AWARDS***

7 *“SEC. 455. (a) The Secretary, in consultation with the*
8 *Directors of the National Institutes of Health and the Na-*
9 *tional Institute of Mental Health, shall provide through*
10 *the Office of the Director of the National Institutes of Health*
11 *National Research Service Awards in the following manner:*

12 *“(1) The Secretary shall establish and maintain*
13 *National Research Service Awards for—*

14 *“(A) biomedical and behavioral research at the*
15 *National Institutes of Health and the National Institute*
16 *of Mental Health, and*

17 *“(B) training at such institutes of individuals to*
18 *undertake research in matters relating to the cause,*
19 *diagnosis, prevention, and treatment of the disease or*
20 *diseases to which the activities of such institutes are*
21 *directed. Any references in this section to the National*
22 *Institutes of Health and National Institute of Mental*
23 *Health shall be considered a reference to the Institutes*

1 *and their respective research institutes, divisions, and*
2 *bureaus,*

3 “(2) *The Secretary shall establish and maintain*
4 *National Research Service Awards for—*

5 “(A) *biomedical and behavioral research at non-*
6 *Federal public and at nonprofit private institutions, and*

7 “(B) *training at such public and nonprofit private*
8 *institutions of individuals to undertake such research.*

9 “(3) *No National Research Service Award (or*
10 *grants made thereunder) may provide for support of*
11 *residency training.*

12 “(b)(1) *No National Research Service Award may*
13 *be granted under subsection (a) to any individual unless*
14 *such individual provides, in such form and manner as the*
15 *Secretary shall by regulation prescribe, assurances satisfac-*
16 *tory to the Secretary that the individual will meet the require-*
17 *ment of subsection (c)(1).*

18 “(2) *Applicants for National Research Service Awards*
19 *must be sponsored by the accredited institution at which*
20 *training shall be carried out (in accordance with regulations*
21 *promulgated by the Secretary). The grants of National Re-*
22 *search Service Awards by the Secretary under subsection (a)*
23 *shall each be subject to review and approval by the appro-*
24 *priate advisory councils to the Institutes referred to in sub-*
25 *section (a)(1)(A) whose activities relate to the research or*

1 *training under such awards or at which such training*
2 *will be conducted.*

3 “(3) *The period of any National Research Service*
4 *Award provided any individual under subsection (a) may*
5 *not exceed three years in the aggregate unless the Secretary*
6 *for good cause should waive the application of the three-year*
7 *limit to such individual.*

8 “(4)(A) *No National Research Service Award may*
9 *be granted by the Secretary under paragraph (1) or (2)*
10 *of subsection (a) to any individual unless the individual*
11 *has submitted to the Secretary an application therefor and*
12 *the Secretary has approved the application. The application*
13 *shall be in such form, submitted in such manner, and con-*
14 *tain such information as the Secretary may prescribe by*
15 *regulation.*

16 “(B) *National Research Service Awards granted under*
17 *subsection (a) shall provide for such stipends and allowances*
18 *(including travel and subsistence expenses and dependents*
19 *allowances) for the recipients as the Secretary may determine*
20 *necessary.*

21 “(C) *A National Research Service Award under sub-*
22 *section (a)(2) shall also provide for payments to be made*
23 *to the accredited institutions at which programs for research*
24 *or training for individual recipients of the National Re-*
25 *search Service Award are conducted, for the cost of support*

1 *services (including, but not limited to, a portion of faculty*
2 *salaries, supplies, equipment, staff, general research support,*
3 *and overhead) provided such recipients by such institution.*
4 *The amount of such awards to such institutions shall be*
5 *determined by the Secretary and shall bear a direct relation-*
6 *ship to the reasonable costs to the institution for establishing*
7 *and maintaining the quality of biomedical or behavioral re-*
8 *search and training programs at such institution.*

9 “(5) Notwithstanding sections 103(a) and 106 of the
10 *National Research Service Award Act the Secretary shall*
11 *maintain all existing commitments for research training*
12 *grants and fellowships existing on the date of enactment of this*
13 *Act but shall make no new commitments for research training*
14 *grants and fellowships except as authorized by section 455 of*
15 *this Act for National Research Service Awards.*

16 “(c)(1)(A) *Each individual who receives a National*
17 *Research Service Award under subsection (a) shall in ac-*
18 *cordance with paragraph (2) of this subsection—*

19 “(i) *engage in health research or teaching at an*
20 *accredited institution, or*

21 “(ii) *if authorized by clause (B) serve as a*
22 *member of the National Health Service Corps (estab-*
23 *lished under section 329) utilizing the specialty for which*
24 *he has been trained, and for which such award was*
25 *granted; serve in his specialty in private practice in a geo-*

