

103D CONGRESS  
1ST SESSION

# H. R. 4

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 1993

Mr. WAXMAN (for himself, Mr. UPTON, Mrs. SCHROEDER, Ms. SNOWE, Mrs. COLLINS of Illinois, Ms. DANNER, Ms. ENGLISH, Mrs. JOHNSON of Connecticut, Mrs. KENNELLY, Ms. LAMBERT, Mr. LEHMAN, Mrs. LOWEY of New York, Mrs. LLOYD, Mr. MARKEY, Mrs. MINK, Mrs. MORELLA, Ms. MOLINARI, Ms. NORTON, Mr. RICHARDSON, Ms. PELOSI, Mr. SANDERS, Ms. SCHENK, Mr. SHARP, Ms. SLAUGHTER, Mr. STUDDS, Mr. SYNAR, Mr. TOWNS, Mrs. UNSOELD, Ms. WATERS, Ms. WOOLSEY, and Mr. WYDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “National Institutes of Health Revitalization Act of  
6 1993”.

1 (b) TABLE OF CONTENTS.—The table of contents for  
2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF  
PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL  
RESEARCH

Sec. 101. Establishment of certain provisions regarding research conducted or supported by National Institutes of Health.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.

Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue as directed donation for use in transplantation.

Sec. 113. Nullification of moratorium.

Sec. 114. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.

Sec. 132. Peer review.

Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

Sec. 141. Establishment.

Subtitle C—Scientific Integrity

Sec. 151. Establishment of Office of Scientific Integrity.

Sec. 152. Commission on Scientific Integrity.

Sec. 153. Protection of whistleblowers.

Sec. 154. Requirement of regulations regarding protection against financial conflicts of interest in certain projects of research.

Sec. 155. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

Sec. 201. Health promotion research dissemination.

Sec. 202. Programs for increased support regarding certain States and researchers.

Sec. 203. Children's vaccine initiative.

Sec. 204. Plan for use of animals in research.

Sec. 205. Increased participation of women and disadvantaged individuals in fields of biomedical and behavioral research.

- Sec. 206. Requirements regarding surveys of sexual behavior.
- Sec. 207. Discretionary fund of Director of National Institutes of Health.
- Sec. 208. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL  
RESEARCH INSTITUTES

- Sec. 301. Appointment and authority of Directors of national research institutes.
- Sec. 302. Program of research on osteoporosis, Paget's disease, and related disorders.
- Sec. 303. Establishment of interagency program for trauma research.

TITLE IV—NATIONAL CANCER INSTITUTE

- Sec. 401. Expansion and intensification of activities regarding breast cancer.
- Sec. 402. Expansion and intensification of activities regarding prostate cancer.
- Sec. 403. Authorization of appropriations.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

- Sec. 501. Education and training.
- Sec. 502. Centers for the study of pediatric cardiovascular diseases.
- Sec. 503. National Center on Sleep Disorders.
- Sec. 504. Authorization of appropriations.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE  
AND KIDNEY DISEASES

- Sec. 601. Provisions regarding nutritional disorders.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND  
MUSCULOSKELETAL AND SKIN DISEASES

- Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

- Sec. 801. Alzheimer's disease registry.
- Sec. 802. Aging processes regarding women.
- Sec. 803. Authorization of appropriations.
- Sec. 804. Conforming amendment.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS  
DISEASES

- Sec. 901. Tropical diseases.
- Sec. 902. Chronic fatigue syndrome.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN  
DEVELOPMENT

Subtitle A—Research Centers With Respect to Contraception and Research  
Centers With Respect to Infertility

- Sec. 1001. Grants and contracts for research centers.
- Sec. 1002. Loan repayment program for research with respect to contraception and infertility.

Subtitle B—Program Regarding Obstetrics and Gynecology

Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health.

Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL  
DISORDERS AND STROKE

Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH  
SCIENCES

Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.

Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

Sec. 1411. Establishment of program of grants for development of education technologies.

Subtitle C—National Information Center on Health Services Research and  
Health Care Technology

Sec. 1421. Establishment of Center.

Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF  
HEALTH

Subtitle A—Division of Research Resources

Sec. 1501. Redesignation of Division as National Center for Research Resources.

Sec. 1502. Biomedical and behavioral research facilities.

Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.

Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

Sec. 1601. Requirement regarding women and individuals from disadvantaged backgrounds.

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by National Institutes of Health

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Date certain for appointment of Board members.

Sec. 1702. Miscellaneous provisions.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Sec. 1801. Revision and extension of various programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.

Sec. 1905. Personnel study of recruitment, retention and turnover.

Sec. 1906. Procurement.

TITLE XX—MISCELLANEOUS PROVISIONS

Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio Conte, and limitation on number of members.

Sec. 2002. Technical corrections.

Sec. 2003. Biennial report on carcinogens.

Sec. 2004. Master plan for physical infrastructure for research.

Sec. 2005. Transfer of provisions of title xxvii.

Sec. 2006. Certain authorization of appropriations.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

1 **TITLE I—GENERAL PROVISIONS**  
 2 **REGARDING TITLE IV OF PUB-**  
 3 **LIC HEALTH SERVICE ACT**  
 4 **Subtitle A—Research Freedom**

5 **PART I—REVIEW OF PROPOSALS FOR**  
 6 **BIOMEDICAL AND BEHAVIORAL RESEARCH**

7 **SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-**  
 8 **GARDING RESEARCH CONDUCTED OR SUP-**  
 9 **PORTED BY NATIONAL INSTITUTES OF**  
 10 **HEALTH.**

11 Part G of title IV of the Public Health Service Act  
 12 (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
 13 tion 492 the following new section:

14 “CERTAIN PROVISIONS REGARDING REVIEW AND  
 15 APPROVAL OF PROPOSALS FOR RESEARCH

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

18 “(1) PROTECTION OF HUMAN RESEARCH SUB-  
 19 JECTS.—

20 “(A) In the case of any application submit-  
 21 ted to the Secretary for financial assistance to  
 22 conduct research, the Secretary may not ap-  
 23 prove or fund any application that is subject to  
 24 review under section 491(a) by an Institutional  
 25 Review Board unless the application has under-

1           gone review in accordance with such section and  
2           has been recommended for approval by a major-  
3           ity of the members of the Board conducting  
4           such review.

5           “(B) In the case of research that is subject  
6           to review under procedures established by the  
7           Secretary for the protection of human subjects  
8           in clinical research conducted by the National  
9           Institutes of Health, the Secretary may not au-  
10          thorize the conduct of the research unless the  
11          research has, pursuant to such procedures, been  
12          recommended for approval.

13          “(2) PEER REVIEW.—In the case of any appli-  
14          cation submitted to the Secretary for financial as-  
15          sistance to conduct research, the Secretary may not  
16          approve or fund any application that is subject to  
17          technical and scientific peer review under section  
18          492(a) unless the application has undergone peer re-  
19          view in accordance with such section and has been  
20          recommended for approval by a majority of the  
21          members of the entity conducting such review.

22          “(b) ETHICAL REVIEW OF RESEARCH.—

23                 “(1) PROCEDURES REGARDING WITHHOLDING  
24                 OF FUNDS.—If research has been recommended for  
25                 approval for purposes of subsection (a), the Sec-

1       retary may not withhold funding for the research on  
2       ethical grounds unless—

3               “(A) the Secretary convenes an advisory  
4               board in accordance with paragraph (4) to  
5               study the ethical implications of the research;  
6               and

7               “(B) the majority of the advisory board  
8               recommends that, on ethical grounds, the Sec-  
9               retary withhold funds for the research.

10              “(2) APPLICABILITY.—The limitation estab-  
11              lished in paragraph (1) regarding the authority to  
12              withhold funds on ethical grounds shall apply with-  
13              out regard to whether the withholding of funds is  
14              characterized as a disapproval, a moratorium, a pro-  
15              hibition, or other description.

16              “(3) PRELIMINARY MATTERS REGARDING USE  
17              OF PROCEDURES.—

18              “(A) If the Secretary makes a determina-  
19              tion that an advisory board should be convened  
20              for purposes of paragraph (1), the Secretary  
21              shall, through a statement published in the  
22              Federal Register, announce the intention of the  
23              Secretary to convene such a board.

24              “(B) A statement issued under subpara-  
25              graph (A) shall include a request that inter-



1           ested individuals submit to the Secretary rec-  
2           ommendations specifying the particular individ-  
3           uals who should be appointed to the advisory  
4           board involved. The Secretary shall consider  
5           such recommendations in making appointments  
6           to the board.

7           “(C) The Secretary may not make appoint-  
8           ments to an advisory board under paragraph  
9           (1) until the expiration of the 30-day period be-  
10          ginning on the date on which the statement re-  
11          quired in subparagraph (A) is made with re-  
12          spect to the board.

13          “(4) ETHICS ADVISORY BOARDS.—

14          “(A) Any advisory board convened for pur-  
15          poses of paragraph (1) shall be known as an  
16          ethics advisory board (hereafter in this para-  
17          graph referred to as an ‘ethics board’).

18          “(B)(i) An ethics board shall advise, con-  
19          sult with, and make recommendations to the  
20          Secretary regarding the ethics of the project of  
21          biomedical or behavioral research with respect  
22          to which the board has been convened.

23          “(ii) Not later than 180 days after the  
24          date on which the statement required in para-  
25          graph (3)(A) is made with respect to an ethics

1 board, the board shall submit to the Secretary,  
2 and to the Committee on Energy and Com-  
3 merce of the House of Representatives and the  
4 Committee on Labor and Human Resources of  
5 the Senate, a report describing the findings of  
6 the board regarding the project of research in-  
7 volved and making a recommendation under  
8 clause (i) of whether the Secretary should or  
9 should not withhold funds for the project. The  
10 report shall include the information considered  
11 in making the findings.

12 “(C) An ethics board shall be composed of  
13 no fewer than 14, and no more than 20, indi-  
14 viduals who are not officers or employees of the  
15 United States. The Secretary shall make ap-  
16 pointments to the board from among individ-  
17 uals with special qualifications and competence  
18 to provide advice and recommendations regard-  
19 ing ethical matters in biomedical and behavioral  
20 research. Of the members of the board—

21 “(i) no fewer than 1 shall be an attor-  
22 ney;

23 “(ii) no fewer than 1 shall be an  
24 ethicist;

1           “(iii) no fewer than 1 shall be a prac-  
2           ticing physician;

3           “(iv) no fewer than 1 shall be a theo-  
4           logian; and

5           “(v) no fewer than one-third, and no  
6           more than one-half, shall be scientists with  
7           substantial accomplishments in biomedical  
8           or behavioral research.

9           “(D) The term of service as a member of  
10          an ethics board shall be for the life of the  
11          board. If such a member does not serve the full  
12          term of such service, the individual appointed to  
13          fill the resulting vacancy shall be appointed for  
14          the remainder of the term of the predecessor of  
15          the individual.

16          “(E) A member of an ethics board shall be  
17          subject to removal from the board by the Sec-  
18          retary for neglect of duty or malfeasance or for  
19          other good cause shown.

20          “(F) The Secretary shall designate an indi-  
21          vidual from among the members of an ethics  
22          board to serve as the chair of the board.

23          “(G) In carrying out subparagraph (B)(i)  
24          with respect to a project of research, an ethics

1 board shall conduct inquiries and hold public  
2 hearings.

3 “(H) With respect to information relevant  
4 to the duties described in subparagraph (B)(i),  
5 an ethics board shall have access to all such in-  
6 formation possessed by the Department of  
7 Health and Human Services, or available to the  
8 Secretary from other agencies.

9 “(I) Members of an ethics board shall re-  
10 ceive compensation for each day engaged in car-  
11 rying out the duties of the board, including  
12 time engaged in traveling for purposes of such  
13 duties. Such compensation may not be provided  
14 in an amount in excess of the maximum rate of  
15 basic pay payable for GS-18 of the General  
16 Schedule.

17 “(J) The Secretary, acting through the Di-  
18 rector of the National Institutes of Health,  
19 shall provide to each ethics board such staff  
20 and other assistance as may be necessary to  
21 carry out the duties of the board.

22 “(K) An ethics board shall terminate 30  
23 days after the date on which the report required  
24 in subparagraph (B)(ii) is submitted to the Sec-

1           retary and the congressional committees speci-  
2           fied in such subparagraph.”.

3   **PART II—RESEARCH ON TRANSPLANTATION OF**  
4                                   **FETAL TISSUE**

5   **SEC. 111. ESTABLISHMENT OF AUTHORITIES.**

6           Part G of title IV of the Public Health Service Act  
7 (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
8 tion 498 the following new section:

9    “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

10    “SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

11           “(1) IN GENERAL.—The Secretary may conduct  
12           or support research on the transplantation of human  
13           fetal tissue for therapeutic purposes.

14           “(2) SOURCE OF TISSUE.—Human fetal tissue  
15           may be used in research carried out under para-  
16           graph (1) regardless of whether the tissue is ob-  
17           tained pursuant to a spontaneous or induced abor-  
18           tion or pursuant to a stillbirth.

19    “(b) INFORMED CONSENT OF DONOR.—

20           “(1) IN GENERAL.—In research carried out  
21           under subsection (a), human fetal tissue may be  
22           used only if the woman providing the tissue makes  
23           a statement, made in writing and signed by the  
24           woman, declaring that—

25                   “(A) the woman donates the fetal tissue  
26           for use in research described in subsection (a);

1           “(B) the donation is made without any re-  
2           striction regarding the identity of individuals  
3           who may be the recipients of transplantations  
4           of the tissue; and

5           “(C) the woman has not been informed of  
6           the identity of any such individuals.

7           “(2) ADDITIONAL STATEMENT.—In research  
8           carried out under subsection (a), human fetal tissue  
9           may be used only if the attending physician with re-  
10          spect to obtaining the tissue from the woman in-  
11          volved makes a statement, made in writing and  
12          signed by the physician, declaring that—

13           “(A) in the case of tissue obtained pursu-  
14          ant to an induced abortion—

15           “(i) the consent of the woman for the  
16          abortion was obtained prior to requesting  
17          or obtaining consent for the tissue to be  
18          used in such research; and

19           “(ii) no alteration of the timing,  
20          method, or procedures used to terminate  
21          the pregnancy was made solely for the pur-  
22          poses of obtaining the tissue;

23           “(B) the tissue has been donated by the  
24          woman in accordance with paragraph (1); and

1           “(C) full disclosure has been provided to  
2 the woman with regard to—

3                   “(i) such physician’s interest, if any,  
4 in the research to be conducted with the  
5 tissue; and

6                   “(ii) any known medical risks to the  
7 woman or risks to her privacy that might  
8 be associated with the donation of the tis-  
9 sue and that are in addition to risks of  
10 such type that are associated with the  
11 woman’s medical care.

12           “(c) INFORMED CONSENT OF RESEARCHER AND  
13 DONEE.—In research carried out under subsection (a),  
14 human fetal tissue may be used only if the individual with  
15 the principal responsibility for conducting the research in-  
16 volved makes a statement, made in writing and signed by  
17 the individual, declaring that the individual—

18                   “(1) is aware that—

19                           “(A) the tissue is human fetal tissue;

20                           “(B) the tissue may have been obtained  
21 pursuant to a spontaneous or induced abortion  
22 or subsequent to a stillbirth; and

23                           “(C) the tissue was donated for research  
24 purposes;

1           “(2) has provided such information to other in-  
2           dividuals with responsibilities regarding the research;

3           “(3) will require, prior to obtaining the consent  
4           of an individual to be a recipient of a transplan-  
5           tation of the tissue, written acknowledgment of re-  
6           ceipt of such information by such recipient; and

7           “(4) has had no part in any decisions as to the  
8           timing, method, or procedures used to terminate the  
9           pregnancy made solely for the purposes of the re-  
10          search.

11          “(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

12           “(1) IN GENERAL.—In research carried out  
13           under subsection (a), human fetal tissue may be  
14           used only if the head of the agency or other entity  
15           conducting the research involved certifies to the Sec-  
16           retary that the statements required under sub-  
17           sections (a)(3), (b)(2), and (c) will be available for  
18           audit by the Secretary.

19           “(2) CONFIDENTIALITY OF AUDIT.—Any audit  
20           conducted by the Secretary pursuant to paragraph  
21           (1) shall be conducted in a confidential manner to  
22           protect the privacy rights of the individuals and enti-  
23           ties involved in such research, including such indi-  
24           viduals and entities involved in the donation, trans-  
25           fer, receipt, or transplantation of human fetal tissue.



1 With respect to any material or information obtained  
2 pursuant to such audit, the Secretary shall—

3 “(A) use such material or information only  
4 for the purposes of verifying compliance with  
5 the requirements of this section;

6 “(B) not disclose or publish such material  
7 or information, except where required by Fed-  
8 eral law, in which case such material or infor-  
9 mation shall be coded in a manner such that  
10 the identities of such individuals and entities  
11 are protected; and

12 “(C) not maintain such material or infor-  
13 mation after completion of such audit, except  
14 where necessary for the purposes of such audit.

15 “(e) APPLICABILITY OF STATE AND LOCAL LAW.—

16 “(1) RESEARCH CONDUCTED BY RECIPIENTS  
17 OF ASSISTANCE.—The Secretary may not provide  
18 support for research under subsection (a) to conduct  
19 the research in accordance with applicable State and  
20 local law.

21 “(2) RESEARCH CONDUCTED BY SECRETARY.—  
22 The Secretary may conduct research under sub-  
23 section (a) only in accordance with applicable State  
24 and local law.

1       “(f) DEFINITION.—For purposes of this section, the  
2 term ‘human fetal tissue’ means tissue or cells obtained  
3 from a dead human embryo or fetus after a spontaneous  
4 or induced abortion, or after a stillbirth.”.

5 **SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**  
6 **TION OR ACCEPTANCE OF TISSUE AS DI-**  
7 **RECTED DONATION FOR USE IN TRANSPLAN-**  
8 **TATION.**

9       Part G of title IV of the Public Health Service Act,  
10 as amended by section 111 of this Act, is amended by in-  
11 serting after section 498A the following new section:

12       “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

13       “SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be  
14 unlawful for any person to knowingly acquire, receive, or  
15 otherwise transfer any human fetal tissue for valuable con-  
16 sideration if the transfer affects interstate commerce.

17       “(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS  
18 DIRECTED DONATION FOR USE IN TRANSPLANTATION.—  
19 It shall be unlawful for any person to solicit or knowingly  
20 acquire, receive, or accept a donation of human fetal tissue  
21 for the purpose of transplantation of such tissue into an-  
22 other person if the donation affects interstate commerce,  
23 the tissue will be or is obtained pursuant to an induced  
24 abortion, and—

25       “(1) the donation will be or is made pursuant  
26 to a promise to the donating individual that the do-

1 nated tissue will be transplanted into a recipient  
2 specified by such individual;

3 “(2) the donated tissue will be transplanted  
4 into a relative of the donating individual; or

5 “(3) the person who solicits or knowingly ac-  
6 quires, receives, or accepts the donation has provided  
7 valuable consideration for the costs associated with  
8 such abortion.

9 “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

10 “(1) IN GENERAL.—Any person who violates  
11 subsection (a) or (b) shall be fined in accordance  
12 with title 18, United States Code, subject to para-  
13 graph (2), or imprisoned for not more than 10  
14 years, or both.

15 “(2) PENALTIES APPLICABLE TO PERSONS RE-  
16 CEIVING CONSIDERATION.—With respect to the im-  
17 position of a fine under paragraph (1), if the person  
18 involved violates subsection (a) or (b)(3), a fine shall  
19 be imposed in an amount not less than twice the  
20 amount of the valuable consideration received.

21 “(d) DEFINITIONS.—For purposes of this section:

22 “(1) The term ‘human fetal tissue’ has the  
23 meaning given such term in section 498A(f).

1           “(2) The term ‘interstate commerce’ has the  
2 meaning given such term in section 201(b) of the  
3 Federal Food, Drug, and Cosmetic Act.

4           “(3) The term ‘valuable consideration’ does not  
5 include reasonable payments associated with the  
6 transportation, implantation, processing, preserva-  
7 tion, quality control, or storage of human fetal  
8 tissue.”.

9 **SEC. 113. NULLIFICATION OF MORATORIUM.**

10       (a) IN GENERAL.—Except as provided in subsection  
11 (c), no official of the executive branch may impose a policy  
12 that the Department of Health and Human Services is  
13 prohibited from conducting or supporting any research on  
14 the transplantation of human fetal tissue for therapeutic  
15 purposes. Such research shall be carried out in accordance  
16 with section 498A of the Public Health Service Act (as  
17 added by section 111 of this Act), without regard to any  
18 such policy that may have been in effect prior to the date  
19 of the enactment of this Act.

20       (b) PROHIBITION AGAINST WITHHOLDING OF FUNDS  
21 IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

22           (1) IN GENERAL.—In the case of any proposal  
23 for research on the transplantation of human fetal  
24 tissue for therapeutic purposes, the Secretary of

1 Health and Human Services may not withhold funds  
2 for the research if—

3 (A) the research has been approved for  
4 purposes of section 492A(a) of the Public  
5 Health Service Act (as added by section 101 of  
6 this Act);

7 (B) the research will be carried out in ac-  
8 cordance with section 498A of such Act (as  
9 added by section 111 of this Act); and

10 (C) there are reasonable assurances that  
11 the research will not utilize any human fetal tis-  
12 sue that has been obtained in violation of sec-  
13 tion 498B(a) of such Act (as added by section  
14 112 of this Act).

15 (2) STANDING APPROVAL REGARDING ETHICAL  
16 STATUS.—In the case of any proposal for research  
17 on the transplantation of human fetal tissue for  
18 therapeutic purposes, the issuance in December  
19 1988 of the Report of the Human Fetal Tissue  
20 Transplantation Research Panel shall be deemed to  
21 be a report—

22 (A) issued by an ethics advisory board pur-  
23 suant to section 492A(b)(4)(B)(ii) of the Public  
24 Health Service Act (as added by section 101 of  
25 this Act); and

1 (B) finding, on a basis that is neither arbi-  
2 trary nor capricious, that there are no ethical  
3 grounds for withholding funds for the research.

4 (c) **AUTHORITY FOR WITHHOLDING FUNDS FROM**  
5 **RESEARCH.**—In the case of any research on the transplan-  
6 tation of human fetal tissue for therapeutic purposes, the  
7 Secretary of Health and Human Services may withhold  
8 funds for the research if any of the conditions specified  
9 in any of subparagraphs (A) through (C) of subsection  
10 (b)(1) are not met with respect to the research.

11 (d) **DEFINITION.**—For purposes of this section, the  
12 term “human fetal tissue” has the meaning given such  
13 term in section 498A(f) of the Public Health Service Act  
14 (as added by section 111 of this Act).

15 **SEC. 114. REPORT BY GENERAL ACCOUNTING OFFICE ON**  
16 **ADEQUACY OF REQUIREMENTS.**

17 (a) **IN GENERAL.**—With respect to research on the  
18 transplantation of human fetal tissue for therapeutic pur-  
19 poses, the Comptroller General of the United States shall  
20 conduct an audit for the purpose of determining—

21 (1) whether and to what extent such research  
22 conducted or supported by the Secretary of Health  
23 and Human Services has been conducted in accord-  
24 ance with section 498A of the Public Health Service  
25 Act (as added by section 111 of this Act); and

1           (2) whether and to what extent there have been  
2           violations of section 498B of such Act (as added by  
3           section 112 of this Act).

