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001: list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
002: list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
003: note	re: Questions on EO [partial] (1 page)	n.d.	P3/b(3)
004: fax	To Elizabeth Drye (1 page)	n.d.	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
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FOLDER TITLE:

Executive Order on Classified Research

Racheal Carter
2014-0046-S
rc1443

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

--- DRAFT ---

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES THAT CONDUCT OR
SUPPORT HUMAN SUBJECTS RESEARCH RESEARCH

SUBJECT: Strengthened Protections for Human Subjects of
 Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal government's protections for human subjects of classified research.

In January, 1994 I established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, *Final Report, Advisory Committee on Human Radiation Experiments*). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct secret research on human subjects where such research serves an important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval processes for human research that is to be classified." ACHRE recommend that all classified research meet the following requirements:

- 1) researchers obtain informed consent from all human subjects;
- 2) researchers inform subjects of the identity of the sponsoring agency;
- 3) researchers inform subjects that the project involves classified research; and
- 4) the project is approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

This memorandum implements recommendations 1-3. For classified research, it prohibits waiver of informed consent, requires researchers to disclose that the project is classified, and requires researchers to inform subjects of the sponsoring agency.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. The memorandum requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board that believes a project should not go forward can appeal the board's decision to approve it. This approach differs from that recommended by ACHRE but addresses ACHRE's underlying concerns.

Finally, this memorandum sets forth additional steps to fully ensure that classified human subjects research is rare. It requires each of you to disclose annually the number of secret human subjects research projects undertaken by your agency. It also prohibits agencies to conduct secret human subjects research without first issuing the Federal Policy for the Protection of Human Subjects.

These steps will preserve the government's ability to conduct any necessary classified research ^{using} ~~on~~ human subjects while ensuring adequate protection of these subjects.

Sec 1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that conduct or support research involving human subjects shall, within 60 days, publish in the Federal Register the following revisions to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") as it affects classified research.

(a) The agencies shall propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

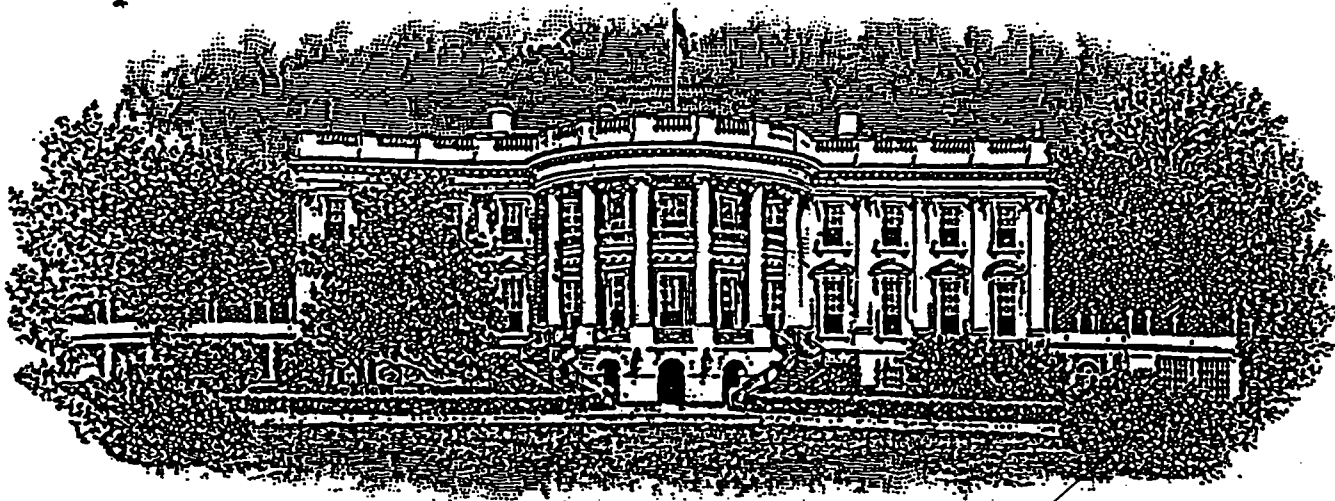
- 1) the identity of the sponsoring Federal agency; and
- 2) a statement that the project is classified.

(c) The agencies shall propose to modify the institutional review board (IRB) approval process for classified human subjects research as follows:

(1) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall propose to require that the member "not otherwise affiliated with the institution," meets the existing criteria and is also a non-governmental member with the appropriate security clearance.

CONFIDENTIAL

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Dr. Ruth Fader

FAX NUMBER: 410-614-9567

TELEPHONE NUMBER: _____

FROM: Elizabeth Drye

TELEPHONE NUMBER: 202-456-5573

PAGES (INCLUDING COVER): 8

COMMENTS: For your review only, attached
is revised discussion of notification
policy. Thanks so much for your
continued help.

PP 21-27
Sent 1/30
1407
JML

Part 3: Righting Past Wrongs

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Overview

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II; research with prisoners; and research on patients who had previously been exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered “experiments.” These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE’s findings and recommendations in the areas of notification, apology, and compensation and presents the Administration’s response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

The ACHRE report reviewed in detail several case studies of government-supported human radiation research

ACHRE Findings and Recommendations on Notification

The Advisory Committee found “no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health.” In addition, the Committee found no evidence that descendants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects.