1 *graphic area designated by the Secretary as requiring*
2 *that specialty; or serve in his specialty as a member of a*
3 *nonprofit prepaid group practice authorized for reim-*
4 *bursement under title XVIII of the Social Security Act,*
5 *for a period computed as follows: For each year during*
6 *which the individual receives a National Research Serv-*
7 *ice Award the individual shall—*

8 “(aa) engage in twelve months of health re-
9 search or teaching at an accredited institution,

10 “(bb) if so authorized, serve in his specialty as
11 a member of the National Health Service Corps for
12 a period of twelve months,

13 “(cc) if so authorized serve in his specialty in
14 such designated private practice area for a period
15 of twenty months or

16 “(dd) if so authorized serve in his specialty in
17 such prepaid group practice for a period of twenty
18 months.

19 “(B) Any individual who—

20 “(i) received a National Research Service Award,
21 and trained to provide health care directly to individual
22 patients may, upon application to the Secretary, be au-
23 thorized by the Secretary to serve in any capacity de-
24 scribed in section (c)(1)(A)(ii) in lieu of engaging
25 in health research or teaching if the Secretary determines

1 that there are no suitable health research or teaching
2 positions available to such individual to enable him to
3 comply with the research or teaching requirement of this
4 paragraph or if the Secretary determines that such skills
5 may be better utilized in another authorized capacity.

6 “(2) The requirements of paragraph (1) shall be com-
7 plied with by any individual to whom it applies within a
8 reasonable period of time, after the completion of such indi-
9 vidual's National Research Service Award, as the Secretary
10 shall by regulation prescribe. The Secretary shall by reg-
11 ulation prescribe the type of research and teaching in which
12 individuals may engage to comply with such requirements
13 and such other requirements respecting such research and
14 teaching as he deems necessary.

15 “(3)(A) If any individual to whom the requirement of
16 paragraph (1) is applicable, fails within the period prescribed
17 by paragraph (2), to comply with such requirement, the
18 United States shall be entitled to recover from such individual
19 an amount equal to the product of—

20 “(i) the aggregate of (I) the amount of assistance
21 provided to such individual under subsection (a), and
22 (II) the sums of the interest which would be payable on
23 such assistance if, at the time such assistance was pro-
24 vided, such assistance were a loan bearing interest at a
25 rate fixed by the Secretary of the Treasury, after taking

1 *into consideration private consumer rates of interest pre-*
2 *vailing at the time such assistance was provided and if*
3 *the interest on each such assistance had been compounded*
4 *annually, and*

5 *“(ii) a fraction (I) the numerator of which is the*
6 *number obtained by subtracting the number of months*
7 *equal to one-half the number of months of research or*
8 *teaching performed by the individual in compliance with*
9 *paragraph (1) from the total number of months in the*
10 *period of research or teaching required to be performed*
11 *by such individual by such paragraph, and (II) the*
12 *denominator of which is a number equal to such total*
13 *number of months.*

14 *Any amount which the United States is entitled to recover*
15 *under this subparagraph shall, within the three-year period*
16 *beginning on the date the United States becomes entitled to*
17 *recover such amount, be paid to the United States. Until any*
18 *amount due the United States under this subparagraph on*
19 *account of any assistance provided under this section is paid,*
20 *there shall accrue to the United States interest on such*
21 *amount at the same rate as that fixed by the Secretary of*
22 *the Treasury pursuant to clause (i) with respect to the as-*
23 *sistance on account of which such amount is due the United*
24 *States.*

1 *medical research personnel, (B) the subject areas in*
2 *which such personnel are needed and the number of such*
3 *personnel needed in each such area, and (C) the kinds*
4 *and extent of training which should be provided such*
5 *personnel;*

6 *“(2) assess (A) current training programs avail-*
7 *able for the training of biomedical research personnel*
8 *which are conducted under the Public Health Act at*
9 *or through the National Institutes of Health, the Na-*
10 *tional Institute of Mental Health, and their respective*
11 *research institutes, and (B) other current training pro-*
12 *grams available for the training of such personnel;*

13 *“(3) identify the kinds of research positions avail-*
14 *able to and held by individuals completing such training*
15 *programs;*

16 *“(4) determine, to the extent feasible, whether the*
17 *programs referred to in paragraph (2)(B) would*
18 *be adequate to meet the needs established under para-*
19 *graph (1) if the programs referred to in paragraph*
20 *(2)(A) were terminated; and*

21 *“(5) determine what modifications in the programs*
22 *referred to in paragraph (2) are required to meet the*
23 *needs established under paragraph (1).*