4           (b) REPORT.—Not later than May 19, 1995, the  
5           Comptroller General of the United States shall complete  
6           the audit required in subsection (a) and submit to the  
7           Committee on Energy and Commerce of the House of  
8           Representatives, and to the Committee on Labor and  
9           Human Resources of the Senate, a report describing the  
10          findings made pursuant to the audit.

11           **PART III—MISCELLANEOUS REPEALS**

12          **SEC. 121. REPEALS.**

13          (a) CERTAIN BIOMEDICAL ETHICS BOARD.—Title III  
14          of the Public Health Service Act (42 U.S.C. 241 et seq.)  
15          is amended by striking part J.

16          (b) OTHER REPEALS.—Part G of title IV of the Pub-  
17          lic Health Service Act (42 U.S.C. 289 et seq.) is amend-  
18          ed—

19                 (1) in section 498, by striking subsection (c);

20          and

21                 (2) by striking section 499; and

22                 (3) by redesignating section 499A as section  
23          499.

24          (c) NULLIFICATION OF CERTAIN REGULATION.—The  
25          provisions of section 204(d) of part 46 of title 45 of the

1 Code of Federal Regulations (45 CFR 46.204(d)) shall  
2 not have any legal effect.

3 **Subtitle B—Clinical Research Eq-**  
4 **uity Regarding Women and Mi-**  
5 **norities**

6 **PART I—WOMEN AND MINORITIES AS SUBJECTS**  
7 **IN CLINICAL RESEARCH**

8 **SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.**

9 Part G of title IV of the Public Health Service Act,  
10 as amended by section 101 of this Act, is amended by in-  
11 serting after section 492A the following new section:

12 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL  
13 RESEARCH

14 “SEC. 492B. (a) In conducting or supporting clinical  
15 research for purposes of this title, the Director of NIH  
16 shall, subject to subsection (b), ensure that—

17 “(1) women are included as subjects in each  
18 project of such research; and

19 “(2) members of minority groups are included  
20 as subjects in such research.

21 “(b) The requirement established in subsection (a)  
22 regarding women and members of minority groups shall  
23 not apply to a project of clinical research if the inclusion,  
24 as subjects in the project, of women and members of mi-  
25 nority groups, respectively—



1           “(1) is inappropriate with respect to the health  
2           of the subjects;

3           “(2) is inappropriate with respect to the pur-  
4           pose of the research; or

5           “(3) is inappropriate under such other cir-  
6           cumstances as the Director of NIH may designate.

7           “(c) In the case of any project of clinical research  
8           in which women or members of minority groups will under  
9           subsection (a) be included as subjects in the research, the  
10          Director of NIH shall ensure that the project is designed  
11          and carried out in a manner sufficient to provide for a  
12          valid analysis of whether the variables being tested in the  
13          research affect women or members of minority groups, as  
14          the case may be, differently than other subjects in the  
15          research.

16          “(d)(1) The Director of NIH, in consultation with the  
17          Director of the Office of Research on Women’s Health,  
18          shall establish guidelines regarding—

19                  “(A) the circumstances under which the inclu-  
20                  sion of women and minorities in projects of clinical  
21                  research is inappropriate for purposes of subsection  
22                  (b);

23                  “(B) the manner in which such projects are re-  
24                  quired to be designed and carried out for purposes  
25                  of subsection (c), including a specification of the cir-

1       cumstances in which the requirement of such sub-  
2       section does not apply on the basis of impracticabil-  
3       ity; and

4               “(C) the conduct of outreach programs for the  
5       recruitment of women and members of minority  
6       groups as subjects in such research.

7       “(2) With respect to the circumstances under which  
8       the inclusion of women or members of minority groups (as  
9       the case may be) as subjects in clinical research is inap-  
10      propriate for purposes of subsection (b), the guidelines es-  
11      tablished under paragraph (1)(A)—

12              “(A) shall provide that the costs of such inclu-  
13      sion in a project of clinical research is not a permis-  
14      sible consideration in determining whether such in-  
15      clusion is inappropriate unless the data of com-  
16      parable quality regarding women or members of mi-  
17      nority groups, respectively, that would be obtained in  
18      such project in the event that such inclusion were re-  
19      quired will be obtained through other means; and

20              “(B) may provide that such inclusion in a  
21      project of clinical research is not required if there is  
22      substantial scientific data demonstrating that there  
23      is no significant difference between—

1           “(i) the effects that the variables to be  
2           studied in the project have on women or mem-  
3           bers of minority groups, respectively; and

4           “(ii) the effects that the variables have on  
5           the individuals who would serve as subjects in  
6           the project in the event that such inclusion were  
7           not required.

8           “(3) The guidelines required in paragraph (1) shall  
9           be established and published in the Federal Register not  
10          later than 120 days after the date of the enactment of  
11          the National Institutes of Health Revitalization Act of  
12          1993.

13          “(4) For fiscal year 1994 and subsequent fiscal years,  
14          the Director of NIH may not approve any proposal of clin-  
15          ical research to be conducted or supported by any agency  
16          of the National Institutes of Health unless the proposal  
17          specifies the manner in which the research will comply  
18          with subsection (a).

19          “(e) The advisory council of each national research  
20          institute shall annually submit to the Director of NIH and  
21          the Director of the institute involved a report describing  
22          the manner in which the agency has complied with sub-  
23          section (a).”.

1 **SEC. 132. PEER REVIEW.**

2 Section 492 of the Public Health Service Act (42  
3 U.S.C. 289a) is amended by adding at the end the follow-  
4 ing new subsection:

5 “(c)(1) In technical and scientific peer review under  
6 this section of proposals for clinical research, the consider-  
7 ation of any such proposal (including the initial consider-  
8 ation) shall, except as provided in paragraph (2), include  
9 an evaluation of the technical and scientific merit of the  
10 proposal regarding compliance with section 492B(a).

11 “(2) Paragraph (1) shall not apply to any proposal  
12 for clinical research that, pursuant to subsection (b) of  
13 section 492B, is not subject to the requirement of sub-  
14 section (a) of such section regarding the inclusion of  
15 women and members of minority groups as subjects in  
16 clinical research.”.

17 **SEC. 133. APPLICABILITY TO CURRENT PROJECTS.**

18 Section 492B of the Public Health Service Act, as  
19 added by section 131 of this Act, shall not apply with re-  
20 spect to projects of clinical research for which initial fund-  
21 ing was provided prior to the date of the enactment of  
22 this Act. With respect to the inclusion of women and mi-  
23 norities as subjects in clinical research conducted or sup-  
24 ported by the National Institutes of Health, any policies  
25 of the Secretary of Health and Human Services regarding  
26 such inclusion that are in effect on the day before the date

1 of the enactment of this Act shall continue to apply to  
2 the projects referred to in the preceding sentence.

3 **PART II—OFFICE OF RESEARCH ON WOMEN’S**  
4 **HEALTH**

5 **SEC. 141. ESTABLISHMENT.**

6 (a) IN GENERAL.—Title IV of the Public Health  
7 Service Act, as amended by section 2 of Public Law 101–  
8 613, is amended—

9 (1) by redesignating section 486 as section  
10 485A;

11 (2) by redesignating parts F through H as  
12 parts G through I, respectively; and

13 (3) by inserting after part E the following new  
14 part:

15 “PART F—RESEARCH ON WOMEN’S HEALTH

16 “SEC. 486. OFFICE OF RESEARCH ON WOMEN’S HEALTH.

17 “(a) ESTABLISHMENT.—There is established within  
18 the Office of the Director of NIH an office to be known  
19 as the Office of Research on Women’s Health (in this part  
20 referred to as the ‘Office’). The Office shall be headed by  
21 a director, who shall be appointed by the Director of NIH.

22 “(b) PURPOSE.—The Director of the Office shall—

23 “(1) identify projects of research on women’s  
24 health that should be conducted or supported by the  
25 national research institutes;

1           “(2) identify multidisciplinary research relating  
2           to research on women’s health that should be so con-  
3           ducted or supported;

4           “(3) carry out paragraphs (1) and (2) with re-  
5           spect to the aging process in women, with priority  
6           given to menopause;

7           “(4) promote coordination and collaboration  
8           among entities conducting research identified under  
9           any of paragraphs (1) through (3);

10          “(5) encourage the conduct of such research by  
11          entities receiving funds from the national research  
12          institutes;

13          “(6) recommend an agenda for conducting and  
14          supporting such research;

15          “(7) promote the sufficient allocation of the re-  
16          sources of the national research institutes for con-  
17          ducting and supporting such research;

18          “(8) assist in the administration of section  
19          492B with respect to the inclusion of women as sub-  
20          jects in clinical research; and

21          “(9) prepare the report required in section  
22          486B.

23          “(c) COORDINATING COMMITTEE.—

24                 “(1) In carrying out subsection (b), the Direc-  
25                 tor of the Office shall establish a committee to be

1 known as the Coordinating Committee on Research  
2 on Women’s Health (hereafter in this subsection re-  
3 ferred to as the ‘Coordinating Committee’).

4 “(2) The Coordinating Committee shall be com-  
5 posed of the Directors of the national research insti-  
6 tutes (or the designees of the Directors).

7 “(3) The Director of the Office shall serve as  
8 the chair of the Coordinating Committee.

9 “(4) With respect to research on women’s  
10 health, the Coordinating Committee shall assist the  
11 Director of the Office in—

12 “(A) identifying the need for such re-  
13 search, and making an estimate each fiscal year  
14 of the funds needed to adequately support the  
15 research;

16 “(B) identifying needs regarding the co-  
17 ordination of research activities, including in-  
18 tramural and extramural multidisciplinary ac-  
19 tivities;

20 “(C) supporting the development of meth-  
21 odologies to determine the circumstances in  
22 which obtaining data specific to women (includ-  
23 ing data relating to the age of women and the  
24 membership of women in ethnic or racial

1 groups) is an appropriate function of clinical  
2 trials of treatments and therapies;

3 “(D) supporting the development and ex-  
4 pansion of clinical trials of treatments and  
5 therapies for which obtaining such data has  
6 been determined to be an appropriate function;  
7 and

8 “(E) encouraging the national research in-  
9 stitutes to conduct and support such research,  
10 including such clinical trials.

11 “(d) ADVISORY COMMITTEE.—

12 “(1) In carrying out subsection (b), the Direc-  
13 tor of the Office shall establish an advisory commit-  
14 tee to be known as the Advisory Committee on Re-  
15 search on Women’s Health (hereafter in this sub-  
16 section referred to as the ‘Advisory Committee’).

17 “(2) The Advisory Committee shall be com-  
18 posed of no fewer than 12, and not more than 18  
19 individuals, who are not officers or employees of the  
20 Federal Government. The Director of the Office  
21 shall make appointments to the Advisory Committee  
22 from among physicians, practitioners, scientists, and  
23 other health professionals, whose clinical practice,  
24 research specialization, or professional expertise in-  
25 cludes a significant focus on research on women’s



1 health. A majority of the members of the Advisory  
2 Committee shall be women.

3 “(3) The Director of the Office shall serve as  
4 the chair of the Advisory Committee.

5 “(4) The Advisory Committee shall—

6 “(A) advise the Director of the Office on  
7 appropriate research activities to be undertaken  
8 by the national research institutes with respect  
9 to—

10 “(i) research on women’s health;

11 “(ii) research on gender differences in  
12 clinical drug trials, including responses to  
13 pharmacological drugs;

14 “(iii) research on gender differences  
15 in disease etiology, course, and treatment;

16 “(iv) research on obstetrical and gyne-  
17 cological health conditions, diseases, and  
18 treatments; and

19 “(v) research on women’s health con-  
20 ditions which require a multidisciplinary  
21 approach;

22 “(B) report to the Director of the Office  
23 on such research;

24 “(C) provide recommendations to such Di-  
25 rector regarding activities of the Office (includ-

1           ing recommendations on the development of the  
2           methodologies described in subsection (c)(4)(C)  
3           and recommendations on priorities in carrying  
4           out research described in subparagraph (A));  
5           and

6           “(D) assist in monitoring compliance with  
7           section 492B regarding the inclusion of women  
8           in clinical research.

9           “(5)(A) The Advisory Committee shall prepare  
10          a biennial report describing the activities of the  
11          Committee, including findings made by the Commit-  
12          tee regarding—

13                 “(i) compliance with section 492B;

14                 “(ii) the extent of expenditures made for  
15                 research on women’s health by the agencies of  
16                 the National Institutes of Health; and

17                 “(iii) the level of funding needed for such  
18                 research.

19           “(B) The report required in subparagraph (A)  
20          shall be submitted to the Director of NIH for inclu-  
21          sion in the report required in section 403.

22          “(e) REPRESENTATION OF WOMEN AMONG RE-  
23          SEARCHERS.—The Secretary, acting through the Assist-  
24          ant Secretary for Personnel and in collaboration with the  
25          Director of the Office, shall determine the extent to which

1 women are represented among senior physicians and sci-  
2 entists of the national research institutes and among phy-  
3 sicians and scientists conducting research with funds pro-  
4 vided by such institutes, and as appropriate, carry out ac-  
5 tivities to increase the extent of such representation.

6 “(f) DEFINITIONS.—For purposes of this part:

7 “(1) The term ‘women’s health conditions’, with  
8 respect to women of all age, ethnic, and racial  
9 groups, means all diseases, disorders, and conditions  
10 (including with respect to mental health)—

11 “(A) unique to, more serious, or more  
12 prevalent in women;

13 “(B) for which the factors of medical risk  
14 or types of medical intervention are different  
15 for women, or for which it is unknown whether  
16 such factors or types are different for women;  
17 or

18 “(C) with respect to which there has been  
19 insufficient clinical research involving women as  
20 subjects or insufficient clinical data on women.

21 “(2) The term ‘research on women’s health’  
22 means research on women’s health conditions, in-  
23 cluding research on preventing such conditions.

1 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE**  
2 **ON RESEARCH ON WOMEN’S HEALTH.**

3 “(a) DATA SYSTEM.—

4 “(1) The Director of NIH, in consultation with  
5 the Director of the Office, shall establish a data sys-  
6 tem for the collection, storage, analysis, retrieval,  
7 and dissemination of information regarding research  
8 on women’s health that is conducted or supported by  
9 the national research institutes. Information from  
10 the data system shall be available through informa-  
11 tion systems available to health care professionals  
12 and providers, researchers, and members of the  
13 public.

14 “(2) The data system established under para-  
15 graph (1) shall include a registry of clinical trials of  
16 experimental treatments that have been developed  
17 for research on women’s health. Such registry shall  
18 include information on subject eligibility criteria,  
19 sex, age, ethnicity or race, and the location of the  
20 trial site or sites. Principal investigators of such  
21 clinical trials shall provide this information to the  
22 registry within 30 days after it is available. Once a  
23 trial has been completed, the principal investigator  
24 shall provide the registry with information pertain-  
25 ing to the results, including potential toxicities or

1 adverse effects associated with the experimental  
2 treatment or treatments evaluated.

3 “(b) CLEARINGHOUSE.—The Director of NIH, in  
4 consultation with the Director of the Office and with the  
5 National Library of Medicine, shall establish, maintain,  
6 and operate a program to provide information on research  
7 and prevention activities of the national research institutes  
8 that relate to research on women’s health.

9 **“SEC. 486B. BIENNIAL REPORT.**

10 “(a) IN GENERAL.—With respect to research on  
11 women’s health, the Director of the Office shall, not later  
12 than February 1, 1994, and biennially thereafter, prepare  
13 a report—

14 “(1) describing and evaluating the progress  
15 made during the preceding 2 fiscal years in research  
16 and treatment conducted or supported by the Na-  
17 tional Institutes of Health;

18 “(2) describing and analyzing the professional  
19 status of women physicians and scientists of such  
20 Institutes, including the identification of problems  
21 and barriers regarding advancements;

22 “(3) summarizing and analyzing expenditures  
23 made by the agencies of such Institutes (and by  
24 such Office) during the preceding 2 fiscal years; and

1           “(4) making such recommendations for legisla-  
2           tive and administrative initiatives as the Director of  
3           the Office determines to be appropriate.

4           “(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR  
5           OF NIH.—The Director of the Office shall submit each  
6           report prepared under subsection (a) to the Director of  
7           NIH for inclusion in the report submitted to the President  
8           and the Congress under section 403.”.

9           (b) REQUIREMENT OF SUFFICIENT ALLOCATION OF  
10          RESOURCES OF INSTITUTES.—Section 402(b) of the Pub-  
11          lic Health Service Act (42 U.S.C. 282(b)) is amended—

12           (1) in paragraph (10), by striking “and” after  
13          the semicolon at the end;

14           (2) in paragraph (11), by striking the period at  
15          the end and inserting “; and”; and

16           (3) by inserting after paragraph (11) the fol-  
17          lowing new paragraph:

18           “(12) after consultation with the Director of  
19          the Office of Research on Women’s Health, shall en-  
20          sure that resources of the National Institutes of  
21          Health are sufficiently allocated for projects of re-  
22          search on women’s health that are identified under  
23          section 486(b).”.

1       **Subtitle C—Scientific Integrity**

2       **SEC. 151. ESTABLISHMENT OF OFFICE OF SCIENTIFIC IN-**  
3               **TEGRITY.**

4           (a) IN GENERAL.—Section 493 of the Public Health  
5       Service Act (42 U.S.C. 289b) is amended to read as fol-  
6       lows:

7                       “OFFICE OF SCIENTIFIC INTEGRITY

8           “SEC. 493. (a) ESTABLISHMENT.—

9                       “(1) IN GENERAL.—Not later than 90 days  
10       after the date of enactment of this section, the Sec-  
11       retary shall establish an office to be known as the  
12       Office of Scientific Integrity (hereafter referred to in  
13       this section as the ‘Office’), which shall be estab-  
14       lished as an independent entity in the Department  
15       of Health and Human Services.

16                      “(2) DIRECTOR.—The Office shall be headed by  
17       a Director, who shall be appointed by the Secretary,  
18       be experienced and specially trained in the conduct  
19       of research, and have experience in the conduct of  
20       investigations of scientific misconduct. The Sec-  
21       retary shall carry out this section acting through the  
22       Director of the Office. The Director shall report to  
23       the Secretary.

24                      “(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS  
25       CONDITION OF FUNDING FOR RESEARCH.—The Secretary

1 shall by regulation require that each entity that applies  
2 for a grant, contract, or cooperative agreement under this  
3 Act for any project or program that involves the conduct  
4 of biomedical or behavioral research submit in or with its  
5 application for such grant, contract, or cooperative agree-  
6 ment assurances satisfactory to the Secretary that such  
7 entity—

8           “(1) has established (in accordance with regula-  
9           tions which the Secretary shall prescribe) an admin-  
10           istrative process to review reports of scientific mis-  
11           conduct in connection with biomedical and behav-  
12           ioral research conducted at or sponsored by such en-  
13           tity; and

14           “(2) will report to the Director any investiga-  
15           tion of alleged scientific misconduct in connection  
16           with projects for which funds have been made avail-  
17           able under this Act that appears substantial.

18           “(c) PROCESS FOR RESPONSE OF DIRECTOR.—The  
19           Secretary shall establish by regulation a process to be fol-  
20           lowed by the Director for the prompt and appropriate—

21           “(1) response to information provided to the  
22           Director respecting scientific misconduct in connec-  
23           tion with projects for which funds have been made  
24           available under this Act;



1           “(2) receipt of reports by the Director of such  
2 information from recipients of funds under this Act;

3           “(3) conduct of investigations, when appro-  
4 priate; and

5           “(4) taking of other actions, including appro-  
6 priate remedies, with respect to such misconduct.

7           “(d) MONITORING BY DIRECTOR.—The Secretary  
8 shall by regulation establish procedures for the Director  
9 to monitor administrative processes and investigations  
10 that have been established or carried out under this sec-  
11 tion.

12           “(e) EFFECT ON PRESENT INVESTIGATIONS.—Noth-  
13 ing in this section shall affect investigations which have  
14 been or will be commenced prior to the promulgation of  
15 final regulations under this section.”.

16           (b) ESTABLISHMENT OF DEFINITION OF SCIENTIFIC  
17 MISCONDUCT.—Not later than 90 days after the date on  
18 which the report required under section 152(d) is submit-  
19 ted to the Secretary of Health and Human Services, such  
20 Secretary shall by regulation establish a definition for the  
21 term “scientific misconduct” for purposes of section 493  
22 of the Public Health Service Act, as amended by sub-  
23 section (a) of this section.

1 **SEC. 152. COMMISSION ON SCIENTIFIC INTEGRITY.**

2 (a) IN GENERAL.—The Secretary of Health and  
3 Human Services shall establish a commission to be known  
4 as the Commission on Scientific Integrity (in this section  
5 referred to as the “Commission”).

6 (b) DUTIES.—The Commission shall develop rec-  
7 ommendations for the Secretary of Health and Human  
8 Services on the administration of section 493 of the Public  
9 Health Service Act (as amended and added by section 151  
10 of this Act).

11 (c) COMPOSITION.—The Commission shall be com-  
12 posed of 12 members to be appointed by the Secretary  
13 of Health and Human Services from among individuals  
14 who are not officers or employees of the United States.  
15 Of the members appointed to the Commission—

16 (1) three shall be scientists with substantial ac-  
17 complishments in biomedical or behavioral research;

18 (2) three shall be individuals with experience in  
19 investigating allegations of misconduct with respect  
20 to scientific research;

21 (3) three shall be representatives of institutions  
22 of higher education at which biomedical or behav-  
23 ioral research is conducted; and

24 (4) three shall be individuals who are not de-  
25 scribed in paragraphs (1), (2), or (3), at least one

1 of whom shall be an attorney and at least one of  
2 whom shall be an ethicist.

3 (d) REPORT.—Not later than 120 days after the date  
4 of enactment of this section, the Commission shall prepare  
5 and submit to the Secretary of Health and Human Serv-  
6 ices, the Committee on Energy and Commerce of the  
7 House of Representatives, and the Committee on Labor  
8 and Human Resources of the Senate, a report containing  
9 the recommendations developed under subsection (b).

10 **SEC. 153. PROTECTION OF WHISTLEBLOWERS.**

11 Section 493 of the Public Health Service Act, as  
12 amended by section 151 of this Act, is amended by adding  
13 at the end the following new subsection:

14 “(f) PROTECTION OF WHISTLEBLOWERS.—

15 “(1) IN GENERAL.—In the case of any entity  
16 required to establish administrative processes under  
17 subsection (b), the Secretary shall by regulation es-  
18 tablish standards for preventing, and for responding  
19 to the occurrence of retaliation by such entity, its of-  
20 ficials or agents, against an employee in the terms  
21 and conditions of employment in response to the em-  
22 ployee having in good faith—

23 “(A) made an allegation that the entity, its  
24 officials or agents, has engaged in or failed to

1           adequately respond to an allegation of scientific  
2           misconduct; or

3           “(B) cooperated with an investigation of  
4           such an allegation.

5           “(2) MONITORING BY SECRETARY.—The Sec-  
6           retary shall establish by regulation procedures for  
7           the Director to monitor the implementation of the  
8           standards established by an entity under paragraph  
9           (1) for the purpose of determining whether the pro-  
10          cedures have been established, and are being uti-  
11          lized, in accordance with the standards established  
12          under such paragraph.

