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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 3, 1995

EXECUTIVE ORDER 12975

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PROTECTION OF HUMAN RESEARCH SUBJECTS AND
CREATION OF NATIONAL BIOETHICS ADVISORY COMMISSION

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Review of Policies and Procedures. (a) Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall promptly review the protections of the rights and welfare of human research subjects that are afforded by the department's or agency's existing policies and procedures. In conducting this review, departments and agencies shall take account of the recommendations contained in the report of the Advisory Committee on Human Radiation Experiments.

(b) Within 120 days of the date of this order, each department and agency that conducts, supports, or regulates research involving human subjects shall report the results of the review required by paragraph (a) of this section to the National Bioethics Advisory Commission, created pursuant to this order. The report shall include an identification of measures that the department or agency plans or proposes to implement to enhance human subject protections. As set forth in section 5 of this order, the National Bioethics Advisory Commission shall pursue, as its first priority, protection of the rights and welfare of human research subjects.

(c) For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the 1991 Federal Policy for the Protection of Human Subjects.

Sec. 2. Research Ethics. Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall, to the extent practicable and appropriate, develop professional and public educational programs to enhance activities related to human subjects protection, provide forums for addressing ongoing and emerging issues in human subjects research, and familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects. Where appropriate, such professional and educational programs should be organized and conducted with the participation of medical schools, universities, scientific societies, voluntary health organizations, or other interested parties.

Sec. 3. Establishment of National Bioethics Advisory Commission. (a) There is hereby established a National Bioethics Advisory Commission ("NBAC"). NBAC shall be composed of not more than 15 members to be appointed by the President. NBAC shall be subject to the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

(b) The President shall designate a Chairperson from among the members of NBAC.

Sec. 4. Functions. (a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

(1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and

(2) applications, including the clinical applications, of that research.

(b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(c) NBAC shall not be responsible for the review and approval of specific projects.

(d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

Sec. 5. Priorities. (a) As a first priority, NBAC shall direct its attention to consideration of: protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting.

(b) NBAC shall consider four criteria in establishing the other priorities for its activities:

(1) the public health or public policy urgency of the bioethical issue;

(2) the relation of the bioethical issue to the goals for Federal investment in science and technology;

(3) the absence of another entity able to deliberate appropriately on the bioethical issue; and

(4) the extent of interest in the issue within the Federal Government.

Sec. 6. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide NBAC with such information as it may require for purposes of carrying out its functions.

(b) NBAC may conduct inquiries, hold hearings, and establish subcommittees, as necessary. The Assistant to the President for Science and Technology and the Secretary of Health and Human Services shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration, and estimated frequency of meetings of the subcommittee.

(c) NBAC is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on NBAC, the Secretary of Health and Human Services may contract for the services of nongovernmental consultants who may conduct analyses, prepare reports and background papers, or prepare other materials for consideration by NBAC, as appropriate.

(d) Members of NBAC shall be compensated in accordance with Federal

law. Members of NBAC may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide NBAC with such funds as may be necessary for the performance of its functions. The Secretary of Health and Human Services shall provide management and support services to NBAC.

Sec. 7. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to NBAC, except that of reporting annually to the Congress, shall be performed by the Secretary of Health and Human Services, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) NBAC shall terminate two years from the date of this order unless extended prior to that date.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

THE WHITE HOUSE,
October 3, 1995.

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E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

16-Sep-1996 02:31pm

TO: (See Below)

FROM: Darby Stott
Office of Press Secretary

SUBJECT: STATEMENT RE: NATIONAL BIOETHICS ADVISORY BOARD

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

September 16, 1996

EXECUTIVE ORDER

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AMENDING EXECUTIVE ORDER NO. 12975

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to add 3 members to the National Bioethics Advisory Commission, it is hereby ordered that the number "15" in the second sentence of section 3(a) of Executive Order No. 12975 is deleted and the number "18" is inserted in lieu thereof.

WILLIAM J. CLINTON

THE WHITE HOUSE,
September 16, 1996.

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NATIONAL BIOETHICS ADVISORY COMMISSION

Independent

AUTHORITY:

Executive Order 12975, October 3, 1995 (establishes)
Executive Order 13018, September 16, 1996 (increases
membership)
Executive Order 13046, May 16, 1997 (extends
termination date)

METHOD:

Appointed by the President

MEMBERS:

Not more than **EIGHTEEN**

CHAIRPERSON:

Designated by the President from among the members

TERM:

Pleasure of the President

SALARY:

Members shall be compensated in accordance with Federal law and may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

PURPOSE:

Commission shall (a) provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

- (1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and
 - (2) applications, including the clinical applications, of that research.
- (b) Shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(CONTINUED - PAGE TWO)

NATIONAL BIOETHICS ADVISORY COMMISSION

Independent

- (c) Shall not be responsible for the review and approval of specific projects.
- (d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, the Commission also may accept suggestions of issues for consideration from both the Congress and the public. The Commission also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

ADMINISTRATIVE
SUPPORT:

The Secretary of Health and Human Services shall provide management and support services to the Commission.

TERMINATION:

Shall terminate on October 3, 1999, unless extended by the President prior to that date.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 3, 1995

EXECUTIVE ORDER 12975

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WILLIAM J. CLINTON

THE WHITE HOUSE,
October 3, 1995.

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