24 *“(b)(1) The Secretary shall request the National Acad-*
25 *emy of Sciences to conduct such ongoing studies, required*

1 *by subsection (a), under an arrangement under which the ac-*
2 *tual expenses incurred by such Academy in conducting such*
3 *studies will be paid by the Secretary. If the National Academy*
4 *of Sciences is willing to do so, the Secretary shall enter into*
5 *such an arrangement with such Academy for the conduct of*
6 *such studies.*

7 “(2) *If the National Academy of Science is unwilling*
8 *to conduct one or more such studies under such an arrange-*
9 *ment, then the Secretary shall enter into a similar arrange-*
10 *ment with other appropriate nonprofit private groups or*
11 *associations under which such groups or associations will con-*
12 *duct such studies and prepare and submit the reports thereon*
13 *as provided in subsection (c).*

14 “(c) *The information required by subsection (a) pur-*
15 *suant to the studies thereunder shall be reported annually*
16 *and the first such report is to be completed within the one-year*
17 *period from the date of the enactment of this Act. Except for*
18 *the first report, the reports on the results of such studies shall*
19 *be annually submitted by the Secretary not later than Jan-*
20 *uary 31 of each year to the Committee on Interstate and*
21 *Foreign Commerce of the House of Representatives and the*
22 *Committee on Labor and Public Welfare of the Senate.*

23 “(d) *National Research Service Awards shall be granted*
24 *in any specialty only when the Secretary has certified, on the*
25 *basis of evaluation of the study report required under sub-*

1 *section (c), that there is a need for additional manpower in*
 2 *that specialty. Such evaluation shall be completed within*
 3 *ninety days after submission of the first report as required*
 4 *under subsection (c).*

5 *“DEFINITIONS*

6 *“SEC. 457. (a) As used in this title of the Public Health*
 7 *Service Act, the term “residency training” means that medical*
 8 *training in an accredited institution where less than six*
 9 *months per year of training is devoted to research in a*
 10 *laboratory.*

11 *“(b) As used in this title of the Public Health Service*
 12 *Act, the term ‘accredited institution’ means a nonprofit insti-*
 13 *tution designated by the Secretary to carry out the purposes*
 14 *of this Act.”.*

15 *SEX DISCRIMINATION*

16 *SEC. 104. Section 799A of part H, title VII, of the*
 17 *Public Health Service Act, is amended by adding at the end*
 18 *thereof the following:*

19 *“In the case of a school of medicine which—*
 20 *“(1) on the date of the enactment of this sentence*
 21 *is in the process of changing its status as an institution*
 22 *which admits only female students to that of an institu-*
 23 *tion which admits students without regard to their sex,*
 24 *and*

1 *the words "except for training in biomedical and behavioral*
2 *research" after the word "training" in paragraph (3) and*
3 *by striking paragraph (4) and by redesignating paragraphs*
4 *(5), (6), and (7) as paragraphs (4), (5), and (6),*
5 *respectively.*

6 *(e) Section 407(b) of such Act is amended by adding*
7 *at the end of paragraph (7) "no training stipends, fellow-*
8 *ships, or carrier awards shall be made for training in bio-*
9 *medical or behavioral research."*

10 *(f) Section 408(b) of such Act is amended by adding*
11 *after the words "training (including training for allied health*
12 *personnel)" the words "except for training in biomedical and*
13 *behavioral research."*

14 *(g) Section 412 of such Act is amended by striking*
15 *paragraph (7).*

16 *(h) Section 413(a) of such Act is amended by striking*
17 *paragraph (7) and redesignating paragraphs (8), (9), and*
18 *(10) as paragraphs (7), (8), and (9), respectively.*

19 *(i) (1) Section 415(a)(2) of such Act is amended by*
20 *adding in paragraph (C) after the word "disease." the words*
21 *"Such programs shall not provide for training in biomedical*
22 *or behavioral research."*

23 *(2) Section 415(b) of such Act is amended by insert-*
24 *ing after the word "personnel," in paragraph (3) "except*
25 *for training for biomedical and behavioral research".*

1 (j) Section 422 of such Act is amended by striking
 2 paragraph (c) and by redesignating paragraphs (d) and (e)
 3 as paragraphs (c), (d), and (e), respectively, and by insert-
 4 ing in paragraph (e) as redesignated after the words "main-
 5 tain traineeships," the words "except traineeships in bio-
 6 medical and behavioral research."

7 (k) Section 434(c) of such Act is amended by adding
 8 at the end of clause (2), "such programs shall not provide
 9 for training in biomedical and behavioral research."

10 (l) Sections 433(a), 444, and 453 of such Act are
 11 amended by striking the second sentence of each section.