13          “(3) NONCOMPLIANCE.—The Secretary shall by  
14          regulation establish remedies for noncompliance by  
15          an entity, its officials or agents, which has engaged  
16          in retaliation in violation of the standards estab-  
17          lished under paragraph (1). Such remedies may in-  
18          clude termination of funding provided by the Sec-  
19          retary for such project or recovery of funding being  
20          provided by the Secretary for such project, or other  
21          actions as appropriate.

22          “(4) FINAL RULE FOR REGULATIONS.—The  
23          Secretary shall issue a final rule for the regulations  
24          required in paragraph (1) not later than 180 days

1 after the date of the enactment of the National In-  
2 stitutes of Health Revitalization Act of 1993.

3 “(5) REQUIRED AGREEMENTS.—For any fiscal  
4 year beginning after the date on which the regula-  
5 tions required in paragraph (1) are issued, the Sec-  
6 retary may not provide a grant, cooperative agree-  
7 ment, or contract under this Act for biomedical or  
8 behavioral research unless the entity seeking such fi-  
9 nancial assistance agrees that the entity—

10 “(A) will maintain the procedures de-  
11 scribed in the regulations; and

12 “(B) will otherwise be subject to the regu-  
13 lations.”.

14 **SEC. 154. REQUIREMENT OF REGULATIONS REGARDING**  
15 **PROTECTION AGAINST FINANCIAL CON-**  
16 **FLICTS OF INTEREST IN CERTAIN PROJECTS**  
17 **OF RESEARCH.**

18 Part H of title IV of the Public Health Service Act,  
19 as redesignated by section 141(a)(2) of this Act, is amend-  
20 ed by inserting after section 493 the following new section:

21 “PROTECTION AGAINST FINANCIAL CONFLICTS OF  
22 INTEREST IN CERTAIN PROJECTS OF RESEARCH

23 “SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

24 “(1) IN GENERAL.—The Secretary shall define  
25 by regulation, the specific circumstances that con-  
26 stitute the existence of a financial interest in a

1 project on the part of an entity or individual that  
2 will, or may be reasonably expected to, create a bias  
3 in favor of obtaining results in such project that are  
4 consistent with such financial interest. Such defini-  
5 tion shall apply uniformly to each entity or individ-  
6 ual conducting a research project under this Act. In  
7 the case of any entity or individual receiving assist-  
8 ance from the Secretary for a project of research de-  
9 scribed in paragraph (2), the Secretary shall by reg-  
10 ulation establish standards for responding to, includ-  
11 ing managing, reducing, or eliminating, the existence  
12 of such a financial interest. The entity may adopt  
13 individualized procedures for implementing the  
14 standards.

15 “(2) RELEVANT PROJECTS.—A project of re-  
16 search referred to in paragraph (1) is a project of  
17 clinical research whose purpose is to evaluate the  
18 safety or effectiveness of a drug, medical device, or  
19 treatment and for which such entity is receiving as-  
20 sistance from the Secretary.

21 “(3) IDENTIFYING AND REPORTING TO THE DI-  
22 RECTOR.—The Secretary shall ensure that the  
23 standards established under paragraph (1) specify  
24 that as a condition of receiving assistance from the

1 Secretary for the project involved, an entity de-  
2 scribed in such subsection is required—

3 “(A) to have in effect at the time the en-  
4 tity applies for the assistance and throughout  
5 the period during which the assistance is re-  
6 ceived, a process for identifying such financial  
7 interests as defined in paragraph (1) that exist  
8 regarding the project; and

9 “(B) to report to the Director such finan-  
10 cial interest as defined in paragraph (1) identi-  
11 fied by the entity and how any such financial  
12 interest identified by the entity will be managed  
13 or eliminated such that the project in question  
14 will be protected from bias that may stem from  
15 such financial interest.

16 “(4) MONITORING OF PROCESS.—The Secretary  
17 shall monitor the establishment and conduct of the  
18 process established by an entity pursuant to para-  
19 graph (1).

20 “(5) RESPONSE.—In any case in which the Sec-  
21 retary determines that an entity has failed to comply  
22 with paragraph (3) regarding a project of research  
23 described in paragraph (1), the Secretary—

24 “(A) shall require that, as a condition of  
25 receiving assistance, the entity disclose the ex-

1           istence of a financial interest as defined in  
2           paragraph (1) in each public presentation of the  
3           results of such project; and

4                   “(B) may take such other actions as the  
5           Secretary determines to be appropriate.

6           “(6) DEFINITION.—As used in this section:

7                   “(A) The term ‘financial interest’ includes  
8           the receipt of consulting fees or honoraria and  
9           the ownership of stock or equity.

10                   “(B) The term ‘assistance’, with respect to  
11           conducting a project of research, means a  
12           grant, contract, or cooperative agreement.

13           “(b) FINAL RULE FOR REGULATIONS.—The Sec-  
14           retary shall issue a final rule for the regulations required  
15           in subsection (a) not later than 180 days after the date  
16           of the enactment of the National Institutes of Health Re-  
17           vitalization Act of 1993.”.

18           **SEC. 155. EFFECTIVE DATES.**

19           (a) IN GENERAL.—The amendments made by this  
20           subtitle shall become effective on the date that occurs 180  
21           days after the date on which the final rule required under  
22           section 493(f)(4) of the Public Health Service Act, as  
23           amended by sections 151 and 153, is published in the Fed-  
24           eral Register.



1 (b) AGREEMENTS AS A CONDITION OF FUNDING.—  
2 The requirements of subsection (f)(5) of section 493 of  
3 the Public Health Service Act, as amended by sections 151  
4 and 153, with respect to agreements as a condition of  
5 funding shall not be effective in the case of projects of  
6 research for which initial funding under the Public Health  
7 Service Act was provided prior to the effective date de-  
8 scribed in subsection (a).

9 **TITLE II—NATIONAL INSTITUTES**  
10 **OF HEALTH IN GENERAL**

11 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINA-**  
12 **TION.**

13 Section 402(f) of the Public Health Service Act (42  
14 U.S.C. 282(f)) is amended by striking “other public and  
15 private entities.” and all that follows through the end and  
16 inserting “other public and private entities, including ele-  
17 mentary, secondary, and post-secondary schools. The As-  
18 sociate Director shall—

19 “(1) annually review the efficacy of existing  
20 policies and techniques used by the national research  
21 institutes to disseminate the results of disease pre-  
22 vention and behavioral research programs;

23 “(2) recommend, coordinate, and oversee the  
24 modification or reconstruction of such policies and  
25 techniques to ensure maximum dissemination, using

1 advanced technologies to the maximum extent prac-  
2 ticable, of research results to such entities; and

3 “(3) annually prepare and submit to the Direc-  
4 tor of NIH a report concerning the prevention and  
5 dissemination activities undertaken by the Associate  
6 Director, including—

7 “(A) a summary of the Associate Direc-  
8 tor’s review of existing dissemination policies  
9 and techniques together with a detailed state-  
10 ment concerning any modification or restructur-  
11 ing, or recommendations for modification or re-  
12 structuring, of such policies and techniques;  
13 and

14 “(B) a detailed statement of the expendi-  
15 tures made for the prevention and dissemina-  
16 tion activities reported on and the personnel  
17 used in connection with such activities.”.

18 **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**  
19 **ING CERTAIN STATES AND RESEARCHERS.**

20 Section 402 of the Public Health Service Act (42  
21 U.S.C. 282) is amended by adding at the end the following  
22 new subsection:

23 “(g)(1)(A) In the case of entities described in sub-  
24 paragraph (B), the Director of NIH, acting through the  
25 Director of the National Center for Research Resources,

1 shall establish a program to enhance the competitiveness  
2 of such entities in obtaining funds from the national re-  
3 search institutes for conducting biomedical and behavioral  
4 research.

5       “(B) The entities referred to in subparagraph (A) are  
6 entities that conduct biomedical and behavioral research  
7 and are located in a State in which the aggregate success  
8 rate for applications to the national research institutes for  
9 assistance for such research by the entities in the State  
10 has historically constituted a low success rate of obtaining  
11 such funds, relative to such aggregate rate for such enti-  
12 ties in other States.

13       “(C) With respect to enhancing competitiveness for  
14 purposes of subparagraph (A), the Director of NIH, in  
15 carrying out the program established under such subpara-  
16 graph, may—

17               “(i) provide technical assistance to the entities  
18 involved, including technical assistance in the prepa-  
19 ration of applications for obtaining funds from the  
20 national research institutes;

21               “(ii) assist the entities in developing a plan for  
22 biomedical or behavioral research proposals; and

23               “(iii) assist the entities in implementing such  
24 plan.

1       “(2) The Director of NIH shall establish a program  
2 of supporting projects of biomedical or behavioral research  
3 whose principal researchers are individuals who have not  
4 previously served as the principal researchers of such  
5 projects supported by the Director.”.

6 **SEC. 203. CHILDREN’S VACCINE INITIATIVE.**

7       Part A of title IV of the Public Health Service Act  
8 (42 U.S.C. 281 et seq.) is amended by adding at the end  
9 the following new section:

10               “CHILDREN’S VACCINE INITIATIVE

11       “SEC. 404. (a) DEVELOPMENT OF NEW VACCINES.—  
12 The Secretary, in consultation with the Director of the  
13 National Vaccine Program under title XXI and acting  
14 through the Directors of the National Institute for Allergy  
15 and Infectious Diseases, the National Institute for Child  
16 Health and Human Development, the National Institute  
17 for Aging, and other public and private programs, shall  
18 carry out activities, which shall be consistent with the  
19 global Children’s Vaccine Initiative, to develop affordable  
20 new and improved vaccines to be used in the United States  
21 and in the developing world that will increase the efficacy  
22 and efficiency of the prevention of infectious diseases. In  
23 carrying out such activities, the Secretary shall, to the ex-  
24 tent practicable, develop and make available vaccines that  
25 require fewer contacts to deliver, that can be given early  
26 in life, that provide long lasting protection, that obviate

1 refrigeration, needles and syringes, and that protect  
2 against a larger number of diseases.

3 “(b) REPORT.—In the report required in section  
4 2104, the Secretary, acting through the Director of the  
5 National Vaccine Program under title XXI, shall include  
6 information with respect to activities and the progress  
7 made in implementing the provisions of this section and  
8 achieving its goals.

9 “(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-  
10 dition to any other amounts authorized to be appropriated  
11 for activities of the type described in this section, there  
12 are authorized to be appropriated to carry out this section  
13 \$50,000,000 for fiscal year 1994, and such sums as may  
14 be necessary for each of the fiscal years 1995 and 1996.”.

15 **SEC. 204. PLAN FOR USE OF ANIMALS IN RESEARCH.**

16 (a) IN GENERAL.—Part A of title IV of the Public  
17 Health Service Act, as amended by section 203 of this Act,  
18 is amended by adding at the end the following new section:

19 “PLAN FOR USE OF ANIMALS IN RESEARCH

20 “SEC. 404A. (a) The Director of NIH, after consulta-  
21 tion with the committee established under subsection (e),  
22 shall prepare a plan—

23 “(1) for the National Institutes of Health to  
24 conduct or support research into—

1           “(A) methods of biomedical research and  
2           experimentation that do not require the use of  
3           animals;

4           “(B) methods of such research and experi-  
5           mentation that reduce the number of animals  
6           used in such research; and

7           “(C) methods of such research and experi-  
8           mentation that produce less pain and distress in  
9           such animals;

10          “(2) for establishing the validity and reliability  
11          of the methods described in paragraph (1);

12          “(3) for encouraging the acceptance by the sci-  
13          entific community of such methods that have been  
14          found to be valid and reliable; and

15          “(4) for training scientists in the use of such  
16          methods that have been found to be valid and reli-  
17          able.

18          “(b) Not later than October 1, 1993, the Director  
19          of NIH shall submit to the Committee on Energy and  
20          Commerce of the House of Representatives, and to the  
21          Committee on Labor and Human Resources of the Senate,  
22          the plan required in subsection (a) and shall begin imple-  
23          mentation of the plan.

24          “(c) The Director of NIH shall periodically review,  
25          and as appropriate, make revisions in the plan required

1 under subsection (a). A description of any revision made  
2 in the plan shall be included in the first biennial report  
3 under section 403 that is submitted after the revision is  
4 made.

5 “(d) The Director of NIH shall take such actions as  
6 may be appropriate to convey to scientists and others who  
7 use animals in biomedical or behavioral research or experi-  
8 mentation information respecting the methods found to be  
9 valid and reliable under subsection (a)(2).

10 “(e)(1) The Director of NIH shall establish within  
11 the National Institutes of Health a committee to be known  
12 as the Interagency Coordinating Committee on the Use  
13 of Animals in Research (hereafter in this subsection re-  
14 ferred to as the ‘Committee’).

15 “(2) The Committee shall provide advice to the Direc-  
16 tor of NIH on the preparation of the plan required in sub-  
17 section (a).

18 “(3) The Committee shall be composed of—

19 “(A) the Directors of each of the national re-  
20 search institutes and the Director of the Center for  
21 Research Resources (or the designees of such Direc-  
22 tors); and

23 “(B) representatives of the Environmental Pro-  
24 tection Agency, the Food and Drug Administration,  
25 the Consumer Product Safety Commission, the Na-

1 tional Science Foundation, and such additional agen-  
2 cies as the Director of NIH determines to be appro-  
3 priate.”.

4 (b) CONFORMING AMENDMENT.—Section 4 of the  
5 Health Research Extension Act of 1985 (Public Law 99–  
6 158; 99 Stat. 880) is repealed.

7 **SEC. 205. INCREASED PARTICIPATION OF WOMEN AND DIS-**  
8 **ADVANTAGED INDIVIDUALS IN FIELDS OF**  
9 **BIOMEDICAL AND BEHAVIORAL RESEARCH.**

10 Section 402 of the Public Health Service Act, as  
11 amended by section 202 of this Act, is amended by adding  
12 at the end the following new subsection:

13 “(h) The Secretary, acting through the Director of  
14 NIH and the Directors of the agencies of the National  
15 Institutes of Health, may conduct and support programs  
16 for research, research training, recruitment, and other ac-  
17 tivities to provide for an increase in the number of women  
18 and individuals from disadvantaged backgrounds in the  
19 fields of biomedical and behavioral research.”.

20 **SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEX-**  
21 **UAL BEHAVIOR.**

22 Part A of title IV of the Public Health Service Act,  
23 as amended by section 204 of this Act, is amended by add-  
24 ing at the end the following new section:



1       “REQUIREMENTS REGARDING SURVEYS OF SEXUAL  
2                                   BEHAVIOR

3       “SEC. 404B. With respect to any survey of human  
4 sexual behavior proposed to be conducted or supported  
5 through the National Institutes of Health, the survey may  
6 not be carried out unless—

7           “(1) the proposal has undergone review in ac-  
8 cordance with any applicable requirements of sec-  
9 tions 491 and 492; and

10          “(2) the Secretary, in accordance with section  
11 492A, makes a determination that the information  
12 expected to be obtained through the survey will as-  
13 sist—

14           “(A) in reducing the incidence of sexually  
15 transmitted diseases, the incidence of infection  
16 with the human immunodeficiency virus, or the  
17 incidence of any other infectious disease; or

18           “(B) in improving reproductive health or  
19 other conditions of health.”.

20 **SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NA-**  
21 **TIONAL INSTITUTES OF HEALTH.**

22       Section 402 of the Public Health Service Act, as  
23 amended by section 205 of this Act, is amended by adding  
24 at the end the following new subsection:

1       “(i)(1) There is established a fund, consisting of  
2 amounts appropriated under paragraph (3) and made  
3 available for the fund, for use by the Director of NIH to  
4 carry out the activities authorized in this Act for the Na-  
5 tional Institutes of Health. The purposes for which such  
6 fund may be expended include—

7           “(A) providing for research on matters that  
8 have not received significant funding relative to  
9 other matters, responding to new issues and sci-  
10 entific emergencies, and acting on research opportu-  
11 nities of high priority;

12           “(B) supporting research that is not exclusively  
13 within the authority of any single agency of such In-  
14 stitutes; and

15           “(C) purchasing or renting equipment and  
16 quarters for activities of such Institutes.

17       “(2) Not later than February 10 of each fiscal year,  
18 the Secretary shall submit to the Committee on Energy  
19 and Commerce of the House of Representatives, and to  
20 the Committee on Labor and Human Resources of the  
21 Senate, a report describing the activities undertaken and  
22 expenditures made under this section during the preceding  
23 fiscal year. The report may contain such comments of the  
24 Secretary regarding this section as the Secretary deter-  
25 mines to be appropriate.

1       “(3) For the purpose of carrying out this subsection,  
2 there are authorized to be appropriated \$25,000,000 for  
3 fiscal year 1994, and such sums as may be necessary for  
4 each of the fiscal years 1995 and 1996.”.

5 **SEC. 208. MISCELLANEOUS PROVISIONS.**

6       (a) **TERM OF OFFICE FOR MEMBERS OF ADVISORY**  
7 **COUNCILS.**—Section 406(c) of the Public Health Service  
8 Act (42 U.S.C. 284a(c)) is amended in the second sen-  
9 tence by striking “until a successor has been appointed”  
10 and inserting the following: “for 180 days after the date  
11 of such expiration”.

12       (b) **LITERACY REQUIREMENTS.**—Section 402(e) of  
13 the Public Health Service Act (42 U.S.C. 282(e)) is  
14 amended—

15           (1) in paragraph (3), by striking “and” at the  
16 end;

17           (2) in paragraph (4), by striking the period and  
18 inserting “; and”; and

19           (3) by adding at the end thereof the following  
20 new paragraph:

21           “(5) ensure that, after January 1, 1994, at  
22 least one-half of all new or revised health education  
23 and promotion materials developed or funded by the  
24 National Institutes of Health is in a form that does  
25 not exceed a level of functional literacy, as defined

1 in the National Literacy Act of 1991 (Public Law  
2 102-73).”.

3 (c) DAY CARE REGARDING CHILDREN OF EMPLOY-  
4 EES.—Section 402 of the Public Health Service Act, as  
5 amended by section 207 of this Act, is amended by adding  
6 at the end the following new subsection:

7 “(i)(1) The Director of NIH may establish a program  
8 to provide day care service for the employees of the Na-  
9 tional Institutes of Health similar to those services pro-  
10 vided by other Federal agencies (including the availability  
11 of day care service on a 24-hour-a-day basis).

12 “(2) Any day care provider at the National Institutes  
13 of Health shall establish a sliding scale of fees that takes  
14 into consideration the income and needs of the employee.

15 “(3) For purposes regarding the provision of day care  
16 service, the Director of NIH may enter into rental or lease  
17 purchase agreements.”.

18 **TITLE III—GENERAL PROVI-**  
19 **SIONS RESPECTING NA-**  
20 **TIONAL RESEARCH INSTI-**  
21 **TUTES**

22 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**  
23 **OF NATIONAL RESEARCH INSTITUTES.**

24 (a) ESTABLISHMENT OF GENERAL AUTHORITY RE-  
25 GARDING DIRECT FUNDING.—

1           (1) IN GENERAL.—Section 405(b)(2) of the  
2 Public Health Service Act (42 U.S.C. 284(b)(2)) is  
3 amended—

4           (A) in subparagraph (A), by striking  
5 “and” after the semicolon at the end;

6           (B) in subparagraph (B), by striking the  
7 period at the end and inserting “; and”; and

8           (C) by adding at the end the following new  
9 subparagraph:

10           “(C) shall receive from the President and the  
11 Office of Management and Budget directly all funds  
12 appropriated by the Congress for obligation and ex-  
13 penditure by the Institute.”.

14           (2) CONFORMING AMENDMENT.—Section  
15 413(b)(9) of the Public Health Service Act (42  
16 U.S.C. 285a-2(b)(9)) is amended—

17           (A) by striking “(A)” after “(9)”; and

18           (B) by striking “advisory council;” and all  
19 that follows and inserting “advisory council.”.

20           (b) APPOINTMENT AND DURATION OF TECHNICAL  
21 AND SCIENTIFIC PEER REVIEW GROUPS.—Section 405(c)  
22 of the Public Health Service Act (42 U.S.C. 284(c)) is  
23 amended—

24           (1) by amending paragraph (3) to read as fol-  
25 lows:

1           “(3) may, in consultation with the advisory  
2           council for the Institute and with the approval of the  
3           Director of NIH—

4                   “(A) establish technical and scientific peer  
5           review groups in addition to those appointed  
6           under section 402(b)(6); and

7                   “(B) appoint the members of peer review  
8           groups established under subparagraph (A);  
9           and”;

10           (2) by adding after and below paragraph (4)  
11           the following:

12           “The Federal Advisory Committee Act shall not apply to  
13           the duration of a peer review group appointed under para-  
14           graph (3).”.

15           **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**  
16                   **PAGET’S DISEASE, AND RELATED BONE DIS-**  
17                   **ORDERS.**

18           Part B of title IV of the Public Health Service Act  
19           (42 U.S.C. 284 et seq.), as amended by section 121(b)  
20           of Public Law 102-321 (106 Stat. 358), is amended by  
21           adding at the end the following new section:

22           “RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND  
23                   RELATED BONE DISORDERS

24           “SEC. 410. (a) ESTABLISHMENT.—The Directors of  
25           the National Institute of Arthritis and Musculoskeletal  
26           and Skin Diseases, the National Institute on Aging, and

1 the National Institute of Diabetes, Digestive and Kidney  
2 Diseases, shall expand and intensify the programs of such  
3 Institutes with respect to research and related activities  
4 concerning osteoporosis, Paget's disease, and related bone  
5 disorders.

6       “(b) COORDINATION.—The Directors referred to in  
7 subsection (a) shall jointly coordinate the programs re-  
8 ferred to in such subsection and consult with the Arthritis  
9 and Musculoskeletal Diseases Interagency Coordinating  
10 Committee and the Interagency Task Force on Aging Re-  
11 search.

12       “(c) INFORMATION CLEARINGHOUSE.—

13               “(1) IN GENERAL.—In order to assist in carry-  
14 ing out the purpose described in subsection (a), the  
15 Director of NIH shall provide for the establishment  
16 of an information clearinghouse on osteoporosis and  
17 related bone disorders to facilitate and enhance  
18 knowledge and understanding on the part of health  
19 professionals, patients, and the public through the  
20 effective dissemination of information.

21               “(2) ESTABLISHMENT THROUGH GRANT OR  
22 CONTRACT.—For the purpose of carrying out para-  
23 graph (1), the Director of NIH shall enter into a  
24 grant, cooperative agreement, or contract with a  
25 nonprofit private entity involved in activities regard-

1       ing the prevention and control of osteoporosis and  
2       related bone disorders.

3       “(d) AUTHORIZATION OF APPROPRIATIONS.—For the  
4       purpose of carrying out this section, there are authorized  
5       to be appropriated \$40,000,000 for fiscal year 1994, and  
6       such sums as may be necessary for each of the fiscal years  
7       1995 and 1996.”.

