EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FAX TRANSMISSION

TO: Phil Caplan

FAX NUMBER 6-6704

FROM:
ROBERT G. DAMUS
Office of the General Counsel
Telephone: (202) 395-5044
Fax No.: (202) 395-7289

DATE: 2-4-94

COMMENTS:

I have determined that it is in the best interests of the Nation to conduct a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal Departments and Agencies regarding the protection of human subjects of biomedical or behavioral research which such Departments and Agencies currently conduct or support, and (2) of the implementation -- including oversight of compliance -- of such rules, policies, guidelines, and regulations by such Departments and Agencies. The review shall include appropriate recommendations for legislative and administrative action.

Adoption of the common Federal Policy for the Protection of Human Subjects (June 18, 1991; 56 FR 28003) marked an important step forward for the Federal government's attention to bioethical considerations. It is incumbent upon us, however, to exercise constant vigilance over the adequacy and implementation of the Federal Policy and related guidelines. In the course of the review prescribed above, I request specific attention to the adequacy of protections for vulnerable populations. In addition, I request a full appraisal of the ~~resources allocated by each agency to~~ adequacy of enforcement of their rules, policies, guidelines, and regulations. These specific requests should not be interpreted to limit the scope of the inquiry deemed necessary by the relevant Departments and Agencies.

This should not focus on resources -- simply more budget. There is no reason to think budget is more a problem than anything else.

The Assistant to the President for Science and Technology will coordinate this review under the National Science and Technology Council (Council). He will deliver a comprehensive report, including recommendations for appropriate legislative and administrative action, to the Council no later than August 1, 1994.

THE WHITE HOUSE

WASHINGTON

OFFICE OF LEGISLATIVE AFFAIRS

FAX COVER SHEET

NOTE: **THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS CONFIDENTIAL AND INTENDED FOR THE RECIPIENT ONLY.**

DATE: _____

TO: Phil Caplan

FAX #: 66704

FROM: Tracey Thornton

RE: _____

PAGE 1 OF 3

If there are any problems with this transmission, please call (202) 456-6493.

FAX SENT: ___

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

Telephone: (202) 224-4751
Fax: (202) 224-9682

Fax Transmission

Date: 1/26	**Pages Attached:** 1

TO: Tracy Thornton

FROM: Chris Kline

RE: _____

Comments:

Attached are the concerns of NARA as expressed to us. We will be following up on this w/individual agencies.

Chris

The National Archives and Records Administration, while not a part of the taskforce on review and declassification of records relating to radiation experiments by the U.S. Government, has supplied advice to the effort through the Office of the [White House] Counsel. That advice consisted of the following broad outline of four areas or steps that the process of review and release must consider:

I. Preparation

-Develop survey parameters
-Identify potential records repositories
*-Establish standard automated format
*-Establish level of description
*-Establish data elements and central database
*-Develop training materials
*-Conduct training

II. Survey

-Review records schedules
-Review location registers
-Enter data
-Ship diskettes
*-Read into central database

III. Consolidation

-Determine whether described material has research potential
*-Declassify and complete transfer documentation
-Ship

IV. Access

-Notification of individuals
-Use by official reviewers (Commission, taskforce)
-Use by biomedical researchers?
-Privacy review?
*-Use by public

*Areas where the Archives can provide specific assistance and advice

National Archives feels strongly that it should be involved in the information policy setting on this project due to our mission and experience (Watergate, Iran-Contra, JFK Assassination Records, etc.). Not entirely clear what our ongoing role will be.

THE WHITE HOUSE

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January 19, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

1. Each Agency should establish forthwith an initial procedure for locating records of human radiation experiments conducted by the Agency or under a contract or grant of the Agency. Agencies should coordinate the development of procedures for the retrieval and inventory of records with the Human Radiation Interagency Working Group (the "Interagency Working Group")[1] to ensure, where appropriate, that common procedures for the retrieval and inventory of records are applied at each Agency. Each Agency should provide to the Interagency Working Group a written copy of its initial directive and other documents implementing the Agency's record location, retrieval and inventory procedures.

2. (a) As used herein, "Agency" means Department of Defense, Department of Energy, Department of Health and Human Services, Central Intelligence Agency, Department of Veterans Affairs, and National Aeronautics and Space Administration.

(b) As used herein, "human radiation experiments" means:

(1) Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation.