12 TITLE II—PROTECTION OF HUMAN

13 SUBJECTS

14 SHORT TITLE

15 SEC. 201. This title may be cited as the "Protection of
 16 Human Subjects Act".

17 SEC. 202. The Public Health Service Act (42 U.S.C.
 18 201) is amended by adding after title XI the following new
 19 title:

20 "TITLE XII—PROTECTION OF HUMAN

21 SUBJECTS

22 "ESTABLISHMENT OF COMMISSION

23 "SEC. 1201. (a) There is hereby established within the
 24 Department of Health, Education, and Welfare, the National

1 *Commission for the Protection of Human Subjects of Bio-*
2 *medical and Behavioral Research.*

3 “(b) *The Commission shall be composed of eleven*
4 *members who shall be appointed by the President from*
5 *persons who are especially qualified to serve on the Com-*
6 *mission by virtue of their training, experience, or back-*
7 *ground. The members of the Commission shall be appointed*
8 *from the general public and from among individuals in the*
9 *fields of medicine, law, ethics, theology, biological science,*
10 *physical science, social science, philosophy, humanities, health*
11 *administration, government, and public affairs.*

12 “(c)(1) *The President shall appoint, by and with the*
13 *advice and consent of the Senate, one of the members to serve*
14 *as Chairman and one to serve as Co-Chairman each for a*
15 *term of four years at the time of appointment.*

16 “(2) *Of the persons designated under subsection (c)(1)*
17 *at least, but no more than, one shall have conducted bio-*
18 *medical or behavioral research involving human subjects.*

19 “(d) *Not more than five members of the Commission*
20 *shall be appointed who are or who have been engaged in*
21 *biomedical or behavioral research involving human subjects.*

22 “(e) *The terms of each member shall be four years except*
23 *that—*

24 “(1) *the members first appointed shall serve as des-*

1 *ignated by the President, three for a term of two years,*
2 *four for a term of three years, and four for a term of*
3 *four years; and*

4 “(2) *any member appointed to fill a vacancy occur-*
5 *ring prior to expiration of such term shall serve only for*
6 *the remainder of the term for which his predecessor was*
7 *appointed.*

8 “(f) *In appointing the members of the Commission con-*
9 *sideration shall be given to nominees from the National Acad-*
10 *emy of Sciences and other appropriate, independent, non-*
11 *governmental organizations.*

12 “(g) *No member shall serve for more than two full terms.*

13 “(h) *A vacancy in the Commission shall not affect the*
14 *activities of the Commission and seven members thereof shall*
15 *constitute a quorum. Appointed members may serve after*
16 *the expiration of their terms until their successors have taken*
17 *office.*

18 “(i) *Members of the Commission who are not officers or*
19 *employees of the United States shall receive for each day*
20 *they are engaged in the performance of the duties of the Com-*
21 *mission compensation at rates equal to the daily equivalent*
22 *of the annual rate in effect for GS-18 of the General Sched-*
23 *ule, including traveltime; and all members while so serving*
24 *away from their homes or regular place of business, may be*
25 *allowed travel expenses, including per diem in lieu of sub-*

1 *sistence, in the same manner as such expenses are authorized*
2 *by section 5703, title 5, United States Code, for persons in*
3 *Government service employed intermittently.*

4 “(j) *The Secretary shall make available to the Com-*
5 *mission such staff, consultants, experts, information, equip-*
6 *ment, office space, and other assistance as it may require to*
7 *carry out its activities.*

8 “(k) *The Commission shall appoint an executive direc-*
9 *tor who shall serve full time and whose duty it shall be*
10 *to administer the daily activities of the Commission. Such*
11 *executive director shall be compensated at a rate equivalent*
12 *to the annual rate for a person serving at the level of GS-*
13 *18 of the General Schedule.*

14 “DUTIES OF THE COMMISSION

15 “SEC. 1202. (a) *The Commission shall—*

16 “(1) *undertake a comprehensive investigation and*
17 *study to identify the basic ethical principles and develop*
18 *guidelines which should underlie the conduct of biomed-*
19 *ical and behavioral research involving human subjects and*
20 *develop and implement policies and regulations to assure*
21 *that such research is carried out in accordance with the*
22 *ethical principles identified by the Commission in order*
23 *to assure the full protection of the rights of the subjects of*
24 *such research;*

1 “(2) develop procedures for the certification of
2 *Institutional Review Boards*;

3 “(3) develop and recommend to the Congress the im-
4 plementation of an appropriate range of sanctions (and
5 the conditions for their use) for failure of certified Insti-
6 tutional Review Boards to respond to Commission rules,
7 regulations, and procedures;

8 “(4) develop and recommend to the Congress a
9 mechanism for the compensation of individuals and their
10 families for injuries or death proximately caused by the
11 participation of such individuals in a biomedical or be-
12 havioral research program; and

13 “(5) develop and recommend to the Congress within
14 one year after the date of enactment of this section an
15 appropriate mechanism to broaden the scope of the Com-
16 mission’s jurisdiction in order to assure that all human
17 subjects in biomedical and behavioral research programs,
18 demonstrations, and activities are protected.