8       **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**  
9                               **FOR TRAUMA RESEARCH.**

10       (a) IN GENERAL.—Title XII of the Public Health  
11       Service Act (42 U.S.C. 300d et seq.) is amended by adding  
12       at the end the following part:

13       “PART E—INTERAGENCY PROGRAM FOR TRAUMA  
14                               RESEARCH

15       **“SEC. 1251. ESTABLISHMENT OF PROGRAM.**

16       “(a) IN GENERAL.—The Secretary, acting through  
17       the Director of the National Institutes of Health (here-  
18       after in this section referred to as the ‘Director’), shall  
19       establish a comprehensive program of conducting basic  
20       and clinical research on trauma (hereafter in this section  
21       referred to as the ‘Program’). The Program shall include  
22       research regarding the diagnosis, treatment, rehabilita-  
23       tion, and general management of trauma.

24       (b) PLAN FOR PROGRAM.—



1           “(1) IN GENERAL.—The Director, in consulta-  
2           tion with the Trauma Research Interagency Coordi-  
3           nating Committee established under subsection (g),  
4           shall establish and implement a plan for carrying  
5           out the activities of the Program, including the ac-  
6           tivities described in subsection (d). All such activities  
7           shall be carried out in accordance with the plan. The  
8           plan shall be periodically reviewed, and revised as  
9           appropriate.

10           “(2) SUBMISSION TO CONGRESS.—Not later  
11           than June 1, 1993, the Director shall submit the  
12           plan required in paragraph (1) to the Committee on  
13           Energy and Commerce of the House of Representa-  
14           tives, and to the Committee on Labor and Human  
15           Resources of the Senate, together with an estimate  
16           of the funds needed for each of the fiscal years 1994  
17           through 1996 to implement the plan.

18           “(c) PARTICIPATING AGENCIES; COORDINATION AND  
19           COLLABORATION.—The Director—

20           “(1) shall provide for the conduct of activities  
21           under the Program by the Directors of the agencies  
22           of the National Institutes of Health involved in re-  
23           search with respect to trauma;

24           “(2) shall ensure that the activities of the Pro-  
25           gram are coordinated among such agencies; and

1           “(3) shall, as appropriate, provide for collabora-  
2           tion among such agencies in carrying out such ac-  
3           tivities.

4           “(d) CERTAIN ACTIVITIES OF PROGRAM.—The Pro-  
5           gram shall include—

6           “(1) studies with respect to all phases of trau-  
7           ma care, including prehospital, resuscitation, sur-  
8           gical intervention, critical care, infection control,  
9           wound healing, nutritional care and support, and  
10          medical rehabilitation care;

11          “(2) basic and clinical research regarding the  
12          response of the body to trauma and the acute treat-  
13          ment and medical rehabilitation of individuals who  
14          are the victims of trauma; and

15          “(3) basic and clinical research regarding trau-  
16          ma care for pediatric and geriatric patients.

17          “(e) MECHANISMS OF SUPPORT.—In carrying out the  
18          Program, the Director, acting through the Directors of the  
19          agencies referred to in subsection (c)(1), may make grants  
20          to public and nonprofit entities, including designated trau-  
21          ma centers.

22          “(f) RESOURCES.—The Director shall assure the  
23          availability of appropriate resources to carry out the Pro-  
24          gram, including the plan established under subsection (b)  
25          (including the activities described in subsection (d)).

1 “(g) COORDINATING COMMITTEE.—

2 “(1) IN GENERAL.—There shall be established  
3 a Trauma Research Interagency Coordinating Com-  
4 mittee (hereafter in this section referred to as the  
5 ‘Coordinating Committee’).

6 “(2) DUTIES.—The Coordinating Committee  
7 shall make recommendations regarding—

8 “(A) the activities of the Program to be  
9 carried out by each of the agencies represented  
10 on the Committee and the amount of funds  
11 needed by each of the agencies for such activi-  
12 ties; and

13 “(B) effective collaboration among the  
14 agencies in carrying out the activities.

15 “(3) COMPOSITION.—The Coordinating Com-  
16 mittee shall be composed of the Directors of each of  
17 the agencies that, under subsection (c), have respon-  
18 sibilities under the Program, and any other individ-  
19 uals who are practitioners in the trauma field as  
20 designated by the Director of the National Institutes  
21 of Health.

22 “(h) DEFINITIONS.—For purposes of this section:

23 “(1) The term ‘designated trauma center’ has  
24 the meaning given such term in section 1231(1).

1           “(2) The term ‘Director’ means the Director of  
2 the National Institutes of Health.

3           “(3) The term ‘trauma’ means any serious in-  
4 jury that could result in loss of life or in significant  
5 disability and that would meet pre-hospital triage  
6 criteria for transport to a designated trauma cen-  
7 ter.”.

8           (b) CONFORMING AMENDMENT.—Section 402 of the  
9 Public Health Service Act, as amended by section 208(c)  
10 of this Act, is amended by adding at the end the following  
11 new subsection:

12           “(k) The Director of NIH shall carry out the pro-  
13 gram established in part E of title XII (relating to inter-  
14 agency research on trauma).”.

15           **TITLE IV—NATIONAL CANCER**  
16                               **INSTITUTE**

17           **SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-**  
18                               **TIES REGARDING BREAST CANCER.**

19           Subpart 1 of part C of title IV of the Public Health  
20 Service Act (42 U.S.C. 285 et seq.) is amended by adding  
21 at the end the following new section:

22                               “BREAST AND GYNECOLOGICAL CANCERS

23           “SEC. 417. (a) EXPANSION AND COORDINATION OF  
24 ACTIVITIES.—The Director of the Institute, in consulta-  
25 tion with the National Cancer Advisory Board, shall ex-  
26 pand, intensify, and coordinate the activities of the Insti-

1 tute with respect to research on breast cancer, ovarian  
2 cancer, and other cancers of the reproductive system of  
3 women.

4 “(b) COORDINATION WITH OTHER INSTITUTES.—  
5 The Director of the Institute shall coordinate the activities  
6 of the Director under subsection (a) with similar activities  
7 conducted by other national research institutes and agen-  
8 cies of the National Institutes of Health to the extent that  
9 such Institutes and agencies have responsibilities that are  
10 related to breast cancer and other cancers of the reproduc-  
11 tive system of women.

12 “(c) PROGRAMS FOR BREAST CANCER.—

13 “(1) IN GENERAL.—In carrying out subsection  
14 (a), the Director of the Institute shall conduct or  
15 support research to expand the understanding of the  
16 cause of, and to find a cure for, breast cancer. Ac-  
17 tivities under such subsection shall provide for an  
18 expansion and intensification of the conduct and  
19 support of—

20 “(A) basic research concerning the etiology  
21 and causes of breast cancer;

22 “(B) clinical research and related activities  
23 concerning the causes, prevention, detection and  
24 treatment of breast cancer;

1           “(C) control programs with respect to  
2 breast cancer in accordance with section 412;

3           “(D) information and education programs  
4 with respect to breast cancer in accordance with  
5 section 413; and

6           “(E) research and demonstration centers  
7 with respect to breast cancer in accordance with  
8 section 414, including the development and op-  
9 eration of centers for breast cancer research to  
10 bring together basic and clinical, biomedical and  
11 behavioral scientists to conduct basic, clinical,  
12 epidemiological, psychosocial, prevention and  
13 treatment research and related activities on  
14 breast cancer.

15 Not less than six centers shall be operated under  
16 subparagraph (E). Activities of such centers should  
17 include supporting new and innovative research and  
18 training programs for new researchers. Such centers  
19 shall give priority to expediting the transfer of re-  
20 search advances to clinical applications.

21           “(2) IMPLEMENTATION OF PLAN FOR PRO-  
22 GRAMS.—

23           “(A) The Director of the Institute shall en-  
24 sure that the research programs described in  
25 paragraph (1) are implemented in accordance

1 with a plan for the programs. Such plan shall  
2 include comments and recommendations that  
3 the Director of the Institute considers appro-  
4 priate, with due consideration provided to the  
5 professional judgment needs of the Institute as  
6 expressed in the annual budget estimate pre-  
7 pared in accordance with section 413(9). The  
8 Director of the Institute, in consultation with  
9 the National Cancer Advisory Board, shall peri-  
10 odically review and revise such plan.

11 “(B) Not later than May 1, 1993, the Di-  
12 rector of the Institute shall submit a copy of  
13 the plan to the President’s Cancer Panel, the  
14 Secretary and the Director of NIH.

15 “(C) The Director of the Institute shall  
16 submit any revisions of the plan to the Presi-  
17 dent’s Cancer Panel, the Secretary, and the Di-  
18 rector of NIH.

19 “(D) The Secretary shall provide a copy of  
20 the plan submitted under subparagraph (A),  
21 and any revisions submitted under subpara-  
22 graph (C), to the Committee on Energy and  
23 Commerce of the House of Representatives and  
24 the Committee on Labor and Human Resources  
25 of the Senate.

1       “(d) OTHER CANCERS.—In carrying out subsection  
2 (a), the Director of the Institute shall conduct or support  
3 research on ovarian cancer and other cancers of the repro-  
4 ductive system of women. Activities under such subsection  
5 shall provide for the conduct and support of—

6               “(1) basic research concerning the etiology and  
7 causes of ovarian cancer and other cancers of the re-  
8 productive system of women;

9               “(2) clinical research and related activities into  
10 the causes, prevention, detection and treatment of  
11 ovarian cancer and other cancers of the reproductive  
12 system of women;

13               “(3) control programs with respect to ovarian  
14 cancer and other cancers of the reproductive system  
15 of women in accordance with section 412;

16               “(4) information and education programs with  
17 respect to ovarian cancer and other cancers of the  
18 reproductive system of women in accordance with  
19 section 413; and

20               “(5) research and demonstration centers with  
21 respect to ovarian cancer and cancers of the repro-  
22 ductive system in accordance with section 414.

23       “(e) REPORT.—The Director of the Institute shall  
24 prepare, for inclusion in the biennial report submitted  
25 under section 407, a report that describes the activities



1 of the National Cancer Institute under the research pro-  
2 grams referred to in subsection (a), that shall include—

3 “(1) a description of the research plan with re-  
4 spect to breast cancer prepared under subsection (c);

5 “(2) an assessment of the development, revi-  
6 sion, and implementation of such plan;

7 “(3) a description and evaluation of the  
8 progress made, during the period for which such re-  
9 port is prepared, in the research programs on breast  
10 cancer and cancers of the reproductive system of  
11 women;

12 “(4) a summary and analysis of expenditures  
13 made, during the period for which such report is  
14 made, for activities with respect to breast cancer and  
15 cancers of the reproductive system of women con-  
16 ducted and supported by the National Institutes of  
17 Health; and

18 “(5) such comments and recommendations as  
19 the Director considers appropriate.”.

20 **SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-**  
21 **TIES REGARDING PROSTATE CANCER.**

22 Subpart 1 of part C of title IV of the Public Health  
23 Service Act, as amended by section 401 of this Act, is  
24 amended by adding at the end the following new section:

1                                   “PROSTATE CANCER

2           “SEC. 417A. (a) EXPANSION AND COORDINATION OF  
3 ACTIVITIES.—The Director of the Institute, in consulta-  
4 tion with the National Cancer Advisory Board, shall ex-  
5 pand, intensify, and coordinate the activities of the Insti-  
6 tute with respect to research on prostate cancer.

7           “(b) COORDINATION WITH OTHER INSTITUTES.—  
8 The Director of the Institute shall coordinate the activities  
9 of the Director under subsection (a) with similar activities  
10 conducted by other national research institutes and agen-  
11 cies of the National Institutes of Health to the extent that  
12 such Institutes and agencies have responsibilities that are  
13 related to prostate cancer.

14           “(c) PROGRAMS.—

15                   “(1) IN GENERAL.—In carrying out subsection  
16 (a), the Director of the Institute shall conduct or  
17 support research to expand the understanding of the  
18 cause of, and to find a cure for, prostate cancer. Ac-  
19 tivities under such subsection shall provide for an  
20 expansion and intensification of the conduct and  
21 support of—

22                                   “(A) basic research concerning the etiology  
23                                   and causes of prostate cancer;

1           “(B) clinical research and related activities  
2           concerning the causes, prevention, detection and  
3           treatment of prostate cancer;

4           “(C) prevention and control and early de-  
5           tection programs with respect to prostate can-  
6           cer in accordance with section 412, particularly  
7           as it relates to intensifying research on the role  
8           of prostate specific antigen for the screening  
9           and early detection of prostate cancer;

10          “(D) an Inter-Institute Task Force, under  
11          the direction of the Director of the Institute, to  
12          provide coordination between relevant National  
13          Institutes of Health components of research ef-  
14          forts on prostate cancer;

15          “(E) control programs with respect to  
16          prostate cancer in accordance with section 412;

17          “(F) information and education programs  
18          with respect to prostate cancer in accordance  
19          with section 413; and

20          “(G) research and demonstration centers  
21          with respect to prostate cancer in accordance  
22          with section 414, including the development and  
23          operation of centers for prostate cancer re-  
24          search to bring together basic and clinical, bio-  
25          medical and behavioral scientists to conduct

1           basic, clinical, epidemiological, psychosocial,  
2           prevention and treatment research and related  
3           activities on prostate cancer.

4           Not less than six centers shall be operated under  
5           subparagraph (G). Activities of such centers should  
6           include supporting new and innovative research and  
7           training programs for new researchers. Such centers  
8           shall give priority to expediting the transfer of re-  
9           search advances to clinical applications.

10           “(2) IMPLEMENTATION OF PLAN FOR PRO-  
11           GRAMS.—

12           “(A) The Director of the Institute shall en-  
13           sure that the research programs described in  
14           paragraph (1) are implemented in accordance  
15           with a plan for the programs. Such plan shall  
16           include comments and recommendations that  
17           the Director of the Institute considers appro-  
18           priate, with due consideration provided to the  
19           professional judgment needs of the Institute as  
20           expressed in the annual budget estimate pre-  
21           pared in accordance with section 413(9). The  
22           Director of the Institute, in consultation with  
23           the National Cancer Advisory Board, shall peri-  
24           odically review and revise such plan.

1           “(B) Not later than May 1, 1993, the Di-  
2           rector of the Institute shall submit a copy of  
3           the plan to the President’s Cancer Panel, the  
4           Secretary and the Director of NIH.

5           “(C) The Director of the Institute shall  
6           submit any revisions of the plan to the Presi-  
7           dent’s Cancer Panel, the Secretary, and the Di-  
8           rector of NIH.

9           “(D) The Secretary shall provide a copy of  
10          the plan submitted under subparagraph (A),  
11          and any revisions submitted under subpara-  
12          graph (C), to the Committee on Energy and  
13          Commerce of the House of Representatives and  
14          the Committee on Labor and Human Resources  
15          of the Senate.”.

16 **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

17          (a) IN GENERAL.—Subpart 1 of part C of title IV  
18          of the Public Health Service Act, as amended by section  
19          402 of this Act, is amended by adding at the end the fol-  
20          lowing new section:

21                 “AUTHORIZATION OF APPROPRIATIONS

22                 “SEC. 417B. (a) ACTIVITIES GENERALLY.—For the  
23          purpose of carrying out this subpart, there are authorized  
24          to be appropriated \$2,200,000,000 for fiscal year 1994,  
25          and such sums as may be necessary for each of the fiscal  
26          years 1995 and 1996.

1       “(b) BREAST CANCER AND GYNECOLOGICAL CAN-  
2 CERS.—

3           “(1) BREAST CANCER.—

4                   “(A) For the purpose of carrying out sub-  
5 paragraph (A) of section 417(c)(1), there are  
6 authorized to be appropriated \$225,000,000 for  
7 fiscal year 1994, and such sums as may be nec-  
8 essary for each of the fiscal years 1995 and  
9 1996. Such authorizations of appropriations are  
10 in addition to the authorizations of appropria-  
11 tions established in subsection (a) with respect  
12 to such purpose.

13                   “(B) For the purpose of carrying out sub-  
14 paragraphs (B) through (E) of section  
15 417(c)(1), there are authorized to be appro-  
16 priated \$100,000,000 for fiscal year 1994, and  
17 such sums as may be necessary for each of the  
18 fiscal years 1995 and 1996. Such authoriza-  
19 tions of appropriations are in addition to the  
20 authorizations of appropriations established in  
21 subsection (a) with respect to such purpose.

22                   “(2) OTHER CANCERS.—For the purpose of  
23 carrying out subsection (d) of section 417, there are  
24 authorized to be appropriated \$75,000,000 for fiscal  
25 year 1994, and such sums as are necessary for each

1 of the fiscal years 1995 and 1996. Such authoriza-  
2 tions of appropriations are in addition to the author-  
3 izations of appropriations established in subsection  
4 (a) with respect to such purpose.

5 “(c) PROSTATE CANCER.—For the purpose of carry-  
6 ing out section 417A, there are authorized to be appro-  
7 priated \$72,000,000 for fiscal year 1994, and such sums  
8 as may be necessary for each of the fiscal years 1995 and  
9 1996. Such authorizations of appropriations are in addi-  
10 tion to the authorizations of appropriations established in  
11 subsection (a) with respect to such purpose.

12 “(d) ALLOCATION REGARDING CANCER CONTROL.—  
13 Of the amounts appropriated for the National Cancer In-  
14 stitute for a fiscal year, the Director of the Institute shall  
15 make available not less than 10 percent for carrying out  
16 the cancer control activities authorized in section 412 and  
17 for which budget estimates are made under section  
18 413(b)(9) for the fiscal year.”.

19 (b) SPECIAL RULE REGARDING FUNDS FOR SECTION  
20 412 FOR FISCAL YEAR 1994.—Notwithstanding section  
21 417B(d) of the Public Health Service Act, as added by  
22 subsection (a) of this section, the amount made available  
23 under such section for fiscal year 1994 for carrying out  
24 section 412 of such Act shall be an amount not less than  
25 an amount equal to 75 percent of the amount specified

1 for activities under such section 412 in the budget esti-  
2 mate made under section 413(b)(9) of such Act for such  
3 fiscal year.

4 (c) CONFORMING AMENDMENTS.—

5 (1) IN GENERAL.—Section 408 of the Public  
6 Health Service Act (42 U.S.C. 284c) is amended—

7 (A) by striking subsection (a);

8 (B) by redesignating subsection (b) as sub-  
9 section (a);

10 (C) by redesignating paragraph (5) of sub-  
11 section (a) (as so redesignated) as subsection  
12 (b); and

13 (D) by amending the heading for the sec-  
14 tion to read as follows:

15 “CERTAIN USES OF FUNDS”.

16 (2) CROSS-REFERENCE.—Section 464F of the  
17 Public Health Service Act (42 U.S.C. 285m–6) is  
18 amended by striking “section 408(b)(1)” and insert-  
19 ing “section 408(a)(1)”.

20 **TITLE V—NATIONAL HEART,**  
21 **LUNG, AND BLOOD INSTITUTE**

22 **SEC. 501. EDUCATION AND TRAINING.**

23 Section 421(b) of the Public Health Service Act (42  
24 U.S.C. 285b–3(b)) is amended—

25 (1) in paragraph (3), by striking “and” after  
26 the semicolon at the end;



1           (2) in paragraph (4), by striking the period at  
2           the end and inserting “; and”; and

3           (3) by inserting after paragraph (4) the follow-  
4           ing new paragraph:

5           “(5) shall, in consultation with the advisory  
6           council for the Institute, conduct appropriate intra-  
7           mural training and education programs, including  
8           continuing education and laboratory and clinical re-  
9           search training programs.”.

10 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CAR-**  
11 **DIOVASCULAR DISEASES.**

12           Section 422(a)(1) of the Public Health Service Act  
13 (42 U.S.C. 285b-4(a)(1)) is amended—

14           (1) in subparagraph (B), by striking “and” at  
15           the end;

16           (2) in subparagraph (C), by striking the period  
17           and inserting “; and”; and

18           (3) by adding at the end thereof the following  
19           new subparagraph:

20           “(D) three centers for basic and clinical re-  
21           search into, training in, and demonstration of, ad-  
22           vanced diagnostic, prevention, and treatment (in-  
23           cluding genetic studies, intrauterine environment  
24           studies, postnatal studies, heart arrhythmias, and

1       acquired heart disease and preventive cardiology) for  
2       cardiovascular diseases in children.”.

3       **SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.**

4       Subpart 2 of part C of title IV of the Public Health  
5       Service Act (42 U.S.C. 285b et seq.) is amended by adding  
6       at the end the following new section:

7               “NATIONAL CENTER ON SLEEP DISORDERS

8               “SEC. 424. (a) Not later than 1 year after the date  
9       of the enactment of the National Institutes of Health Re-  
10       vitalization Act of 1993, the Director of the Institute shall  
11       establish the National Center on Sleep Disorders (in this  
12       section referred to as the ‘Center’). The Center shall head-  
13       ed by a director, who shall be appointed by the Director  
14       of the Institute.

15              “(b) The general purpose of the Center is the conduct  
16       and support of research, training, health information dis-  
17       semination, and other activities with respect to sleep dis-  
18       orders.”.

19       **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

20       Subpart 2 of part C of title IV of the Public Health  
21       Service Act, as amended by section 503 of this Act, is  
22       amended by adding at the end the following section:

23               “AUTHORIZATION OF APPROPRIATIONS

24              “SEC. 425. (a) For the purpose of carrying out this  
25       subpart, there are authorized to be appropriated  
26       \$1,500,000,000 for fiscal year 1994, and such sums as

1 may be necessary for each of the fiscal years 1995 and  
2 1996.

3 “(b) Of the amounts appropriated under paragraph  
4 (1) for a fiscal year, the Director of the Institute shall  
5 make available not less than 10 percent for carrying out  
6 prevention and control activities authorized in section  
7 419.”.

8 **TITLE VI—NATIONAL INSTITUTE**  
9 **ON DIABETES AND DIGESTIVE**  
10 **AND KIDNEY DISEASES**

11 **SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-**  
12 **ORDERS.**

13 Subpart 3 of part C of title IV of the Public Health  
14 Service Act (42 U.S.C. 285c et seq.) is amended by adding  
15 at the end the following new section:

16 “NUTRITIONAL DISORDERS PROGRAM

17 “SEC. 434. (a) The Director of the Institute shall es-  
18 tablish a program of conducting and supporting research,  
19 training, health information dissemination, and other  
20 activities with respect to nutritional disorders, including  
21 obesity.

22 “(b) In carrying out the program established under  
23 subsection (a), the Director of the Institute shall conduct  
24 and support each of the activities described in such sub-  
25 section. The Director of NIH shall ensure that, as appro-  
26 priate, the other national research institutes and agencies

1 of the National Institutes of Health have responsibilities  
2 regarding such activities.

3 “(c) In carrying out the program established under  
4 subsection (a), the Director of the Institute shall carry out  
5 activities to facilitate and enhance knowledge and under-  
6 standing of nutritional disorders, including obesity, on the  
7 part of health professionals, patients, and the public  
8 through the effective dissemination of information.”.

9 (b) DEVELOPMENT AND EXPANSION OF RESEARCH  
10 AND TRAINING CENTERS.—Section 431 of the Public  
11 Health Service Act (42 U.S.C. 285c-5) is amended—

12 (1) by redesignating subsection (d) as sub-  
13 section (e); and

14 (2) by inserting after subsection (c) the follow-  
15 ing new subsection:

16 “(d)(1) The Director of the Institute shall, subject  
17 to the extent of amounts made available in appropriations  
18 Acts, provide for the development or substantial expansion  
19 of centers for research and training regarding nutritional  
20 disorders, including obesity.