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[1] The members of the Human Radiation Interagency Working Group include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence, and the Director of the Office of Management and Budget.

(2) Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

3. In addition, Agencies should establish forthwith a procedure for retrieval and inventory of records of the following experiments:

(a) The experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 in Hanford, Washington;

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(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other similar human experiments that may later be identified by the Interagency Working Group.

Each agency should include in the directive described in paragraph 1 above a directive initiating the Agency's retrieval and inventory procedure for records of the experiments set forth in this paragraph.

4. The procedures to be established pursuant to paragraph 1 above should address records for human radiation experiments conducted from 1944 to the present. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education and Welfare Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into such experiments is warranted. Further inquiry into such experiments conducted after May 30, 1974, may be pursued if the Advisory Committee on Human Radiation Experiments (to be established pursuant to Executive Order 12891 (Jan. 15, 1994)) determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

5. To the extent permitted by law, each Agency Head should institute procedures, consistent with paragraphs 6 and 7 below, for notifying and making records available to individuals subjected to human radiation experiments or the experiments set forth in paragraph 3 above, and/or their next of kin. Agencies should coordinate the development of these procedures with the Interagency Working Group.

6. Each Agency Head should institute procedures, consistent with existing statutes and regulations, for making records on human radiation experiments, and the experiments set forth in paragraph 3 above, available to members of the public. In implementing these procedures, each Agency Head should immediately issue an order to all elements of the Agency, and undertake all appropriate procedures to instruct and inform the Agency's grantees, contractors or other agents:

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7. Each agency should also:

   (a) Upon locating the records, review all records of human radiation experiments, and the experiments set forth in paragraph 3 above, for national security classification and declassify such records as soon as practicable and to the maximum extent possible. Agencies should avail themselves of every opportunity to cooperate in expediting the declassification process.

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(a) The experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 in Hanford, Washington;

(b) Two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;

(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other similar human experiments that may later be identified by the Interagency Working Group.

Each agency should include in the directive described in paragraph 1 above a directive initiating the Agency's retrieval and inventory procedure for records of the experiments set forth in this paragraph.

4. The procedures to be established pursuant to paragraph 1 above should address records for human radiation experiments conducted from 1944 to the present. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education and Welfare Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into such experiments is warranted. Further inquiry into such experiments conducted after May 30, 1974, may be pursued if the Advisory Committee on Human Radiation Experiments (to be established pursuant to Executive Order 12891 (Jan. 15, 1994)) determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

5. To the extent permitted by law, each Agency Head should institute procedures, consistent with paragraphs 6 and 7 below, for notifying and making records available to individuals subjected to human radiation experiments or the experiments set forth in paragraph 3 above, and/or their next of kin. Agencies should coordinate the development of these procedures with the Interagency Working Group.

6. Each Agency Head should institute procedures, consistent with existing statutes and regulations, for making records on human radiation experiments, and the experiments set forth in paragraph 3 above, available to members of the public. In implementing these procedures, each Agency Head should immediately issue an order to all elements of the Agency, and undertake all appropriate procedures to instruct and inform the Agency's grantees, contractors or other agents:

   (a) Not to destroy any records relating to human radiation experiments or the experiments set forth in paragraph 3 above.

   (b) To locate forthwith all records relating to human radiation experiments and the experiments set forth in paragraph 3 above; and to identify, and undertake all appropriate procedures with regard to, any such records in the possession of grantees, contractors or other agents of the Agencies. Agencies should work together, in coordination with the Interagency Working Group, to standardize the retrieval of such records, which may involve the transfer of files to one or more designated repositories.

7. Each agency should also:

   (a) Upon locating the records, review all records of human radiation experiments, and the experiments set forth in paragraph 3 above, for national security classification and declassify such records as soon as practicable and to the maximum extent possible. Agencies should avail themselves of every opportunity to cooperate in expediting the declassification process.

   (b) Before making any copies of such records available to the public, make any redactions required for the protection of personal privacy interests of individuals subjected to human radiation experiments or the experiments set forth in paragraph 3 above, and/or their next of kin.

8. Agencies should work together with the Interagency Working Group to standardize, where appropriate, the inventory of

records of human radiation experiments and the experiments set forth in paragraph 3 above.

9. Agencies should document the procedures implemented to search for, retrieve and inventory records of human radiation experiments and the experiments set forth in paragraph 3 above.