19 “(b) In fulfilling the mandate of subsection (a) the
20 Commission shall, among other subjects, consider—

21 “(1) developing appropriate guidelines for the selec-
22 tion of human subjects for participation in biomedical or
23 behavioral research projects;

24 “(2) the nature and definition of informed consent
25 in various settings;

1 “(3) the role of assessment of risk-benefit criteria
2 in the determination of the appropriateness of research
3 involving human subjects;

4 “(4) the conditions and procedures by which appeal
5 of an Institutional Review Board decision may be made
6 to the Commission;

7 “(5) defining more precisely the boundary between
8 biomedical and behavioral research involving human
9 subjects and the accepted and routine practice of medi-
10 cine;

11 “(6) evaluating and responding to, when appro-
12 priate, requests from the biomedical and behavioral re-
13 search community and the public for clarification of par-
14 ticular ethical problems confronting society with regard
15 to biomedical and behavioral research;

16 “(7) the need for variation in the review procedures
17 carried out by the Institutional Review Boards;

18 “(8) evaluating and monitoring of the performance
19 of Institutional Review Boards;

20 “(9) the question of conflict of interest in the per-
21 formance of Institutional Review Board duties; and

22 “(10) conditions and procedures by which individ-
23 ual protocols may be referred to the Commission for
24 decision.

25 Wherever there are duplications, overlaps, or conflicts, this

1 *title, and policies established by the Commission, and approved*
2 *by the Secretary under this title, shall take precedence over*
3 *existing Department of Health, Education, and Welfare*
4 *policies governing biomedical and behavioral research involv-*
5 *ing human subjects.*

6 “(c)(1) *In addition to its other duties, the Commission*
7 *shall conduct a study and investigation of the employment*
8 *of psychosurgery with a view to determining the number and*
9 *types of cases, during the five-year period ending Decem-*
10 *ber 31, 1972, in which psychosurgery has been performed*
11 *in all private and public hospitals in the United States, and*
12 *of compiling an analysis, on a case-by-case basis, of a suffi-*
13 *cient number of such cases (together with followup infor-*
14 *mation thereon) to provide the basis for an objective sci-*
15 *entific evaluation of psychosurgery performed during such*
16 *period with regard to the types of psychosurgery so per-*
17 *formed, the conditions for which it was performed, and the*
18 *results thereof. The Commission shall, not later than two*
19 *years after the date of enactment of this subsection, complete*
20 *such study and investigation and shall, on the basis of the*
21 *information gained therefrom, establish policies indicating*
22 *the circumstances (if any) under which the performance of*
23 *psychosurgery is appropriate.*

24 “(2) *As used in this subsection, the term ‘psychosur-*
25 *gery’ means brain surgery on (A) normal brain tissue of an*

1 individual, who does not suffer from any pathological dis-
2 ease, for the purpose of changing or controlling the behavior
3 or emotions of such individual, or (B) on diseased brain tis-
4 sue of an individual, if the sole object of the performance of
5 such surgery is to control, change, or affect any behavioral
6 or emotional disturbance of such individual. Such term does
7 not include brain surgery designed to cure, or ameliorate the
8 effects of epilepsy; nor shall such term be construed to in-
9 clude electric shock treatments.

10

"JURISDICTION

11 "SEC. 1203. The policies and procedures developed by
12 the Commission pursuant to section 1202 shall to the max-
13 imum feasible extent be applied by the Secretary as appro-
14 priate to the delivery of health services in health service
15 programs funded in whole or in part by the Department of
16 Health, Education, and Welfare. Until such policies and
17 procedures are developed, the provisions of section 1207(a),
18 (b), and (c) of this title shall be applied by the Secretary
19 as appropriate to the delivery of health services in health
20 service programs funded in whole or in part by the Depart-
21 ment of Health, Education, and Welfare.