21 “(2) The Director of the Institute shall carry out  
22 paragraph (1) in collaboration with the Director of the  
23 National Cancer Institute and with the Directors of such  
24 other agencies of the National Institutes of Health as the  
25 Director of NIH determines to be appropriate.

1       “(3) Each center developed or expanded under para-  
2 graph (1) shall—

3           “(A) utilize the facilities of a single institution,  
4 or be formed from a consortium of cooperating insti-  
5 tutions, meeting such research and training quali-  
6 fications as may be prescribed by the Director;

7           “(B) conduct basic and clinical research into  
8 the cause, diagnosis, early detection, prevention, con-  
9 trol and treatment of nutritional disorders, including  
10 obesity and the impact of nutrition and diet on child  
11 development;

12           “(C) conduct training programs for physicians  
13 and allied health professionals in current methods of  
14 diagnosis and treatment of such diseases and com-  
15 plications, and in research in such disorders; and

16           “(D) conduct information programs for physi-  
17 cians and allied health professionals who provide pri-  
18 mary care for patients with such disorders or com-  
19 plications.”.

1 **TITLE VII—NATIONAL INSTI-**  
2 **TUTE ON ARTHRITIS AND**  
3 **MUSCULOSKELETAL AND**  
4 **SKIN DISEASES**

5 **SEC. 701. JUVENILE ARTHRITIS.**

6 (a) PURPOSE.—Section 435 of the Public Health  
7 Service Act (42 U.S.C. 285d) is amended by striking “and  
8 other programs” and all that follows and inserting the fol-  
9 lowing: “and other programs with respect to arthritis and  
10 musculoskeletal and skin diseases (including sports-related  
11 disorders), with particular attention to the effect of these  
12 diseases on children.”.

13 (b) PROGRAMS.—Section 436 (42 U.S.C. 285d–1) is  
14 amended—

15 (1) in subsection (a), by inserting after the sec-  
16 ond sentence, the following: “The plan shall place  
17 particular emphasis upon expanding research into  
18 better understanding the causes and the develop-  
19 ment of effective treatments for arthritis affecting  
20 children.”; and

21 (2) in subsection (b)—

22 (A) by striking “and” at the end of para-  
23 graph (3);

24 (B) by striking the period at the end of  
25 paragraph (4) and inserting “; and”; and

1 (C) by adding at the end thereof the fol-  
2 lowing new paragraph:

3 “(5) research into the causes of arthritis affect-  
4 ing children and the development, trial, and evalua-  
5 tion of techniques, drugs and devices used in the di-  
6 agnosis, treatment (including medical rehabilitation),  
7 and prevention of arthritis in children.”.

8 (c) CENTERS.—Section 441 of the Public Health  
9 Service Act (42 U.S.C. 286d–6) is amended by adding at  
10 the end thereof the following new subsection:

11 “(f) Not later than October 1, 1994, the Director  
12 shall establish a multipurpose arthritis and musculo-  
13 skeletal disease center for the purpose of expanding the  
14 level of research into the cause, diagnosis, early detection,  
15 prevention, control, and treatment of, and rehabilitation  
16 of children with arthritis and musculoskeletal diseases.”.

17 (d) ADVISORY BOARD.—

18 (1) TITLE.—Section 442(a) of the Public  
19 Health Service Act (42 U.S.C. 285d–7(a)) is amend-  
20 ed by inserting after “Arthritis” the the first place  
21 such term appears the following: “and Musculo-  
22 skeletal and Skin Diseases”.

23 (2) COMPOSITION.—Section 442(b) of the Pub-  
24 lic Health Service Act (42 U.S.C. 285d–7(b)) is

1 amended—Section 442(b) of the Public Health Serv-  
2 ice Act (42 U.S.C. 285d-7(b)) is amended—

3 (A) in the matter preceding paragraph (1),  
4 by striking “eighteen” and inserting “twenty”;  
5 and

6 (B) in paragraph (1)(B)—

7 (i) by striking “six” and inserting  
8 “eight”; and

9 (ii) by striking “including” and all  
10 that follows and inserting the following:  
11 “including one member who is a person  
12 who has such a disease, one person who is  
13 the parent of an adult with such a disease,  
14 and two members who are parents of chil-  
15 dren with arthritis.”.

16 (3) ANNUAL REPORT.—Section 442(j) of the  
17 Public Health Service Act (42 U.S.C. 285d-7(j)) is  
18 amended—

19 (1) by striking “and” at the end of paragraph  
20 (3);

21 (2) by striking the period at the end of para-  
22 graph (4) and inserting “; and”; and

23 (3) by adding at the end the following para-  
24 graph:



1           “(5) contains recommendations for expanding  
2           the Institute’s funding of research directly applicable  
3           to the cause, diagnosis, early detection, prevention,  
4           control, and treatment of, and rehabilitation of chil-  
5           dren with arthritis and musculoskeletal diseases.”.

## 6           **TITLE VIII—NATIONAL** 7           **INSTITUTE ON AGING**

### 8           **SEC. 801. ALZHEIMER’S DISEASE REGISTRY.**

9           (a) IN GENERAL.—Section 12 of Public Law 99–158  
10          (99 Stat. 885) is—

11           (1) transferred to subpart 5 of part C of title  
12          IV of the Public Health Service Act (42 U.S.C. 285e  
13          et seq.);

14           (2) redesignated as section 445G; and

15           (3) inserted after section 445F of such Act.

16          (b) TECHNICAL AND CONFORMING AMENDMENTS.—  
17          Section 445G of the Public Health Service Act, as trans-  
18          ferred and inserted by subsection (a) of this section, is  
19          amended—

20           (1) by striking the section heading and all that  
21          follows through “may make a grant” in subsection  
22          (a) and inserting the following:

23                           “ALZHEIMER’S DISEASE REGISTRY

24           “SEC. 445G. (a) IN GENERAL.—The Director of the  
25          Institute may make a grant”; and

26           (2) by striking subsection (c).

1 **SEC. 802. AGING PROCESSES REGARDING WOMEN.**

2 Subpart 5 of part C of title IV of the Public Health  
3 Service Act, as amended by section 801 of this Act, is  
4 amended by adding at the end the following new section:

5 “AGING PROCESSES REGARDING WOMEN

6 “SEC. 445H. The Director of the Institute, in addi-  
7 tion to other special functions specified in section 444 and  
8 in cooperation with the Directors of the other national re-  
9 search institutes and agencies of the National Institutes  
10 of Health, shall conduct research into the aging processes  
11 of women, with particular emphasis given to the effects  
12 of menopause and the physiological and behavioral  
13 changes occurring during the transition from pre- to post-  
14 menopause, and into the diagnosis, disorders, and com-  
15 plications related to aging and loss of ovarian hormones  
16 in women.”.

17 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

18 Subpart 5 of part C of title IV of the Public Health  
19 Service Act, as amended by section 802 of this Act, is  
20 amended by adding at the end the following new section:

21 “AUTHORIZATION OF APPROPRIATIONS

22 “SEC. 445I. For the purpose of carrying out this sub-  
23 part, there are authorized to be appropriated  
24 \$500,000,000 for fiscal year 1994, and such sums as may  
25 be necessary for each of the fiscal years 1995 and 1996.”.

1 **SEC. 804. CONFORMING AMENDMENT.**

2 Section 445C of the Public Health Service Act (42  
3 U.S.C. 285e–5(b)) is amended—

4 (1) in subsection (b)(1), in the first sentence,  
5 by inserting after “Council” the following: “on Alz-  
6 heimer’s Disease (hereafter in this section referred  
7 to as the ‘Council’)”; and

8 (2) by adding at the end the following new sub-  
9 section:

10 “(d) For purposes of this section, the term ‘Council  
11 on Alzheimer’s Disease’ means the council established in  
12 section 911(a) of Public Law 99–660.”.

13 **TITLE IX—NATIONAL INSTITUTE**  
14 **OF ALLERGY AND INFEC-**  
15 **TIOUS DISEASES**

16 **SEC. 901. TROPICAL DISEASES.**

17 Section 446 of the Public Health Service Act (42  
18 U.S.C. 285f) is amended by inserting before the period  
19 the following: “, including tropical diseases”.

20 **SEC. 902. CHRONIC FATIGUE SYNDROME.**

21 (a) RESEARCH CENTERS.—Subpart 6 of part C of  
22 title IV of the Public Health Service Act (42 U.S.C. 285f)  
23 is amended by adding at the end the following new section:

1 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE  
2 SYNDROME

3 “SEC. 447. (a) The Director of the Institute, after  
4 consultation with the advisory council for the Institute,  
5 may make grants to, or enter into contracts with, public  
6 or nonprofit private entities for the development and oper-  
7 ation of centers to conduct basic and clinical research on  
8 chronic fatigue syndrome.

9 “(b) Each center assisted under this section shall use  
10 the facilities of a single institution, or be formed from a  
11 consortium of cooperating institutions, meeting such re-  
12 quirements as may be prescribed by the Director of the  
13 Institute.”.

14 (b) EXTRAMURAL STUDY SECTION.—Not later than  
15 6 months after the date of enactment of this Act, the Sec-  
16 retary of Health and Human Services shall establish an  
17 extramural study section for chronic fatigue syndrome re-  
18 search.

19 (c) REPRESENTATIVES.—The Secretary of Health  
20 and Human Services, acting through the Director of the  
21 National Institutes of Health, shall ensure that appro-  
22 priate individuals with expertise in chronic fatigue syn-  
23 drome or neuromuscular diseases and representative of a  
24 variety of disciplines and fields within the research com-

1 munity are appointed to appropriate National Institutes  
2 of Health advisory committees and boards.

3 **TITLE X—NATIONAL INSTITUTE**  
4 **OF CHILD HEALTH AND**  
5 **HUMAN DEVELOPMENT**

6 **Subtitle A—Research Centers With**  
7 **Respect to Contraception and**  
8 **Research Centers With Respect**  
9 **to Infertility**

10 **SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN-**  
11 **TERS.**

12 Subpart 7 of part C of title IV of the Public Health  
13 Service Act, as amended by section 3 of Public Law 101–  
14 613, is amended by adding at the end the following new  
15 section:

16 “RESEARCH CENTERS WITH RESPECT TO  
17 CONTRACEPTION AND INFERTILITY

18 “SEC. 452A. (a) The Director of the Institute, after  
19 consultation with the advisory council for the Institute,  
20 shall make grants to, or enter into contracts with, public  
21 or nonprofit private entities for the development and oper-  
22 ation of centers to conduct activities for the purpose of  
23 improving methods of contraception and centers to con-  
24 duct activities for the purpose of improving methods of  
25 diagnosis and treatment of infertility.

1       “(b) In carrying out subsection (a), the Director of  
2 the Institute shall, subject to the extent of amounts made  
3 available in appropriations Acts, provide for the establish-  
4 ment of three centers with respect to contraception and  
5 for two centers with respect to infertility.

6       “(c)(1) Each center assisted under this section shall,  
7 in carrying out the purpose of the center involved—

8           “(A) conduct clinical and other applied re-  
9 search, including—

10               “(i) for centers with respect to contracep-  
11 tion, clinical trials of new or improved drugs  
12 and devices for use by males and females (in-  
13 cluding barrier methods); and

14               “(ii) for centers with respect to infertility,  
15 clinical trials of new or improved drugs and de-  
16 vices for the diagnosis and treatment of infertil-  
17 ity in males and females;

18           “(B) develop protocols for training physicians,  
19 scientists, nurses, and other health and allied health  
20 professionals;

21           “(C) conduct training programs for such indi-  
22 viduals;

23           “(D) develop model continuing education pro-  
24 grams for such professionals; and

1           “(E) disseminate information to such profes-  
2           sionals and the public.

3           “(2) A center may use funds provided under sub-  
4           section (a) to provide stipends for health and allied health  
5           professionals enrolled in programs described in subpara-  
6           graph (C) of paragraph (1), and to provide fees to individ-  
7           uals serving as subjects in clinical trials conducted under  
8           such paragraph.

9           “(d) The Director of the Institute shall, as appro-  
10          priate, provide for the coordination of information among  
11          the centers assisted under this section.

12          “(e) Each center assisted under subsection (a) shall  
13          use the facilities of a single institution, or be formed from  
14          a consortium of cooperating institutions, meeting such re-  
15          quirements as may be prescribed by the Director of the  
16          Institute.

17          “(f) Support of a center under subsection (a) may  
18          be for a period not exceeding 5 years. Such period may  
19          be extended for one or more additional periods not exceed-  
20          ing 5 years if the operations of such center have been re-  
21          viewed by an appropriate technical and scientific peer re-  
22          view group established by the Director and if such group  
23          has recommended to the Director that such period should  
24          be extended.

1       “(g) For the purpose of carrying out this section,  
2 there are authorized to be appropriated \$30,000,000 for  
3 fiscal year 1994, and such sums as may be necessary for  
4 each of the fiscal years 1995 and 1996.”.

5 **SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH**  
6                   **WITH RESPECT TO CONTRACEPTION AND IN-**  
7                   **FERTILITY.**

8       Part G of title IV of the Public Health Service Act,  
9 as redesignated by section 141(a)(2) of this Act, is amend-  
10 ed by inserting after section 487A the following section:

11       “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH  
12       RESPECT TO CONTRACEPTION AND INFERTILITY

13       “SEC. 487B. (a) The Secretary, in consultation with  
14 the Director of the National Institute of Child Health and  
15 Human Development, shall establish a program of enter-  
16 ing into agreements with qualified health professionals (in-  
17 cluding graduate students) under which such health pro-  
18 fessionals agree to conduct research with respect to con-  
19 traception, or with respect to infertility, in consideration  
20 of the Federal Government agreeing to repay, for each  
21 year of such service, not more than \$20,000 of the prin-  
22 cipal and interest of the educational loans of such health  
23 professionals.

24       “(b) The provisions of sections 338B, 338C, and  
25 338E shall apply to the program established in subsection  
26 (a) to the same extent and in the same manner as such



1 provisions apply to the National Health Service Corps  
2 Loan Repayment Program established in subpart III of  
3 part D of title III.

4 “(c) Amounts appropriated for carrying out this sec-  
5 tion shall remain available until the expiration of the sec-  
6 ond fiscal year beginning after the fiscal year for which  
7 the amounts were appropriated.”.

## 8 **Subtitle B—Program Regarding** 9 **Obstetrics and Gynecology**

### 10 **SEC. 1011. ESTABLISHMENT OF PROGRAM.**

11 Subpart 7 of part C of title IV of the Public Health  
12 Service Act, as amended by section 1001 of this Act, is  
13 amended by adding at the end the following new section:

14 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

15 “SEC. 452B. The Director of the Institute shall es-  
16 tablish and maintain within the Institute an intramural  
17 laboratory and clinical research program in obstetrics and  
18 gynecology.”.

## 19 **Subtitle C—Child Health Research** 20 **Centers**

### 21 **SEC. 1021. ESTABLISHMENT OF CENTERS.**

22 Subpart 7 of part C of title IV of the Public Health  
23 Service Act, as amended by section 1011 of this Act, is  
24 amended by adding at the end the following new section:

1 “CHILD HEALTH RESEARCH CENTERS  
2 “SEC. 452C. The Director of the Institute shall de-  
3 velop and support centers for conducting research with re-  
4 spect to child health. Such centers shall give priority to  
5 the expeditious transfer of advances from basic science to  
6 clinical applications and improving the care of infants and  
7 children.”.

8 **Subtitle D—Study Regarding**  
9 **Adolescent Health**

10 **SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.**

11 Subpart 7 of part C of title IV of the Public Health  
12 Service Act, as amended by section 1021 of this Act, is  
13 amended by adding at the end the following new section:

14 “PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT  
15 HEALTH

16 “SEC. 452D. (a) IN GENERAL.—The Director of the  
17 Institute shall conduct a study for the purpose of provid-  
18 ing information on the general health and well-being of  
19 adolescents in the United States, including, with respect  
20 to such adolescents, information on—

21 “(1) the behaviors that promote health and the  
22 behaviors that are detrimental to health; and

23 “(2) the influence on health of factors particu-  
24 lar to the communities in which the adolescents  
25 reside.

26 “(b) DESIGN OF STUDY.—

1           “(1) IN GENERAL.—The study required in sub-  
2           section (a) shall be a longitudinal study in which a  
3           substantial number of adolescents participate as sub-  
4           jects. With respect to the purpose described in such  
5           subsection, the study shall monitor the subjects  
6           throughout the period of the study to determine the  
7           health status of the subjects and any change in such  
8           status over time.

9           “(2) POPULATION-SPECIFIC ANALYSES.—The  
10          study required in subsection (a) shall be conducted  
11          with respect to the population of adolescents who are  
12          female, the population of adolescents who are male,  
13          various socioeconomic populations of adolescents,  
14          and various racial and ethnic populations of adoles-  
15          cents. The study shall be designed and conducted in  
16          a manner sufficient to provide for a valid analysis of  
17          whether there are significant differences among such  
18          populations in health status and whether and to  
19          what extent any such differences are due to factors  
20          particular to the populations involved.

21          “(c) COORDINATION WITH WOMEN’S HEALTH INI-  
22          TIATIVE.—With respect to the national study of women  
23          being conducted by the Secretary and known as the Wom-  
24          en’s Health Initiative, the Secretary shall ensure that such  
25          study is coordinated with the component of the study re-

1 quired in subsection (a) that concerns adolescent females,  
 2 including coordination in the design of the 2 studies.

3 “(d) ALLOCATION OF FUNDS FOR STUDY.—Of the  
 4 amounts appropriated for each of the fiscal years 1994  
 5 through 1996 for the National Institute of Child Health  
 6 and Human Development, the Secretary of Health and  
 7 Human Services, acting through the Director of such In-  
 8 stitute, shall reserve \$3,000,000 to conduct the study re-  
 9 quired in subsection (a). The amounts so reserved shall  
 10 remain available until expended.”.

11 **TITLE XI—NATIONAL EYE**  
 12 **INSTITUTE**

13 **SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.**

14 (a) IN GENERAL.—Subpart 9 of part C of title IV  
 15 of the Public Health Service Act (42 U.S.C. 285i) is  
 16 amended by adding at the end the following new section:

17 “CLINICAL RESEARCH ON EYE CARE AND DIABETES

18 “SEC. 456. (a) PROGRAM OF GRANTS.—The Director  
 19 of the Institute, in consultation with the advisory council  
 20 for the Institute, may award not more than three grants  
 21 for the establishment and support of centers for clinical  
 22 research on eye care for individuals with diabetes.

23 “(b) AUTHORIZED EXPENDITURES.—The purposes  
 24 for which a grant under subsection (a) may be expended  
 25 include equipment for the research described in such sub-

1 section and the construction and modernization of facili-  
2 ties for such research.”.

3 (b) CONFORMING AMENDMENT.—Section 455 of the  
4 Public Health Service Act (42 U.S.C. 285i) is amended  
5 in the second sentence by striking “The Director” and in-  
6 serting “Subject to section 456, the Director”.

7 **TITLE XII—NATIONAL INSTI-**  
8 **TUTE OF NEUROLOGICAL DIS-**  
9 **ORDERS AND STROKE**

10 **SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.**

11 Subpart 10 of part C of title IV of the Public Health  
12 Service Act (42 U.S.C. 285j et seq.) is amended by adding  
13 at the end the following new section:

14 “RESEARCH ON MULTIPLE SCLEROSIS

15 “SEC. 460. The Director of the Institute shall con-  
16 duct and support research on multiple sclerosis, especially  
17 research on effects of genetics and hormonal changes on  
18 the progress of the disease.”.

19 **TITLE XIII—NATIONAL INSTI-**  
20 **TUTE OF ENVIRONMENTAL**  
21 **HEALTH SCIENCES**

22 **SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TEST-**  
23 **ING PROGRAM.**

24 (a) IN GENERAL.—Subpart 12 of part C of title IV  
25 of the Public Health Service Act (42 U.S.C. 285l) is  
26 amended by adding at the end the following new section:



1           “(5) to communicate the results of research to  
2           government agencies, to medical, scientific, and reg-  
3           ulatory communities, and to the public; and

4           “(6) to integrate related activities of the De-  
5           partment of Health and Human Services.”.

6           (b) TECHNICAL AMENDMENT.—Section 463 of the  
7           Public Health Service Act (42 U.S.C. 285l) is amended  
8           by inserting after “Sciences” the following: “(hereafter in  
9           this subpart referred to as the ‘Institute’)”.

## 10   **TITLE XIV—NATIONAL LIBRARY** 11                                   **OF MEDICINE**

### 12   **Subtitle A—General Provisions**

#### 13   **SEC. 1401. ADDITIONAL AUTHORITIES.**

14           (a) IN GENERAL.—Section 465(b) of the Public  
15           Health Service Act (42 U.S.C. 286(b)) is amended—

16                   (1) by striking “and” after the semicolon at the  
17                   end of paragraph (5);

18                   (2) by redesignating paragraph (6) as para-  
19                   graph (8); and

20                   (3) by inserting after paragraph (5) the follow-  
21                   ing new paragraphs:

22                           “(6) publicize the availability from the Library  
23                   of the products and services described in any of  
24                   paragraphs (1) through (5);

1           “(7) promote the use of computers and tele-  
2           communications by health professionals (including  
3           health professionals in rural areas) for the purpose  
4           of improving access to biomedical information for  
5           health care delivery and medical research; and”.

6           (b) LIMITATION REGARDING GRANTS.—Section  
7           474(b)(2) of the Public Health Service Act (42 U.S.C.  
8           286b–S(b)(2)) is amended by striking “\$750,000” and in-  
9           serting “\$1,000,000”.

10          (c) TECHNICAL AND CONFORMING AMENDMENTS.—

11           (1) REPEAL OF CERTAIN AUTHORITY.—Section  
12           215 of the Department of Health and Human Serv-  
13           ices Appropriations Act, 1988, as contained in sec-  
14           tion 101(h) of Public Law 100–202 (101 Stat.  
15           1329–275), is repealed.

16           (2) APPLICABILITY OF CERTAIN NEW AUTHOR-  
17           ITY.—With respect to the authority established for  
18           the National Library of Medicine in section  
19           465(b)(6) of the Public Health Service Act, as added  
20           by subsection (a) of this section, such authority shall  
21           be effective as if the authority had been established  
22           on December 22, 1987.

23   **SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.**

24           (a) ESTABLISHMENT OF SINGLE AUTHORIZATION.—  
25           Subpart 1 of part D of title IV of the Public Health Serv-



1 ice Act (42 U.S.C. 286 et seq.) is amended by adding at  
2 the end the following section:

3           “AUTHORIZATION OF APPROPRIATIONS

4           “SEC. 468. (a) For the purpose of carrying out this  
5 part, there are authorized to be appropriated  
6 \$150,000,000 for fiscal year 1994, and such sums as may  
7 be necessary for each of the fiscal years 1995 and 1996.

8           “(b) Amounts appropriated under subsection (a) and  
9 made available for grants or contracts under any of sec-  
10 tions 472 through 476 shall remain available until the end  
11 of the fiscal year following the fiscal year for which the  
12 amounts were appropriated.”.

13           (b) CONFORMING AMENDMENTS.—Part D of title IV  
14 of the Public Health Service Act (42 U.S.C. 286 et seq.)  
15 is amended by striking section 469 and section 478(c).