10. In developing guidelines for retrieval and inventory of records, Agencies should consider advice and information provided to the Interagency Working Group by the Advisory Committee on Human Radiation Experiments.

OFFICE OF CABINET AFFAIRS

THE WHITE HOUSE

WASHINGTON

FAX

TO: Tara O'Toole

DATE: 1/24

NO. OF PAGES 3
(Including cover)

PHONE:

FAX: 586-0956

PRIORITY: (Y) N

FROM: Phil Caplan

PHONE: (202) 456-2572

FAX: (202) 456-6704

MESSAGE:

I will call you about the attached document as well as Ruth Faden -- both for tomorrow's hearing.

→ Phil

THE WHITE HOUSE

WASHINGTON

January 24, 1994

MEMORANDUM FOR CHRISTINE VARNEY

FROM: John H. Gibbons
Assistant to the President for Science and Technology

SUBJECT: Review of Human Subject Research Protections

In the wake of public announcements about human radiation experiments conducted by the Federal government, a number of prominent individuals have called for a review of human subject research protections. My office has been working closely with several Federal agencies to establish: 1) an interagency committee to review human subject research protections and other bioethical considerations; and 2) establish an independent advisory committee to inform the workings of this interagency committee. It would be appropriate for Secretary O'Leary and other Administration officials to announce this effort at tomorrow's Senate hearing.

BACKGROUND

Since 1991, the Human Subjects Research Subcommittee of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET) has overseen implementation of the Federal Policy for the Protection of Human Subjects (adopted by 16 Departments and Agencies in June 1991). The activities of the FCCSET subcommittee have been subsumed within the National Science and Technology Council (NSTC). We recently decided to establish a Bioethics Policy Committee, which will continue the work of the FCCSET subcommittee and coordinate the development and implementation of a broader array of research guidelines. This NSTC committee could be tasked by Presidential Review Directive to review human research protections.

Also, I have been working with the Department of Energy, the Department of Health and Human Services, and other Federal agencies since last Fall to establish an independent bioethics advisory committee -- the National Bioethics Advisory Commission -- to help bring ethical considerations to bear on the research and development activities of the Federal government and to work with the Bioethics Policy Committee. The President could announce his intention to move forward with chartering this Commission.

ACTION

I recommend that this NSTC activity be announced as a Presidential initiative during the hearing before Senator Glenn on Tuesday, January 25, 1994. The following text would be appropriate for inclusion in the statements by DOE (Secretary O'Leary) and HHS (Dr. D.A. Henderson):

> The President recognizes the need to ensure that ethical considerations influence the design and administration of current and future research. He will issue a directive to the Federal agencies to review their guidelines for human subject research protections and to incorporate advice and comment from the private sector in developing bioethical standards for federally-funded research and development. This review will be coordinated by the Bioethics Policy Committee of the newly established National Science and Technology Council. An independent advisory group -- a National Bioethics Advisory Commission -- will be established to work with the interagency committee.

✓ cc: Phil Caplan

DRAFT 2/9/94

MEMORANDUM FOR THE VICE PRESIDENT
THE SECRETARY OF STATE
THE SECRETARY OF THE TREASURY
THE SECRETARY OF DEFENSE
THE ATTORNEY GENERAL
THE SECRETARY OF THE INTERIOR
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF COMMERCE
THE SECRETARY OF LABOR
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF ENERGY
THE SECRETARY OF EDUCATION
THE SECRETARY OF VETERANS AFFAIRS
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
THE DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
THE DIRECTOR, NATIONAL SCIENCE FOUNDATION
THE DIRECTOR, CENTRAL INTELLIGENCE AGENCY
THE CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION
THE CHAIRMAN, NUCLEAR REGULATORY COMMISSION
THE ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since the promulgation of the Nuremberg Code in 1947, there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and

Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by Departments and Agencies. Therefore, I direct each Department and Agency of government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

DRAFT

January 11, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES OK

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

1. Direction to Agencies

Each Agency shall establish forthwith a procedure for retrieval and inventory of records of human radiation experiments conducted by the Agency or under a contract or grant of the Agency. Agencies shall coordinate their procedures with the Human Radiation Interagency Working Group (the "Interagency Working Group") to ensure, where appropriate, that uniform procedures for the retrieval and inventory of records are applied at each Agency. Each Agency shall provide a written copy of the directive initiating the record retrieval to the Interagency Working Group.