22

CONSCIENCE AMENDMENT

23 "SEC. 1204. (a)(1) No individual shall be required to
24 perform or assist in the performance of any portion of a
25 health service program or research activity for which the

1 *provisions of this title are applicable, funded in whole or in*
2 *part by the Department of Health, Education, and Welfare*
3 *if such performance or assistance would be contrary to his*
4 *religious beliefs or moral convictions.*

5 “(2) *No entity shall be required to make its facilities*
6 *available for the performance of any health service program*
7 *or research activity funded in whole or in part by the Depart-*
8 *ment of Health, Education, and Welfare if such performance*
9 *is prohibited by the entity on the basis of religious beliefs or*
10 *moral convictions.*

11 “(3) *No entity may (A) discriminate in the employ-*
12 *ment, promotion, or termination of employment of any phy-*
13 *sician or other health care personnel, or (B) discriminate*
14 *in the extension of staff or other services to any physician or*
15 *other health care personnel solely because he performed or*
16 *assisted in the performance of a lawful health service pro-*
17 *gram or research activity for which the provisions of this*
18 *title are applicable in an unrelated facility, or solely because*
19 *he refused to perform or assist in the performance of such*
20 *a health service program or research activity, in a facility*
21 *controlled by such entity on the grounds that his performance*
22 *or assistance in the performance of such health service pro-*
23 *gram or research activity would be contrary to his religious*
24 *beliefs or moral convictions.*

25 “(b) *The provisions of this section shall not be construed.*

1 *as superseding the provisions of section 401 of the Health*
2 *Programs Extension Act of 1973.*

3 "PROHIBITION ON RESEARCH

4 "SEC. 1205. *Until such time after certification of Insti-*
5 *tutional Review Boards has been established and the Commis-*
6 *sion develops policies with regard to the conduct of research*
7 *on the living fetus or infants, the Secretary may not conduct*
8 *or support research or experimentation in the United States*
9 *or abroad on a living human fetus or infant, whether before*
10 *or after induced abortion, unless such research or experi-*
11 *mentation is done for the purpose of insuring the survival of*
12 *that fetus or infant.*

13 "INSTITUTIONAL REVIEW BOARDS

14 "SEC. 1206. (a) *No institution may receive Depart-*
15 *ment of Health, Education, and Welfare grants or contracts*
16 *to conduct biomedical or behavioral research involving human*
17 *subjects unless such institution has established an Institutional*
18 *Review Board certified by the Commission.*

19 "(b)(1) *The members and the Chairman of such In-*
20 *stitutional Review Boards shall be appointed by the chief*
21 *executive officer of the institution in accordance with policies,*
22 *regulations, and procedures of the Commission.*

23 "(2) *Such Institutional Review Boards must be com-*
24 *posed of sufficient members (including religious leaders, per-*
25 *sons schooled in ethics, and non-health-care professionals)*

1 *with such varying backgrounds of competence as to assure*
2 *complete and adequate review. No member of such Institu-*
3 *tional Review Boards shall be involved in either the initial or*
4 *continuing review of an activity in which he has a conflict of*
5 *interest as defined by the Commission, except to provide such*
6 *information as may be requested by such Institutional Review*
7 *Boards.*

8 “(c) *Each Institutional Review Board shall establish*
9 *two subcommittees as follows:*

10 “(1) *a Protocol Review Subcommittee, which shall*
11 *be responsible for approving, disapproving, or offering*
12 *suggestions for modifications of protocols for experimen-*
13 *tal procedures;*

14 “(2) *a Subject Advisory Subcommittee, which shall*
15 *be primarily concerned with the protection of the rights*
16 *of subjects of biomedical and behavioral research, and*
17 *shall assure that human subjects are as well informed*
18 *about the nature of the research as is reasonably possible.*

19 “(d) *The membership of the Institutional Review Board*
20 *and its subcommittees established under this section shall be in*
21 *accordance with regulations established by the Commission.*

22 “(e) *Nothing in this section shall prohibit or limit the*
23 *authority of the Secretary to make grants or enter into con-*
24 *tracts for biomedical or behavioral research prior to the*
25 *promulgation of procedures under section 1202(a)(2).*

1 “(3) a fair explanation of the likely results should
2 the experimental procedure fail;

3 “(4) a description of any benefits reasonably to be
4 expected;

5 “(5) a disclosure of any appropriate alternative
6 procedures that might be advantageous for the subject;

7 “(6) an offer to answer any inquiries concerning
8 the procedures; and

9 “(7) an instruction that the subject is free to either
10 decline entrance into a project or to withdraw his consent
11 and to discontinue participation in the project or activity
12 at any time without prejudicing his future care.

13 In addition, the agreement entered into by such person or his
14 legal representative, shall include no exculpatory language
15 through which the subject is made to waive, or to appear to
16 waive, any of his legal rights, or to release the institution or its
17 agents from liability for negligence. Any organization which
18 initiates, directs, or engages in programs of research, develop-
19 ment, or demonstration which require informed consent shall
20 keep a permanent record of such consent and the information
21 provided the subject and develop appropriate documentation
22 and reporting procedures as an essential administrative
23 function.