## 16       **Subtitle B—Financial Assistance**

### 17       **SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR** 18                               **DEVELOPMENT OF EDUCATION TECH-** 19                               **NOLOGIES.**

20           Section 473 of the Public Health Service Act (42  
21 U.S.C. 286b–4) is amended by adding at the end the fol-  
22 lowing new subsection:

23           “(c)(1) The Secretary shall make grants to public or  
24 nonprofit private institutions for the purpose of carrying  
25 out projects of research on, and development and dem-  
26 onstration of, new education technologies.

1       “(2) The purposes for which a grant under paragraph  
2 (1) may be made include projects concerning—

3           “(A) computer-assisted teaching and testing of  
4       clinical competence at health professions and re-  
5       search institutions;

6           “(B) the effective transfer of new information  
7       from research laboratories to appropriate clinical ap-  
8       plications;

9           “(C) the expansion of the laboratory and clini-  
10       cal uses of computer-stored research databases; and

11          “(D) the testing of new technologies for train-  
12       ing health care professionals.

13       “(3) The Secretary may not make a grant under  
14       paragraph (1) unless the applicant for the grant agrees  
15       to make the projects available with respect to—

16          “(A) assisting in the training of health profes-  
17       sions students; and

18          “(B) enhancing and improving the capabilities  
19       of health professionals regarding research and teach-  
20       ing.”.

1 **Subtitle C—National Information**  
2 **Center on Health Services Re-**  
3 **search and Health Care Tech-**  
4 **nology**

5 **SEC. 1421. ESTABLISHMENT OF CENTER.**

6 Part D of title IV of the Public Health Service Act  
7 (42 U.S.C. 286 et seq.) is amended by adding at the end  
8 the following new subpart:

9 “Subpart 4—National Information Center on Health  
10 Services Research and Health Care Technology

11 “NATIONAL INFORMATION CENTER

12 “SEC. 478A. (a) There is established within the Li-  
13 brary an entity to be known as the National Information  
14 Center on Health Services Research and Health Care  
15 Technology (in this section referred to as the ‘Center’).

16 “(b) The purpose of the Center is the collection, stor-  
17 age, analysis, retrieval, and dissemination of information  
18 on health services research, clinical practice guidelines,  
19 and on health care technology, including the assessment  
20 of such technology. Such purpose includes developing and  
21 maintaining data bases and developing and implementing  
22 methods of carrying out such purpose.

23 “(c) The Director of the Center shall ensure that in-  
24 formation under subsection (b) concerning clinical practice  
25 guidelines is collected and maintained electronically and

1 in a convenient format. Such Director shall develop and  
2 publish criteria for the inclusion of practice guidelines and  
3 technology assessments in the information center  
4 database.

5 “(d) The Secretary, acting through the Center, shall  
6 coordinate the activities carried out under this section  
7 through the Center with related activities of the Adminis-  
8 trator for Health Care Policy and Research.”.

9 **SEC. 1422. CONFORMING PROVISIONS.**

10 (a) IN GENERAL.—Section 903 of the Public Health  
11 Service Act, as amended by section 3 of Public Law 102–  
12 410 (106 Stat. 2094), is amended to read as follows:

13 “(e) REQUIRED INTERAGENCY AGREEMENT.—The  
14 Administrator and the Director of the National Library  
15 of Medicine shall enter into an agreement providing for  
16 the implementation of section 478A.”.

17 (b) RULE OF CONSTRUCTION.—The amendments  
18 made by section 3 of Public Law 102–410 (106 Stat.  
19 2094), by section 1421 of this Act, and by subsection (a)  
20 of this section may not be construed as terminating the  
21 information center on health care technologies and health  
22 care technology assessment established under section 904  
23 of the Public Health Service Act, as in effect on the day  
24 before the date of the enactment of Public Law 102–410.  
25 Such center shall be considered to be the center estab-

1 lished in section 478A of the Public Health Service Act,  
2 as added by section 1421 of this Act, and shall be subject  
3 to the provisions of such section 478A.

4 **TITLE XV—OTHER AGENCIES OF**  
5 **NATIONAL INSTITUTES OF**  
6 **HEALTH**

7 **Subtitle A—Division of Research**  
8 **Resources**

9 **SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL**  
10 **CENTER FOR RESEARCH RESOURCES.**

11 Title IV of the Public Health Service Act (42 U.S.C.  
12 281 et seq.) is amended—

13 (1) in section 401(b)(2)(B), by amending such  
14 subparagraph to read as follows:

15 “(B) The National Center for Research Re-  
16 sources.”; and

17 (2) in part E—

18 (A) in the heading for subpart 1, by strik-  
19 ing “Division of” and inserting “National Cen-  
20 ter for”;

21 (B) in section 479, by striking “the Divi-  
22 sion of Research Resources” and inserting the  
23 following: “the National Center for Research  
24 Resources (hereafter in this subpart referred to  
25 as the ‘Center’)”;

1 (C) in sections 480 and 481, by striking  
2 “the Division of Research Resources” each  
3 place such term appears and inserting “the  
4 Center”; and

5 (D) in sections 480 and 481, as amended  
6 by subparagraph (C), by striking “the Division”  
7 each place such term appears and inserting  
8 “the Center”.

9 **SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-**  
10 **CILITIES.**

11 Subpart 1 of part E of title IV of the Public Health  
12 Service Act (42 U.S.C. 287 et seq.) is amended by adding  
13 at the end the following new section:

14 “BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES  
15 “SEC. 481A. (a) MODERNIZATION AND CONSTRUC-  
16 TION OF FACILITIES.—

17 “(1) IN GENERAL.—The Director of NIH, act-  
18 ing through the Director of the Center, may make  
19 grants to public and nonprofit private entities to ex-  
20 pand, remodel, renovate, or alter existing research  
21 facilities or construct new research facilities, subject  
22 to the provisions of this section.

23 “(2) CONSTRUCTION AND COST OF CONSTRUC-  
24 TION.—For purposes of this section, the terms  
25 ‘construction’ and ‘cost of construction’ include the  
26 construction of new buildings and the expansion,

1 renovation, remodeling, and alteration of existing  
2 buildings, including architects' fees, but do not in-  
3 clude the cost of acquisition of land or off-site im-  
4 provements.

5 “(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS  
6 FOR MERIT-BASED REVIEW OF PROPOSALS.—

7 “(1) IN GENERAL; APPROVAL AS PRECONDITION  
8 TO GRANTS.—

9 “(A) There is established within the Center  
10 a Scientific and Technical Review Board on  
11 Biomedical and Behavioral Research Facilities  
12 (hereafter referred to in this section as the  
13 ‘Board’).

14 “(B) The Director of the Center may ap-  
15 prove an application for a grant under  
16 subsection (a) only if the Board has under  
17 paragraph (2) recommended the application for  
18 approval.

19 “(2) DUTIES.—

20 “(A) The Board shall provide advice to the  
21 Director of the Center and the advisory council  
22 established under section 480 (hereafter in this  
23 section referred to as the ‘Advisory Council’) on  
24 carrying out this section.

1           “(B) In carrying out subparagraph (A),  
2 the Board shall make a determination of the  
3 merit of each application submitted for a grant  
4 under subsection (a), after consideration of the  
5 requirements established in subsection (c), and  
6 shall report the results of the determination to  
7 the Director of the Center and the Advisory  
8 Council. Such determinations shall be con-  
9 ducted in a manner consistent with procedures  
10 established under section 492.

11           “(C) In carrying out subparagraph (A),  
12 the Board shall, in the case of applications rec-  
13 ommended for approval, make recommendations  
14 to the Director and the Advisory Council on the  
15 amount that should be provided in the grant.

16           “(D) In carrying out subparagraph (A),  
17 the Board shall prepare an annual report for  
18 the Director of the Center and the Advisory  
19 Council describing the activities of the Board in  
20 the fiscal year for which the report is made.  
21 Each such report shall be available to the pub-  
22 lic, and shall—

23                   “(i) summarize and analyze expendi-  
24 tures made under this section;



1           “(ii) provide a summary of the types,  
2           numbers, and amounts of applications that  
3           were recommended for grants under sub-  
4           section (a) but that were not approved by  
5           the Director of the Center; and

6           “(iii) contain the recommendations of  
7           the Board for any changes in the adminis-  
8           tration of this section.

9           “(3) MEMBERSHIP.—

10           “(A) Subject to subparagraph (B), the  
11           Board shall be composed of such appointed and  
12           ex officio members as the Director of the Cen-  
13           ter may determine.

14           “(B) Not more than 3 individuals who are  
15           officers or employees of the Federal Govern-  
16           ment may serve as members of the Board.

17           “(C) Of the members of the Board—

18           “(i) 12 shall be appointed by the Di-  
19           rector of the Center (without regard to the  
20           civil service laws); and

21           “(ii) 1 shall be an official of the Na-  
22           tional Science Foundation designated by  
23           the National Science Board.

24           “(4) CERTAIN REQUIREMENTS REGARDING  
25           MEMBERSHIP.—In selecting individuals for member-

1 ship on the Board, the Director of the Center shall  
2 ensure that the members are individuals who, by the  
3 virtue of their training or experience, are eminently  
4 qualified to perform peer review functions. In select-  
5 ing such individuals for such membership, the Direc-  
6 tor of the Center shall ensure that the members of  
7 the Board collectively—

8 “(A) are experienced in the planning, con-  
9 struction, financing, and administration of enti-  
10 ties that conduct biomedical or behavioral re-  
11 search sciences;

12 “(B) are knowledgeable in making deter-  
13 minations of the need of entities for biomedical  
14 or behavioral research facilities, including such  
15 facilities for the dentistry, nursing, pharmacy,  
16 and allied health professions;

17 “(C) are knowledgeable in evaluating the  
18 relative priorities for applications for grants  
19 under subsection (a) in view of the overall re-  
20 search needs of the United States; and

21 “(D) are experienced with emerging cen-  
22 ters of excellence, as described in subsection  
23 (c)(3).

24 “(5) CERTAIN AUTHORITIES.—

1           “(A) In carrying out paragraph (2), the  
2 Board may establish subcommittees, convene  
3 workshops and conferences, and collect data as  
4 the Board considers appropriate.

5           “(B) In carrying out paragraph (2), the  
6 Board may establish subcommittees within the  
7 Board. Such subcommittees may hold meetings  
8 as determined necessary to enable the sub-  
9 committee to carry out its duties.

10          “(6) TERMS.—

11           “(A) Except as provided in subparagraph  
12 (B), each appointed member of the Board shall  
13 hold office for a term of 4 years. Any member  
14 appointed to fill a vacancy occurring prior to  
15 the expiration of the term for which such mem-  
16 ber’s predecessor was appointed shall be ap-  
17 pointed for the remainder of the term of the  
18 predecessor.

19           “(B) Of the initial members appointed to  
20 the Board (as specified by the Director of the  
21 Center when making the appointments)—

22           “(i) 3 shall hold office for a term of  
23 3 years;

24           “(ii) 3 shall hold office for a term of  
25 2 years; and

1                   “(iii) 3 shall hold office for a term of  
2                   1 year.

3                   “(C) No member is eligible for reappoint-  
4                   ment to the Board until 1 year has elapsed  
5                   after the end of the most recent term of the  
6                   member.

7                   “(7) COMPENSATION.—Members of the Board  
8                   who are not officers or employees of the United  
9                   States shall receive for each day the members are  
10                  engaged in the performance of the functions of the  
11                  Board compensation at the same rate received by  
12                  members of other national advisory councils estab-  
13                  lished under this title.

14                  “(c) REQUIREMENTS FOR GRANTS.—

15                  “(1) IN GENERAL.—The Director of the Center  
16                  may make a grant under subsection (a) only if the  
17                  applicant for the grant meets the following condi-  
18                  tions:

19                         “(A) The applicant is determined by such  
20                         Director to be competent to engage in the type  
21                         of research for which the proposed facility is to  
22                         be constructed.

23                         “(B) The applicant provides assurances  
24                         satisfactory to the Director that—

1           “(i) for not less than 20 years after  
2 completion of the construction, the facility  
3 will be used for the purposes of research  
4 for which it is to be constructed;

5           “(ii) sufficient funds will be available  
6 to meet the non-Federal share of the cost  
7 of constructing the facility;

8           “(iii) sufficient funds will be available,  
9 when construction is completed, for the ef-  
10 fective use of the facility for the research  
11 for which it is being constructed; and

12           “(iv) the proposed construction will  
13 expand the applicant’s capacity for re-  
14 search, or is necessary to improve or main-  
15 tain the quality of the applicant’s research.

16           “(C) The applicant meets reasonable quali-  
17 fications established by the Director with re-  
18 spect to—

19           “(i) the relative scientific and tech-  
20 nical merit of the applications, and the rel-  
21 ative effectiveness of the proposed facili-  
22 ties, in expanding the capacity for bio-  
23 medical or behavioral research and in im-  
24 proving the quality of such research;

1           “(ii) the quality of the research or  
2           training, or both, to be carried out in the  
3           facilities involved;

4           “(iii) the need of the applicant for  
5           such facilities in order to maintain or ex-  
6           pand the applicant’s research and training  
7           mission;

8           “(iv) the congruence of the research  
9           activities to be carried out within the facil-  
10          ity with the research and investigator man-  
11          power needs of the United States; and

12          “(v) the age and condition of existing  
13          research facilities and equipment.

14          “(D) The applicant has demonstrated a  
15          commitment to enhancing and expanding the  
16          research productivity of the applicant.

17          “(2) CONSIDERATION OF CERTAIN FACTORS.—

18          In making grants under subsection (a), the Director  
19          of the Center may, in addition to the requirements  
20          established in paragraph (1), consider the following  
21          factors:

22                 “(A) To what extent the applicant has the  
23                 capacity to broaden the scope of research and  
24                 research training programs of the applicant by  
25                 promoting—

1 “(i) interdisciplinary research;

2 “(ii) research on emerging tech-  
3 nologies, including those involving novel  
4 analytical techniques or computational  
5 methods; or

6 “(iii) other novel research mechanisms  
7 or programs.

8 “(B) To what extent the applicant has  
9 broadened the scope of research and research  
10 training programs of qualified institutions by  
11 promoting genomic research with an emphasis  
12 on interdisciplinary research, including research  
13 related to pediatric investigations.

14 “(3) INSTITUTIONS OF EMERGING EXCEL-  
15 LENCE.—Of the amounts appropriated under sub-  
16 section (i) for a fiscal year, the Director of the Cen-  
17 ter shall make available 25 percent for grants under  
18 subsection (a) to applicants that, in addition to  
19 meeting the requirements established in paragraph  
20 (1), have demonstrated emerging excellence in bio-  
21 medical or behavioral research, as follows:

22 “(A) The applicant has a plan for research  
23 or training advancement and possesses the abil-  
24 ity to carry out the plan.

1           “(B) The applicant carries out research  
2           and research training programs that have a  
3           special relevance to a problem, concern, or  
4           unmet health need of the United States.

5           “(C) The applicant has been productive in  
6           research or research development and training.

7           “(D) The applicant—

8                 “(i) has been designated as a center  
9                 of excellence under section 739;

10                “(ii) is located in a geographic area a  
11                significant percentage of whose population  
12                has a health-status deficit, and the appli-  
13                cant provides health services to such popu-  
14                lation; or

15                “(iii) is located in a geographic area  
16                in which a deficit in health care tech-  
17                nology, services, or research resources may  
18                adversely affect health status of the popu-  
19                lation of the area in the future, and the  
20                applicant is carrying out activities with re-  
21                spect to protecting the health status of  
22                such population.

23           “(d) REQUIREMENT OF APPLICATION.—The Director  
24           of the Center may make a grant under subsection (a) only  
25           if an application for the grant is submitted to the Director



1 and the application is in such form, is made in such man-  
2 ner, and contains such agreements, assurances, and infor-  
3 mation as the Director determines to be necessary to carry  
4 out this section.

5 “(e) AMOUNT OF GRANT; PAYMENTS.—

6 “(1) AMOUNT.—The amount of any grant  
7 awarded under subsection (a) shall be determined by  
8 the Director of the Center, except that such amount  
9 shall not exceed—

10 “(A) 50 percent of the necessary cost of  
11 the construction of a proposed facility as deter-  
12 mined by the Director; or

13 “(B) in the case of a multipurpose facility,  
14 40 percent of that part of the necessary cost of  
15 construction that the Director determines to be  
16 proportionate to the contemplated use of the fa-  
17 cility.

18 “(2) RESERVATION OF AMOUNTS.—On approval  
19 of any application for a grant under subsection (a),  
20 the Director of the Center shall reserve, from any  
21 appropriation available therefore, the amount of  
22 such grant, and shall pay such amount, in advance  
23 or by way of reimbursement, and in such install-  
24 ments consistent with the construction progress, as  
25 the Director may determine appropriate. The res-

1       ervation of the Director of any amount by the Direc-  
2       tor under this paragraph may be amended by the  
3       Director, either on the approval of an amendment of  
4       the application or on the revision of the estimated  
5       cost of construction of the facility.

6           “(3) EXCLUSION OF CERTAIN COSTS.—In deter-  
7       mining the amount of any grant under this sub-  
8       section (a), there shall be excluded from the cost of  
9       construction an amount equal to the sum of—

10           “(A) the amount of any other Federal  
11       grant that the applicant has obtained, or is as-  
12       sured of obtaining, with respect to construction  
13       that is to be financed in part by a grant author-  
14       ized under this section; and

15           “(B) the amount of any non-Federal funds  
16       required to be expended as a condition of such  
17       other Federal grant.

18           “(4) WAIVER OF LIMITATIONS.—The limita-  
19       tions imposed by paragraph (1) may be waived at  
20       the discretion of the Director for applicants meeting  
21       the conditions described in paragraphs (1) and (2)  
22       of subsection (c).

23           “(f) RECAPTURE OF PAYMENTS.—If, not later than  
24       20 years after the completion of construction for which  
25       a grant has been awarded under subsection (a)—

1           “(1) the applicant or other owner of the facility  
2 shall cease to be a public or nonprofit private entity;  
3 or

4           “(2) the facility shall cease to be used for the  
5 research purposes for which it was constructed (un-  
6 less the Director determines, in accordance with reg-  
7 ulations, that there is good cause for releasing the  
8 applicant or other owner from obligation to do so);  
9 the United States shall be entitled to recover from the ap-  
10 plicant or other owner of the facility the amount bearing  
11 the same ratio to the current value (as determined by an  
12 agreement between the parties or by action brought in the  
13 United States District Court for the district in which such  
14 facility is situated) of the facility as the amount of the  
15 Federal participation bore to the cost of the construction  
16 of such facility.

17           “(g) NONINTERFERENCE WITH ADMINISTRATION OF  
18 ENTITIES.—Except as otherwise specifically provided in  
19 this section, nothing contained in this part shall be con-  
20 strued as authorizing any department, agency, officer, or  
21 employee of the United States to exercise any direction,  
22 supervision, or control over, or impose any requirement  
23 or condition with respect to the administration of any en-  
24 tity funded under this part.



1 year is subject to the availability of qualified applicants  
2 for such awards.

3 “(b) The Director of NIH may not make a grant or  
4 enter into a contract under subsection (a) unless the appli-  
5 cant for such assistance agrees, with respect to the costs  
6 to be incurred by the applicant in carrying out the purpose  
7 described in such subsection, to make available (directly  
8 or through donations from public or private entities) non-  
9 Federal contributions in cash toward such costs in an  
10 amount equal to not less than \$1 for each \$4 of Federal  
11 funds provided in such assistance.”.

## 12 **Subtitle B—National Center for** 13 **Nursing Research**

### 14 **SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR** 15 **NURSING RESEARCH AS NATIONAL INSTI-** 16 **TUTE OF NURSING RESEARCH.**

17 (a) IN GENERAL.—Subpart 3 of part E of title IV  
18 of the Public Health Service Act (42 U.S.C. 287c et seq.)  
19 is amended—

20 (1) in section 483—

21 (A) in the heading for the section, by strik-  
22 ing “CENTER” and inserting “INSTITUTE”; and

23 (B) by striking “The general purpose” and  
24 all that follows through “is” and inserting the  
25 following: “The general purpose of the National

1 Institute of Nursing Research (hereafter in this  
2 subpart referred to as the ‘Institute’) is”;

3 (2) in section 484, by striking “Center” each  
4 place such term appears and inserting “Institute”;

5 (3) in section 485—

6 (A) in subsection (a), in each of para-  
7 graphs (1) through (3), by striking “Center”  
8 each place such term appears and inserting  
9 “Institute”;

10 (B) in subsection (b)—

11 (i) in paragraph (2)(A), by striking  
12 “Center” and inserting “Institute”; and

13 (ii) in paragraph (3)(A), in the first  
14 sentence, by striking “Center” and insert-  
15 ing “Institute”; and

16 (C) in subsections (d) through (g), by  
17 striking “Center” each place such term appears  
18 and inserting “Institute”; and

19 (4) in section 485A (as redesignated by section  
20 141(a)(1) of this Act), by striking “Center” each  
21 place such term appears and inserting “Institute”.

22 (b) CONFORMING AMENDMENTS.—

23 (1) ORGANIZATION OF NATIONAL INSTITUTE OF  
24 HEALTH.—Section 401(b) of the Public Health  
25 Service Act (42 U.S.C. 281(b)) is amended—

1 (A) in paragraph (1), by adding at the end  
2 the following new subparagraph:

3 “(Q) The National Institute of Nursing  
4 Research.”; and

5 (B) in paragraph (2), by striking subpara-  
6 graph (D).

7 (2) TRANSFER OF STATUTORY PROVISIONS.—  
8 Sections 483 through 485A of the Public Health  
9 Service Act, as amended by subsection (a) of this  
10 section—

11 (A) are transferred to part C of title IV of  
12 such Act;

13 (B) are redesignated as sections 464V  
14 through 464Y of such part; and

15 (C) are inserted, in the appropriate se-  
16 quence, at the end of such part.

17 (3) HEADING FOR NEW SUBPART.—Title IV of  
18 the Public Health Service Act, as amended by the  
19 preceding provisions of this section, is amended—

20 (A) in part C, by inserting before section  
21 464V the following new heading:

22 “Subpart 17—National Institute of Nursing Research”;

23 and

24 (B) by striking the heading for subpart 3  
25 of part E.

1           (4) CROSS-REFERENCES.—Title IV of the Pub-  
2           lic Health Service Act, as amended by the preceding  
3           provisions of this section, is amended in subpart 17  
4           of part C—

5                   (A) in section 464W, by striking “section  
6                   483” and inserting “section 464V”;

7                   (B) in section 464X(g), by striking “sec-  
8                   tion 486” and inserting “section 464Y”; and

9                   (C) in section 464Y, in the last sentence,  
10                  by striking “section 485(g)” and inserting “sec-  
11                  tion 464X(g)”.

12 **SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.**

13           (a) IN GENERAL.—The Secretary of Health and  
14           Human Services, acting through the Director of the Na-  
15           tional Institute of Nursing Research, shall enter into a  
16           contract with a public or nonprofit private entity to con-  
17           duct a study for the purpose of determining whether and  
18           to what extent there is a need for an increase in the num-  
19           ber of nurses in hospitals and nursing homes in order to  
20           promote the quality of patient care and reduce the inci-  
21           dence among nurses of work-related injuries and stress.