2. Definitions

(a) "Agency" means Department of Defense, Department of Energy, Department of Health and Human Services, Central Intelligence Agency, Department of Veterans Affairs, and NASA.

(b) "Human radiation experiments" means:

(1) Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation.

(2) Experiments involving intentional environmental releases of radiation which

(A) were designed to test human health effects of ionizing radiation; or

(B) were designed to test the extent of human exposure to ionizing radiation.

3. In addition, Agencies should retrieve and inventory all records pertaining to:

(a) The experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run

test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 in Hanford, Washington;

(b) Two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;

(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Duqway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other experiments which may later be identified by the Human Radiation Interagency Working Group.

4. The Advisory Committee shall review experiments since 1944. Those records of human radiation experiments undertaken since the date of issuance (1974) of the U.S. government biomedical research guidelines will be sampled to determine their priority for review. Further inquiry into such experiments conducted after 1974 may be pursued if warranted.

5. Each Agency Head shall institute procedures for notifying and making records available to subjects of human radiation experiments and their next of kin. Agencies shall coordinate these procedures with the Human Radiation Interagency Working Group.

6. Each Agency Head shall institute procedures for making records on human radiation experiments available to the public. In implementing these procedures, each Agency Head shall immediately issue an order to all elements of the Agency and undertake all appropriate procedures in connection with the Agencies' grantees, contractors or other agents:

(a) Not to destroy any records relating to human radiation experiments.

(b) To locate forthwith all records relating to human radiation experiments in the custody of the Agency, and to identify records and undertake all appropriate procedures with regard to any such records in the possession of grantees, contractors or other agents of the Agency. Agencies shall work together with the Human Radiation Interagency Working Group to standardize the retrieval of these records, which may involve the transfer of files to a designated repository. Until specific instructions are given for the transfer of the records, individual documents shall not be removed from their file series.

7. Each Agency shall:

(a) Review all such records for national security classification and to declassify such records to the maximum extent as soon as possible.

Agencies shall avail themselves of every opportunity to cooperate in expediting this process.

(b) Make any deletions required for the protection of privacy interests of the subjects of the experiments or their next of kin.

8. Agencies shall work together with the Human Radiation Interagency Working Group to standardize the inventory of records of human radiation experiments. Such standards will address methods for describing records, collecting, transcribing and verifying inventory information, and documenting records search strategies.

9. In developing guidelines for retrieval and inventory, Agencies shall take account of advice provided to the Human Radiation Interagency Working Group by the Advisory Committee on Human Radiation Experiments.

DRAFT

January 18, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

1. Each Agency should establish forthwith a procedure for retrieval and inventory of records of human radiation experiments conducted by the Agency or under a contract or grant of the Agency. Agencies should coordinate the development of these procedures with the Human Radiation Interagency Working Group (the "Interagency Working Group")[1] to ensure, where appropriate, that uniform procedures for the retrieval and inventory of records are applied at each Agency. Each Agency should provide to the Interagency Working Group a written copy of its directive initiating the Agency's record retrieval and inventory procedure.

2. (a) As used herein, "Agency" means Department of Defense, Department of Energy, Department of Health and Human Services, Central Intelligence Agency, Department of Veterans Affairs, and National Aeronautics and Space Administration.

(b) As used herein, "human radiation experiments" means:

(1) Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation.

---

[1] The members of the Human Radiation Interagency Working Group include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence, and the Director of the Office of Management and Budget.

(2) **Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.**

3. In addition, Agencies should establish forthwith a procedure for retrieval and inventory of records pertaining to the following experiments:

(a) The experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 in Hanford, Washington;

(b) Two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;

(c) Six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah site;

(d) Four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(e) Any other similar experiments which may later be identified by the Interagency Working Group.

Each agency should provide to the Interagency Working Group a written copy of the directive initiating the Agency's retrieval and inventory procedure for records pertaining to the experiments set forth in this paragraph.