24 “(c) The term ‘exceptional cases’ as used in subsection (a)
25 shall be strictly construed; shall permit the waiver only of

1 *those elements of consent listed in subsection (b) as may be*
2 *justified by the circumstances of each case; and shall require*
3 *the written concurrence in the acting physician's decision by at*
4 *least two other licensed physicians not involved in the research*
5 *project, unless in a life threatening situation, it is not feasible*
6 *to obtain such concurrence.*

7 *"DUTIES OF THE BOARDS*

8 *"SEC. 1208. It shall be the duty of the Institutional*
9 *Review Boards, established under section 1204, to—*

10 *"(1) establish local policies for the review of re-*
11 *search sponsored in whole or part by the Department*
12 *of Health, Education, and Welfare, consistent with the*
13 *national guidelines promulgated under section 1202;*

14 *"(2) advise the Commission with regard to pro-*
15 *cedural modifications deemed necessary for effective*
16 *research;*

17 *"(3) assume full responsibility to ensure that bio-*
18 *medical and behavioral research involving human sub-*
19 *jects is carried out under the safest possible conditions*
20 *with the fully informed consent of the subject (or his*
21 *family) in a manner fully consistent with the ethical*
22 *principles developed by the Commission;*

23 *"(4) seek the consultative services of the Commis-*
24 *sion on any decision, or for the provision of information*
25 *needed to arrive at a decision; and*

1 *the Commission, permit such officer or employee to inspect,*
2 *verify, and copy appropriate books, records, and documents*
3 *relevant to determining whether such program is being con-*
4 *ducted in compliance with standards prescribed pursuant to*
5 *this section.*

6 “(b)(1) *The Commission shall not disclose any infor-*
7 *mation reported to or otherwise obtained by it pursuant to*
8 *this section which concerns any information which contains*
9 *or relates to a trade secret or other matter referred to in*
10 *section 1905 of title 18 of the United States Code, except*
11 *that such information may be disclosed to other officers or*
12 *employees of the Commission and of other agencies concerned*
13 *with carrying out this section, or when relevant in any pro-*
14 *ceeding under this section.*

15 “(2) *Records compiled pursuant to this section which*
16 *concern personal or medical information shall be confidential*
17 *and may be disclosed only for the purposes and under the*
18 *circumstances expressly authorized under paragraph (3) of*
19 *this subsection.*

20 “(3)(A) *If a person, with respect to whom any given*
21 *record referred to in this section is maintained, gives his*
22 *written consent, the content of such record may be disclosed*
23 *to medical personnel for the purposes of diagnosis or treat-*
24 *ment of such person, to governmental personnel for the pur-*
25 *pose of obtaining benefits to which the person is entitled, and*

1 to such personnel as may be designated by the Commission
2 for the purpose of carrying out this section.

3 “(B) If a person, with respect to whom any given
4 record referred to in this section is maintained, does not give
5 his written consent, the content of such record may be dis-
6 closed (i) to medical personnel to the extent necessary to meet
7 a bona fide medical emergency; (ii) to such qualified person-
8 nel as may be designated by the Commission for the purpose
9 of conducting scientific or epidemiological research, but such
10 personnel may not identify, directly or indirectly, any indi-
11 vidual in any report of such record, or otherwise disclose
12 identities in any manner; or (iii) if authorized by an appro-
13 priate order of a court of competent jurisdiction granted
14 after application showing good cause therefor. In assessing
15 good cause the court shall weigh the public interest and the
16 need for disclosure against the injury to the patient, to the
17 physician-patient relationship, and to the research program,
18 and shall determine that the disclosure will not unduly inter-
19 fere with the treatment of the patient or the conduct of the
20 research program. Upon the granting of such order, the court,
21 in determining the extent to which any disclosure of all or
22 any part of any record is necessary, shall impose appropriate
23 safeguards against unauthorized disclosure. This section shall
24 not supersede any other provision of Federal law.

25 “(4) The prohibitions of this section shall apply to

1 *and annually publish and distribute reports of important de-*
 2 *isions. The Commission shall establish such channels of*
 3 *communication among Institutional Review Boards as it*
 4 *determines necessary to carry out its responsibilities under this*
 5 *Act.*

6 "DEFINITIONS

7 "SEC. 1213. *As used in this title the term—*

8 "(1) 'Commission' means the National Commission for
 9 the Protection of Human Subjects of Biomedical and Be-
 10 havioral Research.