22           (b) NATIONAL ACADEMY OF SCIENCES.—The Sec-  
23           retary shall request the National Academy of Sciences to  
24           enter into the contract under subsection (a) to conduct  
25           the study described in such subsection. If such Institute



1 declines to conduct the study, the Secretary shall carry  
2 out such subsection through another public or nonprofit  
3 private entity.

4 (c) DEFINITIONS.—For purposes of this section:

5 (1) The term “nurse” means a registered nurse,  
6 a licensed practical nurse, a licensed vocational  
7 nurse, and a nurse assistant.

8 (2) The term “Secretary” means the Secretary  
9 of Health and Human Services.

10 (d) REPORT.—The Secretary shall ensure that, not  
11 later than October 1, 1994, the study required in sub-  
12 section (a) is completed and a report describing the find-  
13 ings made as a result of the study is submitted to the  
14 Committee on Energy and Commerce of the House of  
15 Representatives, and to the Committee on Labor and  
16 Human Resources of the Senate.

## 17 **Subtitle C—National Center for** 18 **Human Genome Research**

### 19 **SEC. 1521. PURPOSE OF CENTER.**

20 Title IV of the Public Health Service Act, as amended  
21 by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is  
22 amended—

23 (1) in section 401(b)(2), by adding at the end  
24 the following new subparagraph:



1       “(b)(1) Except as provided in paragraph (2), of the  
2 amounts appropriated to carry out subsection (a) for a  
3 fiscal year, the Director of the Center shall make available  
4 not less than 5 percent for carrying out paragraph (6)  
5 of such subsection.

6       “(2) With respect to providing funds under sub-  
7 section (a)(6) for proposals to address the ethical issues  
8 associated with the genome project, paragraph (1) shall  
9 not apply for a fiscal year if the Director of the Center  
10 certifies to the Committee on Energy and Commerce of  
11 the House of Representatives, and to the Committee on  
12 Labor and Human Resources of the Senate, that the Di-  
13 rector has determined that an insufficient number of such  
14 proposals meet the applicable requirements of sections 491  
15 and 492.”.

16                   **TITLE XVI—AWARDS AND**  
17                                   **TRAINING**

18                   **Subtitle A—National Research**  
19                                   **Service Awards**

20   **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**  
21                                   **VIDUALS FROM DISADVANTAGED BACK-**  
22                                   **GROUND.**

23       Section 487(a) of the Public Health Service Act (42  
24 U.S.C. 288(a)(4)) is amended by adding at the end the  
25 following paragraph:

1 “(4) The Secretary shall carry out paragraph (1) in  
2 a manner that will result in the recruitment of women,  
3 and individuals from disadvantaged backgrounds, into  
4 fields of biomedical or behavioral research and in the pro-  
5 vision of research training to women and such individ-  
6 uals.”.

## 7 **Subtitle B—Acquired Immune** 8 **Deficiency Syndrome**

### 9 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

10 Section 487A of the Public Health Service Act (42  
11 U.S.C. 288–1) is amended to read as follows:

12 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH  
13 RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

14 “SEC. 487A. (a) IN GENERAL.—

15 “(1) AUTHORITY FOR PROGRAM.—Subject to  
16 paragraph (2), the Secretary shall carry out a pro-  
17 gram of entering into agreements with appropriately  
18 qualified health professionals under which such  
19 health professionals agree to conduct, as employees  
20 of the National Institutes of Health, research with  
21 respect to acquired immune deficiency syndrome in  
22 consideration of the Federal Government agreeing to  
23 repay, for each year of such service, not more than  
24 \$20,000 of the principal and interest of the edu-  
25 cational loans of such health professionals.

1           “(2) LIMITATION.—The Secretary may not  
2 enter into an agreement with a health professional  
3 pursuant to paragraph (1) unless such profes-  
4 sional—

5                   “(A) has a substantial amount of edu-  
6 cational loans relative to income; and

7                   “(B)(i) was not employed at the National  
8 Institutes of Health during the 1-year period  
9 preceding the date of the enactment of the  
10 Health Professions Reauthorization Act of  
11 1988; or

12                   “(ii) agrees to serve as an employee of  
13 such Institutes for purposes of paragraph (1)  
14 for a period of not less than 3 years.”.

15           “(b) APPLICABILITY OF CERTAIN PROVISIONS.—  
16 With respect to the National Health Service Corps Loan  
17 Repayment Program established in subpart III of part D  
18 of title III, the provisions of such subpart shall, except  
19 as inconsistent with subsection (a) of this section, apply  
20 to the program established in such subsection (a) in the  
21 same manner and to the same extent as such provisions  
22 apply to the National Health Service Corps Loan Repay-  
23 ment Program established in such subpart.

24           “(c) FUNDING; REIMBURSABLE TRANSFERS.—

1           “(1) AUTHORIZATION OF APPROPRIATIONS.—

2           For the purpose of carrying out this section, there  
3           are authorized to be appropriated such sums as may  
4           be necessary for each of the fiscal years 1994  
5           through 1996.

6           “(2) TRANSFERS FOR RELATED PROGRAM.—

7           The Commissioner of Food and Drugs may carry  
8           out for the Food and Drug Administration a pro-  
9           gram similar to the program established in sub-  
10          section (a), which program shall be carried out with  
11          respect to the review of applications concerning ac-  
12          quired immune deficiency syndrome that are submit-  
13          ted to such Commissioner. From the amounts appro-  
14          priated under paragraph (1) for a fiscal year, the  
15          Secretary may transfer amounts to the Commis-  
16          sioner for the purpose of carrying out such program.  
17          The Commissioner shall provide a reimbursement to  
18          the Secretary for the amount so transferred, and the  
19          reimbursement shall be available only for the pro-  
20          gram established in subsection (a). Any transfer and  
21          reimbursement made for purposes of this paragraph  
22          for a fiscal year shall be completed by April 1 of  
23          such year.”.

1     **Subtitle C—Loan Repayment for**  
2                     **Research Generally**

3     **SEC. 1621. ESTABLISHMENT OF PROGRAM.**

4         Part G of title IV of the Public Health Service Act,  
5 as redesignated by section 141(a)(2) of this Act and as  
6 amended by section 1002 of this Act, is amended by in-  
7 serting after section 487B the following new section:

8             “LOAN REPAYMENT PROGRAM FOR RESEARCH  
9                                     GENERALLY

10            “SEC. 487C. (a) IN GENERAL.—

11                     “(1) AUTHORITY FOR PROGRAM.—Subject to  
12 paragraph (2), the Secretary shall carry out a pro-  
13 gram of entering into agreements with appropriately  
14 qualified health professionals under which such  
15 health professionals agree to conduct research, as  
16 employees of the National Institutes of Health, in  
17 consideration of the Federal Government agreeing to  
18 repay, for each year of such service, not more than  
19 \$20,000 of the principal and interest of the edu-  
20 cational loans of such health professionals.

21                     “(2) LIMITATION.—The Secretary may not  
22 enter into an agreement with a health professional  
23 pursuant to paragraph (1) unless such profes-  
24 sional—

1           “(A) has a substantial amount of edu-  
2           cational loans relative to income; and

3           “(B)(i) was not employed at the National  
4           Institutes of Health during the 1-year period  
5           preceding the date of the enactment of the  
6           Health Professions Reauthorization Act of  
7           1988; or

8           “(ii) agrees to serve as an employee of  
9           such Institutes for purposes of paragraph (1)  
10          for a period of not less than 3 years.”.

11          “(b) APPLICABILITY OF CERTAIN PROVISIONS.—  
12          With respect to the National Health Service Corps Loan  
13          Repayment Program established in subpart III of part D  
14          of title III, the provisions of such subpart shall, except  
15          as inconsistent with subsection (a) of this section, apply  
16          to the program established in such subsection (a) in the  
17          same manner and to the same extent as such provisions  
18          apply to the National Health Service Corps Loan Repay-  
19          ment Program established in such subpart.

20          “(c) AUTHORIZATION OF APPROPRIATIONS.—For the  
21          purpose of carrying out this section other than with re-  
22          spect to acquired immune deficiency syndrome, there are  
23          authorized to be appropriated such sums as may be nec-  
24          essary for each of the fiscal years 1994 through 1996.”.



1 **Subtitle D—Scholarship and Loan**  
2 **Repayment Programs Regarding**  
3 **ing Professional Skills Needed**  
4 **by Certain Agencies**

5 **SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL**  
6 **INSTITUTES OF HEALTH.**

7 Part G of title IV of the Public Health Service Act,  
8 as redesignated by section 141(a)(2) of this Act and as  
9 amended by section 1621 of this Act, is amended by in-  
10 serting after section 487C the following new sections:

11 “UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING  
12 PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-  
13 STITUTES

14 “SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

15 “(1) IN GENERAL.—Subject to section  
16 487(a)(1)(C), the Secretary, acting through the Di-  
17 rector of NIH, may carry out a program of entering  
18 into contracts with individuals described in para-  
19 graph (2) under which—

20 “(A) the Director of NIH agrees to provide  
21 to the individuals scholarships for pursuing, as  
22 undergraduates at accredited institutions of  
23 higher education, academic programs appro-  
24 priate for careers in professions needed by the  
25 National Institutes of Health; and

1           “(B) the individuals agree to serve as em-  
2           ployees of the National Institutes of Health, for  
3           the period described in subsection (c), in posi-  
4           tions that are needed by the National Institutes  
5           of Health and for which the individuals are  
6           qualified.

7           “(2) INDIVIDUALS FROM DISADVANTAGED  
8           BACKGROUNDS.—The individuals referred to in  
9           paragraph (1) are individuals who—

10           “(A) are enrolled or accepted for enroll-  
11           ment as full-time undergraduates at accredited  
12           institutions of higher education; and

13           “(B) are from disadvantaged backgrounds.

14           “(b) FACILITATION OF INTEREST OF STUDENTS IN  
15           CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In  
16           providing employment to individuals pursuant to contracts  
17           under subsection (a)(1), the Director of NIH shall carry  
18           out activities to facilitate the interest of the individuals  
19           in pursuing careers as employees of the National Insti-  
20           tutes of Health.

21           “(c) PERIOD OF OBLIGATED SERVICE.—

22           “(1) DURATION OF SERVICE.—For purposes of  
23           subparagraph (B) of subsection (a)(1), the period of  
24           service for which an individual is obligated to serve  
25           as an employee of the National Institutes of Health

1 is 12 months for each academic year for which the  
2 scholarship under such subsection is provided.

3 “(2) SCHEDULE FOR SERVICE.—

4 “(A) Subject to subparagraph (B), the Di-  
5 rector of NIH may not provide a scholarship  
6 under subsection (a) unless the individual ap-  
7 plying for the scholarship agrees that—

8 “(i) the individual will serve as an em-  
9 ployee of the National Institutes of Health  
10 full-time for not less than 10 consecutive  
11 weeks of each year during which the indi-  
12 vidual is attending the educational institu-  
13 tion involved and receiving such a scholar-  
14 ship;

15 “(ii) the period of service as such an  
16 employee that the individual is obligated to  
17 provide under clause (i) is in addition to  
18 the period of service as such an employee  
19 that the individual is obligated to provide  
20 under subsection (a)(1)(B); and

21 “(iii) not later than 60 days after ob-  
22 taining the educational degree involved, the  
23 individual will begin serving full-time as  
24 such an employee in satisfaction of the pe-  
25 riod of service that the individual is obli-

1 gated to provide under subsection  
2 (a)(1)(B).

3 “(B) The Director of NIH may defer the  
4 obligation of an individual to provide a period  
5 of service under subsection (a)(1)(B), if the Di-  
6 rector determines that such a deferral is appro-  
7 priate.

8 “(3) APPLICABILITY OF CERTAIN PROVISIONS  
9 RELATING TO APPOINTMENT AND COMPENSATION.—  
10 For any period in which an individual provides serv-  
11 ice as an employee of the National Institutes of  
12 Health in satisfaction of the obligation of the indi-  
13 vidual under subsection (a)(1)(B) or paragraph  
14 (2)(A)(i), the individual may be appointed as such  
15 an employee without regard to the provisions of title  
16 5, United States Code, relating to appointment and  
17 compensation.

18 “(d) PROVISIONS REGARDING SCHOLARSHIP.—

19 “(1) APPROVAL OF ACADEMIC PROGRAM.—The  
20 Director of NIH may not provide a scholarship  
21 under subsection (a) for an academic year unless—

22 “(A) the individual applying for the schol-  
23 arship has submitted to the Director a proposed  
24 academic program for the year and the Director  
25 has approved the program; and

1           “(B) the individual agrees that the pro-  
2           gram will not be altered without the approval of  
3           the Director.

4           “(2) ACADEMIC STANDING.—The Director of  
5           NIH may not provide a scholarship under subsection  
6           (a) for an academic year unless the individual apply-  
7           ing for the scholarship agrees to maintain an accept-  
8           able level of academic standing, as determined by  
9           the educational institution involved in accordance  
10          with regulations issued by the Secretary.

11          “(3) LIMITATION ON AMOUNT.—The Director  
12          of NIH may not provide a scholarship under sub-  
13          section (a) for an academic year in an amount ex-  
14          ceeding \$20,000.

15          “(4) AUTHORIZED USES.—A scholarship pro-  
16          vided under subsection (a) may be expended only for  
17          tuition expenses, other reasonable educational ex-  
18          penses, and reasonable living expenses incurred in  
19          attending the school involved.

20          “(5) CONTRACT REGARDING DIRECT PAYMENTS  
21          TO INSTITUTION.—In the case of an institution of  
22          higher education with respect to which a scholarship  
23          under subsection (a) is provided, the Director of  
24          NIH may enter into a contract with the institution  
25          under which the amounts provided in the scholarship

1 for tuition and other educational expenses are paid  
2 directly to the institution. Payments to the institu-  
3 tion under the contract may be made without regard  
4 to section 3324 of title 31, United States Code.

5 “(e) PENALTIES FOR BREACH OF SCHOLARSHIP  
6 CONTRACT.—The provisions of section 338E shall apply  
7 to the program established in subsection (a) to the same  
8 extent and in the same manner as such provisions apply  
9 to the National Health Service Corps Loan Repayment  
10 Program established in section 338B.

11 “(f) REQUIREMENT OF APPLICATION.—The Director  
12 of NIH may not provide a scholarship under subsection  
13 (a) unless an application for the scholarship is submitted  
14 to the Director and the application is in such form, is  
15 made in such manner, and contains such agreements, as-  
16 surances, and information as the Director determines to  
17 be necessary to carry out this section.

18 “(g) AVAILABILITY OF AUTHORIZATION OF APPRO-  
19 PRIATIONS.—Amounts appropriated for a fiscal year for  
20 scholarships under this section shall remain available until  
21 the expiration of the second fiscal year beginning after the  
22 fiscal year for which the amounts were appropriated.

23 “LOAN REPAYMENT PROGRAM REGARDING CLINICAL  
24 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

25 “SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

1           “(1) IN GENERAL.—Subject to section  
2           487(a)(1)(C), the Secretary, acting through the Di-  
3           rector of NIH may, subject to paragraph (2), carry  
4           out a program of entering into contracts with appro-  
5           priately qualified health professionals who are from  
6           disadvantaged backgrounds under which such health  
7           professionals agree to conduct clinical research as  
8           employees of the National Institutes of Health in  
9           consideration of the Federal Government agreeing to  
10          pay, for each year of such service, not more than  
11          \$20,000 of the principal and interest of the edu-  
12          cational loans of the health professionals.

13          “(2) LIMITATION.—The Director of NIH may  
14          not enter into a contract with a health professional  
15          pursuant to paragraph (1) unless such professional  
16          has a substantial amount of education loans relative  
17          to income.

18          “(3) APPLICABILITY OF CERTAIN PROVISIONS  
19          REGARDING OBLIGATED SERVICE.—Except to the ex-  
20          tent inconsistent with this section, the provisions of  
21          sections 338C and 338E shall apply to the program  
22          established in paragraph (1) to the same extent and  
23          in the same manner as such provisions apply to the  
24          National Health Service Corps Loan Repayment  
25          Program established in section 338B.

1 “(b) AVAILABILITY OF AUTHORIZATION OF APPRO-  
2 PRIATIONS.—Amounts appropriated for a fiscal year for  
3 contracts under subsection (a) shall remain available until  
4 the expiration of the second fiscal year beginning after the  
5 fiscal year for which the amounts were appropriated.”.

6 **SEC. 1632. FUNDING.**

7 Section 487(a)(1) of the Public Health Service Act  
8 (42 U.S.C. 288(a)(1)) is amended—

9 (1) in subparagraph (A), by striking “and”  
10 after the semicolon at the end;

11 (2) in subparagraph (B), by striking the period  
12 at the end and inserting “; and”; and

13 (3) by adding at the end the following new sub-  
14 paragraph:

15 “(C) provide contracts for scholarships and loan  
16 repayments in accordance with sections 487D and  
17 487E, subject to providing not more than an aggre-  
18 gate 50 such contracts during the fiscal years 1994  
19 through 1996.”.

20 **Subtitle D—Funding**

21 **SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.**

22 Section 487(d) of the Public Health Service Act (42  
23 U.S.C. 288(d)) is amended—

24 (1) in the first sentence, by amending the sen-  
25 tence to read as follows: “For the purpose of carry-



1 ing out this section, there are authorized to be ap-  
2 propriated \$400,000,000 for fiscal year 1994, and  
3 such sums as may be necessary for each of the fiscal  
4 years 1995 and 1996.”; and

5 (2) in paragraph (3)—

6 (A) by striking “one-half of one percent”  
7 each place such term appears and inserting “1  
8 percent”; and

9 (B) by inserting “785,” after “784,”.

10 **TITLE XVII—NATIONAL FOUNDA-**  
11 **TION FOR BIOMEDICAL RE-**  
12 **SEARCH**

13 **SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD**  
14 **MEMBERS.**

15 Section 499 of the Public Health Service Act, as re-  
16 designated by section 121(b)(3) of this Act, is amended  
17 in subsection (c)(1)(C) by inserting after and below clause  
18 (iii) the following:

19 “Not later than March 1, 1993, the Secretary  
20 shall convene a meeting of the ex officio mem-  
21 bers of the Board for the purpose of making  
22 the appointments required in this subpara-  
23 graph.”.

1 **SEC. 1702. MISCELLANEOUS PROVISIONS.**

2 Section 499 of the Public Health Service Act, as re-  
3 designated by section 121(b)(3) of this Act, is amended—

4 (1) in subsection (a)—

5 (A) in the first sentence, by inserting after  
6 “Secretary” the following: “, acting through the  
7 Director of NIH,”; and

8 (B) in the second sentence, by striking  
9 “the purposes of” and all that follows through  
10 “Transfer Act,” and inserting the following:  
11 “the purposes of the Ethics in Government Act  
12 of 1978 and the Stevenson-Wydler Technology  
13 Innovation Act of 1980,”;

14 (2) in subsection (b)(2), by striking “Ethics”  
15 and all that follows and inserting the following:  
16 “Ethics in Government Act of 1978, and the Steven-  
17 son-Wydler Technology Innovation Act of 1980.”;

18 (3) in subsection (c)—

19 (A) in paragraph (1)—

20 (i) in subparagraph (A), in the second  
21 sentence, by inserting “, except the ex  
22 officio members,” after “Foundation”;

23 (ii) in subparagraph (B), in the mat-  
24 ter preceding clause (i), by striking “Coun-  
25 cil” and inserting “Board”; and

1 (iii) in subparagraph (C), in the first  
2 sentence, by striking “Council” and insert-  
3 ing “Board”; and

4 (B) in paragraph (3)(A), by striking  
5 “paragraph (2)(C)” and inserting “paragraph  
6 (1)(C)”;

7 (4) in subsection (g)(8), by striking “subtitle”  
8 and inserting “part”; and  
9 (5) in subsection (i)(1), by striking “1995” and  
10 inserting “1996”.

11 **TITLE XVIII—RESEARCH WITH**  
12 **RESPECT TO ACQUIRED IM-**  
13 **MUNE DEFICIENCY SYN-**  
14 **DROME**

15 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**  
16 **GRAMS.**

17 Title XXIII of the Public Health Service Act (42  
18 U.S.C. 300cc et seq.) is amended—

19 (1) in section 2304(c)(1)—

20 (A) in the matter preceding subparagraph  
21 (A), by inserting after “Director of such Insti-  
22 tute” the following: “(and may provide advice  
23 to the Directors of other agencies of the Na-  
24 tional Institutes of Health, as appropriate)”;  
25 and

1 (B) in subparagraph (A), by inserting be-  
2 fore the semicolon the following: “, including  
3 recommendations on the projects of research  
4 with respect to diagnosing immune deficiency  
5 and with respect to predicting, diagnosing, pre-  
6 venting, and treating opportunistic cancers and  
7 infectious diseases”;

8 (2) in section 2311(a)(1), by inserting before  
9 the semicolon the following: “, including evaluations  
10 of methods of diagnosing immune deficiency and  
11 evaluations of methods of predicting, diagnosing,  
12 preventing, and treating opportunistic cancers and  
13 infectious diseases”;

14 (3) in section 2315—

15 (A) in subsection (a)(2), by striking “inter-  
16 national research” and all that follows and in-  
17 serting “international research and training  
18 concerning the natural history and pathogenesis  
19 of the human immunodeficiency virus and the  
20 development and evaluation of vaccines and  
21 treatments for acquired immune deficiency syn-  
22 drome and opportunistic infections.”; and

23 (B) in subsection (f), by striking “and  
24 1991” and inserting “through 1996”;

25 (4) in section 2318—

1 (A) in subsection (a)(1)—

2 (i) by inserting after “The Secretary”  
3 the following: “, acting through the Direc-  
4 tor of the National Institutes of Health  
5 and after consultation with the Adminis-  
6 trator for Health Care Policy and Re-  
7 search,”; and

8 (ii) by striking “syndrome” and in-  
9 sserting “syndrome, including treatment  
10 and prevention of HIV infection and relat-  
11 ed conditions among women”; and

12 (B) in subsection (e), by striking “1991.”  
13 and inserting the following: “1991, and such  
14 sums as may be necessary for each of the fiscal  
15 years 1994 through 1996.”;

16 (5) in section 2320(b)(1)(A), by striking “syn-  
17 drome” and inserting “syndrome and the natural  
18 history of such infection”;

19 (6)(A) in section 2351(a)—

20 (i) by redesignating paragraphs (2)  
21 through (8) as paragraphs (3) through (9); and

22 (ii) by inserting after paragraph (1) the  
23 following new paragraph:

24 “(2)(A) shall develop and implement a com-  
25 prehensive plan for the conduct and support of such

1 research by the agencies of the National Institutes  
2 of Health, which plan shall specify the objectives to  
3 be achieved, the date by which the objectives are ex-  
4 pected to be achieved, and an estimate of the re-  
5 sources needed to achieve the objectives by such  
6 date; and

7 “(B) shall develop and implement a plan for  
8 evaluating the sufficiency of the plan developed  
9 under subparagraph (A) and for evaluating the ex-  
10 tent to which activities of the National Institutes of  
11 Health have been in accordance with the plan;” and

12 (B) in section 2301(b)(6), by inserting before  
13 the semicolon the following: “, including evaluations  
14 conducted under section 2351(a)(2)(B)”;

15 (7) in section 2361, by striking “For purposes”  
16 and all that follows and inserting the following:

17 “For purposes of this title:

18 “(1) The term ‘infection’, with respect to the  
19 etiologic agent for acquired immune deficiency syn-  
20 drome, includes opportunistic cancers and infectious  
21 diseases and any other conditions arising from infec-  
22 tion with such etiologic agent.