4. Records should be retrieved and inventoried for human radiation experiments conducted from 1944 to the present. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education and Welfare Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into such experiments is warranted. Further inquiry into such experiments conducted after May 30, 1974, may be pursued if the Advisory Committee on Human Radiation Experiments (to be established pursuant to Executive Order 12891 (Jan. 15, 1994)) determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

5. To the extent permitted by law, each Agency Head should institute procedures for notifying and making records available to subjects of human radiation experiments, persons physically affected by the experiments set forth in paragraph 3 above, and their next of kin. Agencies should coordinate these procedures with the Interagency Working Group.

6. Each Agency Head should institute procedures, consistent with existing statutes and regulations, for making records on human radiation experiments, and the experiments set forth in paragraph 3 above, available to members of the public. In implementing these procedures, each Agency Head should immediately issue an order to all elements of the Agency, and undertake all appropriate procedures to instruct and inform the Agency's grantees, contractors or other agents:

   (a) Not to destroy any records relating to human radiation experiments or the experiments set forth in paragraph 3 above.

   (b) To locate forthwith all records relating to human radiation experiments and the experiments set forth in paragraph 3 above; and to identify, and undertake all appropriate procedures with regard to, any such records in the possession of grantees, contractors or other agents of the Agencies. Agencies should work together, in coordination with the Interagency Working Group, to standardize the retrieval of such records, which may involve the transfer of files to one or more designated repositories. Until Agency Heads receive specific instructions from the Interagency Working Group with respect to the transfer of records, individual documents should not be removed from the file series in which they are located.

7. Each agency should also:

   (a) Upon retrieval, review all records of human radiation experiments, and the experiments set forth in paragraph 3 above, for national security classification and declassify such records as soon as practicable and to the maximum extent permitted by law. Agencies should avail themselves of every opportunity to cooperate in expediting the declassification process.

   (b) Before making any copies of such records available to the public, make any redactions, and provide any such notice, required for the protection of personal privacy interests of the subjects of the experiments, other

individuals mentioned in such records, or their next of kin.

8. Agencies should work together with the Interagency Working Group to standardize, where appropriate, the inventory of records of human radiation experiments and the experiments set forth in paragraph 3 above.

9. Agencies should document the procedures implemented to search for, retrieve and inventory records of human radiation experiments and the experiments set forth in paragraph 3 above.

10. In developing guidelines for retrieval and inventory of records, Agencies should consider advice and information provided to the Interagency Working Group by the Advisory Committee on Human Radiation Experiments.

DRAFT 2/14/94

MEMORANDUM FOR THE VICE PRESIDENT
THE SECRETARY OF STATE
THE SECRETARY OF THE TREASURY
THE SECRETARY OF DEFENSE
THE ATTORNEY GENERAL
THE SECRETARY OF THE INTERIOR
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF COMMERCE
THE SECRETARY OF LABOR
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF ENERGY
THE SECRETARY OF EDUCATION
THE SECRETARY OF VETERANS AFFAIRS
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
THE DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
THE DIRECTOR, NATIONAL SCIENCE FOUNDATION
THE DIRECTOR, CENTRAL INTELLIGENCE AGENCY
THE CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION
THE CHAIRMAN, NUCLEAR REGULATORY COMMISSION
THE ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and

were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by Departments and Agencies. Therefore, I direct each Department and Agency of government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

THE WHITE HOUSE

WASHINGTON

February 7, 1994

To: Phil Caplan

From: Steve Neuwirth

Please call as soon as possible with any comments on extension 67903.

Include Pat's language?