11 "(2) 'Institution' means any person or entity (includ-
 12 ing Government departments or agencies) receiving De-
 13 partment of Health, Education, and Welfare support for
 14 biomedical or behavioral research involving human subjects.

15 "(3) 'Health service programs' means all programs
 16 administered by the Secretary except the Social Security Act.

17 "AUTHORIZATION OF APPROPRIATIONS

18 "SEC. 1214. *There are authorized to be appropriated*
 19 *to carry out the purposes of this title \$3,000,000 for each*
 20 *of the fiscal years ending June 30, 1974, and June 30, 1975."*

21 AMENDMENT TO SPECIAL PROJECT GRANT AUTHORITY

22 SEC. 203. *Section 772(a)(7) of the Public Health*
 23 *Service Act is amended by inserting immediately before the*
 24 *semicolon at the end thereof the following: ", or (C) provid-*
 25 *ing increased emphasis on, the ethical, social, legal, and*

1 *moral implications of advances in biomedical research and*
2 *technology with respect to the effects of such advances on*
3 *individuals and society”.*

4 *SEC. 204. That part G, title IV, of the Public Health*
5 *Service Act, as amended by this Act, is further amended by*
6 *adding at the end thereof the following:*

7 “*REVIEW OF GRANT AND CONTRACT AWARDS*

8 “*SEC. 458. The Secretary, after consultation with the*
9 *Director of the National Institutes of Health and, where*
10 *appropriate, with the Director of the National Institute of*
11 *Mental Health, shall, by regulation, provide for the proper*
12 *scientific peer review by assembled groups of qualified inde-*
13 *pendent scientific experts of the review of all grants and for*
14 *research and development contracts (except for grants under*
15 *sections 402(b) and 419A(c) of this Act) administered by*
16 *the National Institutes of Health or the National Institute*
17 *of Mental Health, which will be awarded after the date of*
18 *enactment of this section. Such system of scientific peer re-*
19 *view shall be modeled after and shall utilize to the maximum*
20 *extent possible appropriate peer review study section groups*
21 *established by the National Institutes of Health or National*
22 *Institute of Mental Health and shall be composed principally*
23 *of non-Federal scientists and of no more than 20 per centum*
24 *who are Federal employees in the scientific, biomedical, and*
25 *behavioral research fields.”.*

1 “(1) analysis and evaluation of scientific and tech-
2 nological advances in the biomedical services, past, cur-
3 rent, and projected;

4 “(2) analysis and evaluation of the implications of
5 such advances, both for individuals and for society;

6 “(3) analysis and evaluation of laws, codes, and
7 principles governing the use of technology in medical
8 practice;

9 “(4) analysis and evaluation through the use of sem-
10 inars and public hearings and other appropriate means
11 of public understanding of and attitudes toward such
12 implications; and

13 “(5) analysis and evaluation of implications for pub-
14 lic policy of such findings as are made by the Commis-
15 sion with respect to biomedical advances and public atti-
16 tudes toward such advances.

17 “(b) The Commission shall make maximum feasible use
18 of related investigations and studies conducted by public and
19 private agencies.

20 “(c) The Commission shall transmit to the President and
21 to the Congress, not less than once every twenty-four months,
22 a report containing detailed statements of findings and con-
23 clusions of the studies conducted under subsection (a), to-
24 gether with recommendations for needed legislation or other

93RD CONGRESS
2^D SESSION

H. R. 7724

AN ACT

To amend the Public Health Service Act to establish a national program of biomedical research fellowships, traineeships, and training to assure the continued excellence of biomedical research in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 1974

Ordered to be printed with the amendments of the
Senate

8008424

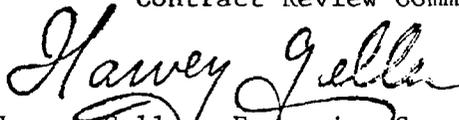
MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

9

TO : Members, Biometry and Epidemiology
Contract Review Committee

DATE: January 28, 1974



FROM : Harvey Geller, Executive Secretary
B&E CRC, NCI

SUBJECT: Confidentiality of Records

The following copies are attached regarding the subject which came up for discussion at the Committee meeting on January 8, 1974:

- 1) DHEW, NIH "Protection of Human Subjects" Policies and Procedures, FEDERAL REGISTER, Vol. 38, No. 221, Nov. 16, 1973
- 2) "Ethical Criteria," editorial article from BRITISH MEDICAL JOURNAL, January 27, 1973
- 3) "Responsibility in the Use of Medical Information for Research," statement by the Medical Research Council, BRITISH MEDICAL JOURNAL, January 27, 1973

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