23 “(2) The term ‘treatment’, with respect to the  
24 etiologic agent for acquired immune deficiency syn-

1 drome, includes primary and secondary prophylaxis.”;

3 (8) in section 2315(f), by striking “there are  
4 authorized” and all that follows and inserting “there  
5 are authorized to be appropriated such sums as may  
6 be necessary for each fiscal year.”;

7 (9) in section 2320(e)(1), by striking “there are  
8 authorized” and all that follows and inserting “there  
9 are authorized to be appropriated such sums as may  
10 be necessary for each fiscal year.”; and

11 (10) in section 2341(d), by striking “there are  
12 authorized” and all that follows and inserting “there  
13 are authorized to be appropriated such sums as may  
14 be necessary for each fiscal year.”.

## 15 **TITLE XIX—STUDIES**

### 16 **SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

#### 17 (a) CERTAIN DRUG-RELEASE MECHANISMS.—

18 (1) The Secretary of Health and Human Services shall, subject to paragraph (2), enter into a contract with a public or nonprofit private entity to conduct a study for the purpose of determining, with respect to acquired immune deficiency syndrome, the impact of parallel-track drug-release mechanisms on public and private clinical research, and on the ac-

1       activities of the Commissioner of Food and Drugs re-  
2       garding the approval of drugs.

3               (2) The Secretary of Health and Human Serv-  
4       ices shall request the Institute of Medicine of the  
5       National Academy of Sciences to enter into the con-  
6       tract under paragraph (1) to conduct the study de-  
7       scribed in such paragraph. If such Institute declines  
8       to conduct the study, the Secretary shall carry out  
9       paragraph (1) through another public or nonprofit  
10      private entity.

11      (b) THIRD-PARTY PAYMENTS REGARDING CERTAIN  
12      CLINICAL TRIALS.—The Secretary of Health and Human  
13      Services, acting through the Director of the National In-  
14      stitutes of Health, shall conduct a study for the purpose  
15      of—

16              (1) determining the policies of third-party  
17      payors regarding the payment of the costs of appro-  
18      priate health services that are provided incident to  
19      the participation of individuals as subjects in clinical  
20      trials conducted in the development of drugs with re-  
21      spect to acquired immune deficiency syndrome; and

22              (2) developing recommendations regarding such  
23      policies.

24      (c) ADVISORY COMMITTEES.—The Secretary of  
25      Health and Human Services, acting through the Director



1 of the National Institutes of Health, shall conduct a study  
2 for the purpose of determining—

3 (1) whether the activities of the various advi-  
4 sory committees established in the National Insti-  
5 tutes of Health regarding acquired immune defi-  
6 ciency syndrome are being coordinated sufficiently;  
7 and

8 (2) whether the functions of any of such advi-  
9 sory committees should be modified in order to  
10 achieve greater efficiency.

11 (d) VACCINES FOR HUMAN IMMUNODEFICIENCY  
12 VIRUS.—

13 (1) IN GENERAL.—The Secretary of Health and  
14 Human Services, acting through the National Insti-  
15 tutes of Health, shall develop a plan for the appro-  
16 priate inclusion of HIV-infected women, including  
17 pregnant women, HIV-infected infants, and HIV-in-  
18 fected children in studies conducted by or through  
19 the National Institutes of Health concerning the  
20 safety and efficacy of HIV vaccines for the treat-  
21 ment and prevention of HIV infection. Such plan  
22 shall ensure the full participation of other Federal  
23 agencies currently conducting HIV vaccine studies  
24 and require that such studies conform fully to the

1 requirements of part 46 of title 45, Code of Federal  
2 Regulations.

3 (2) REPORT.—Not later than 180 days after  
4 the date of the enactment of this Act, the Secretary  
5 of Health and Human Services shall prepare and  
6 submit to the Committee on Energy and Commerce  
7 of the House of Representatives, and the Committee  
8 on Labor and Human Resources of the Senate, a re-  
9 port concerning the plan developed under paragraph  
10 (1).

11 (3) IMPLEMENTATION.—Not later than 12  
12 months after the date of the enactment of this Act,  
13 the Secretary of Health and Human Services shall  
14 implement the plan developed under paragraph (1),  
15 including measures for the full participation of other  
16 Federal agencies currently conducting HIV vaccine  
17 studies.

18 (4) For the purpose of carrying out this sub-  
19 section, there are authorized to be appropriated such  
20 sums as may be necessary for each of the fiscal  
21 years 1994 through 1996.

22 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

23 (a) STUDY.—

24 (1) IN GENERAL.—The Secretary of Health and  
25 Human Services (referred to in this section as the

1 “Secretary”), acting through the National Institute  
2 on Aging, coordinating with the Agency for Health  
3 Care Policy and Research and, to the degree pos-  
4 sible, in consultation with the head of the National  
5 Nutrition Monitoring System established under sec-  
6 tion 1428 of the Food and Agriculture Act of 1977  
7 (7 U.S.C. 3178), shall conduct a 3-year nutrition  
8 screening and intervention activities study of the el-  
9 derly.

10 (2) EFFICACY AND COST-EFFECTIVENESS OF  
11 NUTRITION SCREENING AND INTERVENTION ACTIVI-  
12 TIES.—In conducting the study, the Secretary shall  
13 determine the efficacy and cost-effectiveness of nu-  
14 trition screening and intervention activities con-  
15 ducted in the elderly health and long-term care con-  
16 tinuum, and of a program that would institutionalize  
17 nutrition screening and intervention activities. In  
18 evaluating such a program, the Secretary shall de-  
19 termine—

20 (A) if health or quality of life is measur-  
21 ably improved for elderly individuals who re-  
22 ceive routine nutritional screening and treat-  
23 ment;

24 (B) if federally subsidized home or institu-  
25 tional care is reduced because of increased inde-

1 pendency of elderly individuals resulting from  
2 improved nutritional status;

3 (C) if a multidisciplinary approach to nu-  
4 tritional care is effective in addressing the nu-  
5 tritional needs of elderly individuals; and

6 (D) if reimbursement for nutrition screen-  
7 ing and intervention activities is a cost-effective  
8 approach to improving the health status of el-  
9 derly individuals.

10 (3) POPULATIONS.—The populations of elderly  
11 individuals in which the study will be conducted  
12 shall include populations of elderly individuals who  
13 are—

14 (A) living independently, including—

15 (i) individuals who receive home and  
16 community-based services or family sup-  
17 port;

18 (ii) individuals who do not receive ad-  
19 ditional services and support;

20 (iii) individuals with low incomes; and

21 (iv) individuals who are minorities;

22 (B) hospitalized, including individuals ad-  
23 mitted from home and from institutions; and

24 (C) institutionalized in residential facilities  
25 such as nursing homes and adult homes.

1 (b) MALNUTRITION STUDY.—The Secretary, acting  
2 through the National Institute on Aging, shall conduct a  
3 3-year study to determine the extent of malnutrition in  
4 elderly individuals in hospitals and long-term care facili-  
5 ties and in elderly individuals who are living independ-  
6 ently.

7 (c) REPORT.—The Secretary shall submit a report to  
8 the Committee on Labor and Human Resources of the  
9 Senate and the Committee on Energy and Commerce of  
10 the House of Representatives containing the findings re-  
11 sulting from the studies described in subsections (a) and  
12 (b), including a determination regarding whether a pro-  
13 gram that would institutionalize nutrition screening and  
14 intervention activities should be adopted, and the rationale  
15 for the determination.

16 (d) ADVISORY PANEL.—

17 (1) ESTABLISHMENT.—The Secretary, acting  
18 through the Director of the National Institute on  
19 Aging, shall establish an advisory panel that shall  
20 oversee the design, implementation, and evaluation  
21 of the studies described in subsections (a) and (b).

22 (2) COMPOSITION.—The advisory panel shall in-  
23 clude representatives appointed for the life of the  
24 panel by the Secretary from the Health Care Fi-  
25 nancing Administration, the Social Security Admin-

1       istration, the National Center for Health Statistics,  
2       the Administration on Aging, the National Council  
3       on the Aging, the American Dietetic Association, the  
4       American Academy of Family Physicians, and such  
5       other agencies or organizations as the Secretary de-  
6       termines to be appropriate.

7               (3) COMPENSATION AND EXPENSES.—

8               (A) COMPENSATION.—Each member of the  
9       advisory panel who is not an employee of the  
10      Federal Government shall receive compensation  
11      at the daily equivalent of the rate specified for  
12      level V of the Executive Schedule under section  
13      5316 of title 5, United States Code, for each  
14      day the member is engaged in the performance  
15      of duties for the advisory panel, including at-  
16      tendance at meetings and conferences of the  
17      panel, and travel to conduct the duties of the  
18      panel.

19              (B) TRAVEL EXPENSES.—Each member of  
20      the advisory panel shall receive travel expenses,  
21      including per diem in lieu of subsistence, at  
22      rates authorized for employees of agencies  
23      under subchapter I of chapter 57 of title 5,  
24      United States Code, for each day the member  
25      is engaged in the performance of duties away

1 from the home or regular place of business of  
2 the member.

3 (4) **DETAIL OF FEDERAL EMPLOYEES.**—On the  
4 request of the advisory panel, the head of any Fed-  
5 eral agency shall detail, without reimbursement, any  
6 of the personnel of the agency to the advisory panel  
7 to assist the advisory panel in carrying out its du-  
8 ties. Any detail shall not interrupt or otherwise af-  
9 fect the civil service status or privileges of the Fed-  
10 eral employee.

11 (5) **TECHNICAL ASSISTANCE.**—On the request  
12 of the advisory panel, the head of a Federal agency  
13 shall provide such technical assistance to the advi-  
14 sory panel as the advisory panel determines to be  
15 necessary to carry out its duties.

16 (6) **TERMINATION.**—Notwithstanding section  
17 15 of the Federal Advisory Committee Act (5 U.S.C.  
18 App.), the advisory panel shall terminate 3 years  
19 after the date of enactment of this Act.

20 **SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE**  
21 **SYNDROME.**

22 The Secretary of Health and Human Services shall,  
23 not later than May 1, 1993, and annually thereafter for  
24 the next 3 years, prepare and submit to the Committee  
25 on Energy and Commerce of the House of Representatives

1 and the Committee on Labor and Human Resources of  
2 the Senate, a report that summarizes the research activi-  
3 ties conducted or supported by the National Institutes of  
4 Health concerning chronic fatigue syndrome. Such report  
5 should include information concerning grants made, coop-  
6 erative agreements or contracts entered into, intramural  
7 activities, research priorities and needs, and a plan to ad-  
8 dress such priorities and needs.

9 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**  
10 **AGENTS IN DEVELOPMENT OF DEFENSES**  
11 **AGAINST BIOLOGICAL WARFARE.**

12 The Secretary of Health and Human Services, in con-  
13 sultation with other appropriate executive agencies, shall  
14 report to the House Energy and Commerce Committee  
15 and the Senate Labor and Human Resources Committee  
16 on the appropriateness and impact of the National Insti-  
17 tutes of Health assuming responsibility for the conduct of  
18 all Federal research, development, testing, and evaluation  
19 functions relating to medical countermeasures against  
20 biowarfare threat agents. In preparing the report, the Sec-  
21 retary shall identify the extent to which such activities are  
22 carried out by agencies other than the National Institutes  
23 of Health, and assess the impact (positive and negative)  
24 of the National Institutes of Health assuming responsibil-  
25 ity for such activities, including the impact under the



1 Budget Enforcement Act and the Omnibus Budget Rec-  
2 onciliation Act of 1990 on existing National Institutes of  
3 Health research programs as well as other programs with-  
4 in the category of domestic discretionary spending. The  
5 Secretary shall submit the report not later than 12 months  
6 after the date of the enactment of this Act.

7 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**  
8 **TION AND TURNOVER.**

9 (a) STUDY OF PERSONNEL SYSTEM.—Not later than  
10 1 year after the date of the enactment of this Act, the  
11 Secretary of Health and Human Services, acting through  
12 the Director of the National Institutes of Health, shall  
13 conduct a study to review the retention, recruitment, va-  
14 cancy and turnover rates of support staff, including fire-  
15 fighters, law enforcement, procurement officers, techni-  
16 cians, nurses and clerical employees, to ensure that the  
17 National Institutes of Health is adequately supporting the  
18 conduct of efficient, effective and high quality research for  
19 the American public. The Director of NIH shall work in  
20 conjunction with appropriate employee organizations and  
21 representatives in developing such a study.

22 (b) SUBMISSION TO CONGRESS.—Not later than 1  
23 year after the date of the enactment of this Act, the Sec-  
24 retary of Health and Human Services shall prepare and  
25 submit to the Committee on Energy and Commerce of the

1 House of Representatives, and to the Committee on Labor  
2 and Human Resources of the Senate, a report containing  
3 the study conducted under subsection (a) together with  
4 the recommendations of the Secretary concerning the en-  
5 actment of legislation to implement the results of such  
6 study.

7 **SEC. 1906. PROCUREMENT.**

8 (a) IN GENERAL.—The Director of the National In-  
9 stitutes of Health and the Administrator of the General  
10 Services Administration shall jointly conduct a study to  
11 develop a streamlined procurement system for the Na-  
12 tional Institutes of Health that complies with the require-  
13 ments of Federal law.

14 (b) REPORT.—Not later than March 1, 1994, the of-  
15 ficials specified in subsection (a) shall complete the study  
16 required in such subsection and shall submit to the Com-  
17 mittee on Energy and Commerce of the House of Rep-  
18 resentatives, and the Committee on Labor and Human Re-  
19 sources of the Senate, a report describing the findings  
20 made as a result of the study.

1           **TITLE XX—MISCELLANEOUS**  
2                           **PROVISIONS**

3   **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**  
4                           **SEARCH SERVICE IN HONOR OF SILVIO O.**  
5                           **CONTE, AND LIMITATION ON NUMBER OF**  
6                           **MEMBERS.**

7           (a) IN GENERAL.—Section 228(a) of the Public  
8 Health Service Act (42 U.S.C. 237(a)), as added by sec-  
9 tion 304 of Public Law 101–509, is amended to read as  
10 follows:

11           “(a)(1) There shall be in the Public Health Service  
12 a Silvio O. Conte Senior Biomedical Research Service, not  
13 to exceed 750 members.

14           “(2) The authority established in paragraph (1) re-  
15 garding the number of members in the Silvio O. Conte  
16 Senior Biomedical Research Service is in addition to any  
17 authority established regarding the number of members  
18 in the commissioned Regular Corps, in the Reserve Corps,  
19 and in the Senior Executive Service. Such paragraph may  
20 not be construed to require that the number of members  
21 in the commissioned Regular Corps, in the Reserve Corps,  
22 or in the Senior Executive Service be reduced to offset  
23 the number of members serving in the Silvio O. Conte Sen-  
24 ior Biomedical Research Service (hereafter in this section  
25 referred to as the ‘Service’).”

1 (b) CONFORMING AMENDMENT.—Section 228 of the  
2 Public Health Service Act (42 U.S.C. 237), as added by  
3 section 304 of Public Law 101–509, is amended in the  
4 heading for the section by amending the heading to read  
5 as follows:

6 “SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH  
7 SERVICE”.

8 **SEC. 2002. TECHNICAL CORRECTIONS.**

9 (a) TITLE IV.—Title IV of the Public Health Service  
10 Act (42 U.S.C. 281 et seq.) is amended—

11 (1) in section 406—

12 (A) in subsection (b)(2)(A), by striking  
13 “Veterans’ Administration” each place such  
14 term appears and inserting “Department of  
15 Veterans Affairs”; and

16 (B) in subsection (h)(2)(A)(v), by striking  
17 “Veterans’ Administration” and inserting “De-  
18 partment of Veterans Affairs”;

19 (2) in section 408, in subsection (b) (as redesi-  
20 gnated by section 501(c)(1)(C) of this Act), by strik-  
21 ing “Veterans’ Administration” and inserting “De-  
22 partment of Veterans Affairs”;

23 (3) in section 421(b)(1), by inserting a comma  
24 after “may”;

1 (4) in section 428(b), in the matter preceding  
2 paragraph (1), by striking “the the” and inserting  
3 “the”;

4 (5) in section 430(b)(2)(A)(i), by striking “Vet-  
5 erans’ Administration” and inserting “Department  
6 of Veterans Affairs”;

7 (6) in section 439(b), by striking “Veterans’  
8 Administration” and inserting “Department of Vet-  
9 erans Affairs”;

10 (7) in section 442(b)(2)(A), by striking “Veter-  
11 ans’ Administration” and inserting “Department of  
12 Veterans Affairs”;

13 (8) in section 464D(b)(2)(A), by striking “Vet-  
14 erans’ Administration” and inserting “Department  
15 of Veterans Affairs”;

16 (9) in section 464E—

17 (A) in subsection (d), in the first sentence,  
18 by inserting “Coordinating” before “Commit-  
19 tee”; and

20 (B) in subsection (e), by inserting “Coordi-  
21 nating” before “Committee” the first place  
22 such term appears;

23 (10) in section 464P(b)(6) (as added by section  
24 123 of Public Law 102–321 (106 Stat. 362)), by  
25 striking “Administration” and inserting “Institute”;

1 (11) in section 466(a)(1)(B), by striking “Vet-  
2 erans’ Administration” and inserting “Department  
3 of Veterans Affairs”;

4 (12) in section 480(b)(2)(A), by striking “Vet-  
5 erans’ Administration” and inserting “Department  
6 of Veterans Affairs”;

7 (13) in section 485(b)(2)(A), by striking “Vet-  
8 erans’ Administration” and inserting “Department  
9 of Veterans Affairs”;

10 (14) in section 487(d)(3), by striking “section  
11 304(a)(3)” and inserting “section 304(a)”; and

12 (15) in section 496(a), by striking “Such ap-  
13 propriations,” and inserting the following: “Appro-  
14 priations to carry out the purposes of this title,”.

15 (b) TITLE XXIII.—Part A of title XXIII of the Pub-  
16 lic Health Service Act (42 U.S.C. 300cc et seq.) is amend-  
17 ed—

18 (1) in section 2304—

19 (A) in the heading for the section, by strik-  
20 ing “**CLINICAL RESEARCH REVIEW COM-**  
21 **MITTEE**” and inserting “**RESEARCH ADVI-**  
22 **SORY COMMITTEE**”; and

23 (B) in subsection (a), by striking “AIDS  
24 Clinical Research Review Committee” and in-  
25 serting “AIDS Research Advisory Committee”;

1 (2) in section 2312(a)(2)(A), by striking “AIDS  
2 Clinical Research Review Committee” and inserting  
3 “AIDS Research Advisory Committee”;

4 (3) in section 2314(a)(1), in the matter preced-  
5 ing subparagraph (A), by striking “Clinical Research  
6 Review Committee” and inserting “AIDS Research  
7 Advisory Committee”;

8 (4) in section 2317(d)(1), by striking “Clinical  
9 Research Review Committee” and inserting “AIDS  
10 Research Advisory Committee established under sec-  
11 tion 2304”; and

12 (5) in section 2318(b)(3), by striking “Clinical  
13 Research Review Committee” and inserting “AIDS  
14 Research Advisory Committee”.

15 **SEC. 2003. BIENNIAL REPORT ON CARCINOGENS.**

16 Section 301(b)(4) of the Public Health Service Act  
17 (42 U.S.C. 241(b)(4)) is amended by striking “an annual”  
18 and inserting in lieu thereof “a biennial”.

19 **SEC. 2004. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**  
20 **FOR RESEARCH.**

21 Not later than 90 days after the date of the enact-  
22 ment of this Act, the Secretary of Health and Human  
23 Services, acting through the Director of the National In-  
24 stitutes of Health, shall present to the Congress a master  
25 plan to provide for the replacement or refurbishment of

1 less than adequate buildings, utility equipment and dis-  
2 tribution systems (including the resources that provide  
3 electrical and other utilities, chilled water, air handling,  
4 and other services that the Secretary, acting through the  
5 Director, deems necessary), roads, walkways, parking  
6 areas, and grounds that underpin the laboratory and clini-  
7 cal facilities of the National Institutes of Health. Such  
8 plan may make recommendations for the undertaking of  
9 new projects that are consistent with the objectives of this  
10 section, such as encircling the National Institutes of  
11 Health Federal enclave with an adequate chilled water  
12 conduit.

13 **SEC. 2005. TRANSFER OF PROVISIONS OF TITLE XXVII.**

14 (a) IN GENERAL.—The Public Health Service Act  
15 (42 U.S.C. 201 et seq.), as amended by section 101 of  
16 Public Law 101–381 and section 304 of Public Law 101–  
17 509, is amended—

18 (1) by transferring sections 2701 through 2714  
19 to title II;

20 (2) by redesignating such sections as sections  
21 231 through 244, respectively;

22 (3) by inserting such sections, in the appro-  
23 priate sequence, after section 228;

24 (4) by inserting before section 201 the following  
25 new heading:



1           “PART A—ADMINISTRATION”; and

2           (5) by inserting before section 231 (as redesignig-  
3           nated by paragraph (2) of this subsection) the fol-  
4           lowing new heading:

5           “Part B—Miscellaneous Provisions”.

6           (b) CONFORMING AMENDMENTS.—The Public  
7           Health Service Act (42 U.S.C. 201 et seq.) is amended—

8           (1) in the heading for title II, by inserting  
9           “AND MISCELLANEOUS PROVISIONS” after  
10          “ADMINISTRATION”;

11          (2) in section 406(a)(2), by striking “2701”  
12          and inserting “231”;

13          (3) in section 465(f), by striking “2701” and  
14          inserting “231”;

15          (4) in section 480(a)(2), by striking “2701”  
16          and inserting “231”;

17          (5) in section 485(a)(2), by striking “2701”  
18          and inserting “231”;

19          (6) in section 497, by striking “2701” and in-  
20          serting “231”;

21          (7) in section 505(a)(2), by striking “2701”  
22          and inserting “231”;

23          (8) in section 926(b), by striking “2711” each  
24          place such term appears and inserting “241”; and

1 (9) in title XXVII, by striking the heading for  
2 such title.

3 **SEC. 2006. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

4 Section 399L(a) of the Public Health Service Act (42  
5 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106  
6 Stat. 3376), is amended—

7 (1) in the first sentence, by striking “the Sec-  
8 retary” and all that follows and inserting the follow-  
9 ing: “there are authorized to be appropriated  
10 \$30,000,000 for fiscal year 1994, and such sums as  
11 may be necessary for each of the fiscal years 1995  
12 through 1997.”; and

13 (2) in the second sentence, by striking “Out of  
14 any amounts used” and inserting “Of the amounts  
15 appropriated under the preceding sentence”.

16 **TITLE XXI—EFFECTIVE DATES**

17 **SEC. 2101. EFFECTIVE DATES.**

18 Subject to section 155, this Act and the amendments  
19 made by this Act take effect upon the date of the enact-  
20 ment of this Act.

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