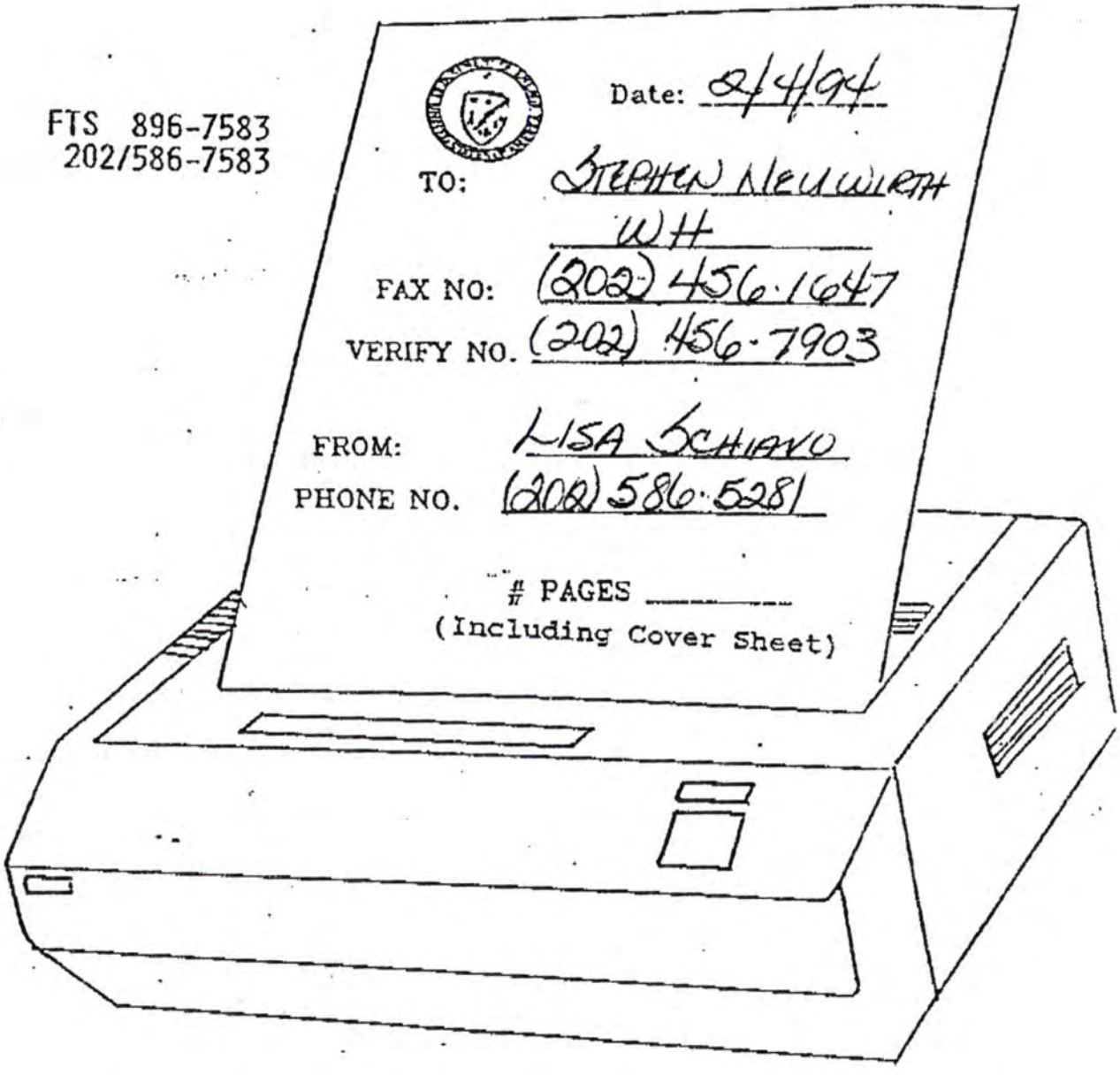
from Ann to Holly Green

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

FAX #: FTS 896-7583
COML: 202/586-7583



Date: 2/4/94

TO: STEPHEN NEUWIRTH
WH

FAX NO: (202) 456-1647

VERIFY NO. (202) 456-7903

FROM: LISA SCHIAVO

PHONE NO. (202) 586-5281

PAGES _____
(Including Cover Sheet)

REMARKS: Please contact D.A. Henderson or Kathy Hudson @ HHS, phone: 202/690-6811, Fax: (202) 690-7360.

DRAFT 2/7/94

MEMORANDUM FOR THE VICE PRESIDENT
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF ENERGY
THE SECRETARY OF COMMERCE
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE ATTORNEY GENERAL
THE SECRETARY OF DEFENSE
THE SECRETARY OF EDUCATION
THE SECRETARY VETERANS' AFFAIRS
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF LABOR
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
THE DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
THE DIRECTOR, NATIONAL SCIENCE FOUNDATION
THE DIRECTOR, CENTRAL INTELLIGENCE AGENCY
THE CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION
THE CHAIRMAN, NUCLEAR REGULATORY COMMISSION
THE ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally-funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since the promulgation of the Nuremberg Code in 1947, there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education, and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in

relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by Agencies. Therefore, I hereby direct each Agency of government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not full comply with the Federal Policy.

Phil--
In response to your request, how about the underlined text?
Kathy Hudson (690-6811)

DRAFT PRESIDENTIAL MEMORANDUM
ON HUMAN RESEARCH SUBJECTS PROTECTIONS
February 8, 1994

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally-funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since **the promulgation of guidelines for research with human subjects in 1947,** there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education, and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

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report to congress of hhs
bureaue of rad health---, imax,

Phil--
How about deleted the underlined text and replacing with the bold text below. The sense is maintained (that human subjects protections didn't just appear, but we get rid of the reference to Nurember).
Kathy Hudson (690-6811)

DRAFT PRESIDENTIAL MEMORANDUM
ON HUMAN RESEARCH SUBJECTS PROTECTIONS
February 8, 1994

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally-funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since **the mid-1940's** ~~the promulgation of the Nuremberg Code in 1947,~~ there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education, and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

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FAX TRANSMITTAL SHEET

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

PUBLIC HEALTH SERVICE

DATE: 02/14/94

FROM: Dr. Kathy Hudson

TITLE: Senior Policy Analayst to the Deputy Assistant Secretary for Health and Science

PHONE: 202/690-6811

FAX: 202/690-7360

TO: Phil Caplan

ADDRESS: The White House

PHONE: 456-2572

FAX: 456-6704

Number of pages (including cover): 2

* *

Message:

declaration
announcement
publication

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

February 10, 1994

MEMO FOR: Mr Phil Caplan

SUBJECT: Final comments on Draft Presidential Memo

Phil:

I would suggest two changes:

(1) First paragraph, last sentence. Human subjects research.....behavioral research, and bioethical.....research. (That is, strike although).

(2) Last paragraph, last sentence. Therefore, I hereby..... .....of Human Subjects. (Strike: and to cease.....or conducting). New sentence: Any experiments involving.....with the Federal Policy must be terminated.

Gordon

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

February 10, 1994

MEMO FOR: Mr Phil Caplan

SUBJECT: Final comments on Draft Presidential Memo

Phil:

I would suggest two changes:

(1) First paragraph, last sentence. Human subjects research.....behavioral research, and bioethical.....research. (That is, strike although).

(2) Last paragraph, last sentence. Therefore, I hereby..... .....of Human Subjects. (Strike: and to cease.....or conducting). New sentence: Any experiments involving.....with the Federal Policy must be terminated.

Gordon

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

FAX TRANSMITTAL SHEET

DATE: 2/8/94

TO: Kathy Hudson; HHS 690-7360
Phil Caplan, HHS 66704

FAX NUMBER: _____

PHONE NUMBER: _____

FROM: Holly Gwin

_____

TELEPHONE: (202) 456-~~7116~~ 2735

FAX: (202) 395-3261

NUMBER OF PAGES (INCLUDING COVER SHEET): 2

SPECIAL INSTRUCTIONS:

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

February 8, 1994

MEMORANDUM FOR KATHY HUDSON

FROM: HOLLY GWIN

SUBJECT: MEMORANDUM ON REVIEW OF HUMAN SUBJECT RESEARCH GUIDELINES

Based on our discussions with members of Congress and their staff and on the spate of articles we are starting to see about federal safeguards for human subjects research, OSTP believes the current draft of the memo lacks an essential element: a coordinated review conducted at the Presidential (NSTC) level to determine whether legislative and/or administrative actions are needed to make improvements in either policies or compliance measures. We fear that if the President simply directs the agencies to "make sure this never happens again" without specifically providing for visible follow through, the Administration leaves itself open for continued criticism.

We suggest inserting the following paragraph at the end of the current draft:

"The Assistant to the President for Science and Technology will coordinate this review under the National Science and Technology Council. He will deliver a comprehensive report, including, if necessary, recommendations for appropriate legislative and administrative action, to the Council no later than August 1, 1994."

The current draft focuses solely on compliance with the existing rule, which seemingly precludes a review of the rule itself. This eliminates consideration, within the context of this review, of the issues surrounding vulnerable populations, which have been raised several times in Congress and in the media. OSTP believes there is some benefit in the President being seen as more proactive on this issue.

Please call me if you have any questions or would like to discuss this further (456-2735).

cc: Phil Caplan

DRAFT PRESIDENTIAL MEMORANDUM
ON HUMAN RESEARCH SUBJECTS PROTECTIONS
February 8, 1994

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally-funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since the promulgation of the Nuremberg Code in 1947, there has been increasingly wide-spread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education, and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, sixteen agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits, (2) there is informed consent, and (3) the rights and welfare of the subjects are maintained. See 56 Fed. Reg. 28003 (June 18, 1991).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by Agencies. Therefore, I hereby direct each Agency of government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not full comply with the Federal Policy.

CENTER FOR THE STUDY OF INTELLIGENCE

PLEASE DELIVER IMMEDIATELY

****

FAX

DOCUMENT TRANSACTION VERIFICATION

SUBJECT: Draft Presidential Memorandum

FROM: David Gries, CIA

FAX NO: 703-243-8343

DELIVER TO: Phil Caplan

FAX NO: 202 456-6704

DATE TRANSMITTED: Feb 3 **PAGES TRANSMITTED:** 1

TRANSMITTED BY:

DATE RECEIVED: **PAGES RECEIVED:**

TIME RECEIVED:

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****

MESSAGE: Phil: CIA concurs. It's a good, clear statement.

Dave

2/7

TT —

- don't include "legislative action"

- just says more problems

THE WHITE HOUSE

WASHINGTON

February 3, 1994

MEMORANDUM TO DISTRIBUTION

FROM: Christine Varney
Phil Caplan

SUBJ: Draft Presidential Memorandum

Please review the attached first draft of a Presidential Memorandum directing all federal departments and agencies engaged in human subject testing to vigorously review their procedures and ensure compliance with current standards.

We hope to be able to have this ready for the President's signature by close of business Monday. Please have comments/edits returned to Phil Caplan (202/456-6704 fax) by close of business Friday. We must move quickly to get this process completed.

FYI -- this will also be faxed to the Legal Issues Subcommittee of the Interagency Working Group.

Thank you.

DISTRIBUTION:

		Phone:	Fax:
DOE:	Rich Rosenzweig	586-6210	586-7644
DOE:	Tara O'Toole	586-6151	586-0956
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VA:	Harold Gracey	535-8900	535-8667
HHS:	Kevin Thurm	690-6133	690-7755
NASA:	Chris Dunn	358-1827	358-2810
DOJ:	Nancy McFadden	514-9500	514-4371
Treas:	Alicia Munnell	622-2200	622-2633
CIA:	David Gries	703/351-2698	703/243-8343

DRAFT: 1/26/94

MEMORANDUM FOR THE VICE PRESIDENT
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF ENERGY
THE SECRETARY OF COMMERCE
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE ATTORNEY GENERAL
THE SECRETARY OF DEFENSE
THE SECRETARY OF EDUCATION
THE SECRETARY OF VETERANS' AFFAIRS
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF LABOR
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
THE DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
THE DIRECTOR, NATIONAL SCIENCE FOUNDATION
THE DIRECTOR, CENTRAL INTELLIGENCE AGENCY
THE CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION
THE CHAIRMAN, NUCLEAR REGULATORY COMMISSION
THE ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: Review of Fedoral Policy for the Protection of Human Subjects

Federally-funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often culminates in experiments that involve human subjects. While human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence its design and administration and necessarily limit certain types of scientific investigation.

I have determined that it is in the best interests of the Nation to conduct a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal Departments and Agencies regarding the protection of human subjects of biomedical or behavioral research which such Departments and Agencies currently conduct or support, and (2) of the implementation -- including oversight of compliance -- of such rules, policies, guidelines, and regulations by such Departments and Agencies. The review shall include appropriate recommendations for legislative and administrative action.

Adoption of the common Federal Policy for the Protection of Human Subjects (June 18, 1991; 56 FR 28003) marked an important step forward for the Federal government's attention to bioethical considerations. It is incumbent upon us, however, to exercise constant vigilance over the adequacy and implementation of the Federal Policy and related guidelines. In the course of the review prescribed above, I request specific attention to the adequacy of protections for vulnerable populations. In addition, I request a full appraisal of the resources allocated by each agency to enforcement of their rules, policies, guidelines, and regulations. These specific requests should not be interpreted to limit the scope of the inquiry deemed necessary by the relevant Departments and Agencies.

The Assistant to the President for Science and Technology will coordinate this review under the National Science and Technology Council (Council). He will deliver a comprehensive report, including recommendations for appropriate legislative and administrative action, to the Council no later than August 1, 1994.