The Advisory Committee recommended that (Recommendation 4):

- For any newly-discovered experiments the government should notify participants and provide medical follow-up for “those

subjects for whom there is a significant risk of developing a radiation-related disease that has not yet occurred, or has occurred but may still be undetected or untreated, and in whom there might be an opportunity to prevent or minimize potential health risks through detection and treatment."

- The government need not notify subjects of experiments reviewed by ACHRE for public health reasons because they did not meet the recommended criteria for notification.

Response

Beyond protecting public health, the government will seek to support as fully as possible individual's right to know about actions that may have affected them.

The Administration's view is that, *in general*, ACHRE's recommendation is correct. For public health reasons, the government will notify any identified subjects who meet the criteria in the ACHRE report. These include any subjects placed at a significant risk for development of a radiation related disease, where there is a recognized medical benefit from early detection and treatment. (Because medical science is not static, the decision whether there is a medical benefit is not static either.)

Beyond protecting public health, the government will seek to support as fully as possible individuals' right to know about actions that may have affected them. Therefore, the government will also notify an identified experimental subject: if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to investigate whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that this approach fulfills the government's grave responsibility to inform subjects while maintaining respect for those people who would not want information that has no tangible benefit.

It is important to be clear that notification is not simply the process of taking a list of names, current addresses, and phone numbers that are in the possession of Federal agencies and contacting people. For most experiments, no names are available. Much information about past experiments comes from the published literature and does not generally include names. Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts. Another barrier to identifying individuals is that much of the information is in the records of private hospitals and universities where confidentiality and privacy rules prohibit government access.

For all of these reasons, the process of locating individuals or next of kin many years after the experiments took place is difficult, time consuming, costly to the taxpayer, and likely to have limited success. Where individuals can be found, it is difficult to assess their exposure and risk given the limited data available.

Notwithstanding the difficulties of undertaking individual notification, the government reaffirms its continuing commitment to openness. Where the government does not undertake individual notification it will continue to make public material relating to human radiation experiments, to respond to individual inquiries relating to these experiments, and to carefully review any newly identified experiments in the light of the Advisory Committee notification criteria.

Discussion

Many of the wrongs in experimentation involved failure to provide subjects with a full and fair disclosure of the risks and benefits (or lack of benefits). At first impression, the solution to this lack of disclosure seems evident, namely, disclose now what was not disclosed in the past. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects, including anxiety; medical harm; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. In light of these considerations, and the difficulty in tracing subjects, ACHRE recommended notification in the limited circumstances where the individual desires notification or where the notification would be of medical benefit to the individual.

This recommendation has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26–27, 1996, held by the Federal departments. Some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government; not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally advocate that the government pursue some form of notification, and provide medical care by physicians of their own choice. Many subjects or families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others have also suggested that subjects would want notification whether or not they were harmed. See "Hearings on Human Radiation Experiments,

Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts.

Senate Committee on Governmental Affairs, March 12, 1996, remarks of Senator Glenn.”

The Administration agrees that the decision of when and how to notify experimental subjects requires a judgment about whether individuals would want to be notified of the government’s potentially wrongful act to them, even if there is no public health reason to notify an individual.

Where records become available that would allow notification, the Administration will notify subjects that meet the ACHRE public health criteria and will also notify those that meet any one of three additional criteria. These criteria are intended to shed light on the non-health benefits that may accrue to those potentially to be notified. As noted above, subjects will be notified if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to understand whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that these other benefits—where they are present—would cause most subjects to prefer notification.

Information requests: Where information is available, potential experimental subjects will be provided information if they so request. The government will use all reasonable means to let potential subjects know that they have the opportunity to ask questions about their own history and a choice about whether to pursue the information.

To make the choice meaningful, the government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. Publicity about the existence of experiments, and the widespread availability of a general description of the research has successfully generated tens of thousands of inquiries from those who want to know whether they were experimental subjects. This large response suggests that the government’s outreach efforts have provided an opportunity for a significant portion of potential subjects to choose whether to seek more information.

Based on the response so far, the Administration believes that continued publication of general information and follow-up of individual inquiries satisfies much of the government’s obligation to notify those who potentially were subjects of experiments.

The government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research.

Additional research: In the event that the departments uncover additional forgotten experiments, any newly-discovered subjects will be notified by the Department that sponsored the research, based on the criteria discussed above.

As experiments are identified there may be uncertainty about whether initial exposures to radiation significantly increased the risk to subjects. In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be enough identifiable subjects to allow for a follow-up study. The follow-up study would be designed to identify any risk to subjects and whether medical follow up could be beneficial. The Administration's policy does not preclude conducting such a study—even though the government cannot answer with certainty what level of risk is faced by former subjects and whether there is any prospect of medical or other benefit to subjects from a follow-up study. Any follow-up study should move forward only under the following conditions:

- 1) All care has been taken to minimize any harmful effects of participating in a study;
- 2) Members of the public have been consulted regarding the study and its fairness to individuals who will be notified of their prior participation in an experimental treatment.

Actions to Date

The most important actions the government has taken to notify potential human subjects are the actions described above in the section on openness. This widespread public availability of information has given individuals the opportunity to choose whether they will seek additional information about their own possible involvement in experiments.

Individual inquiries: Those who would like more information about their individual records can obtain assistance by a phone call; the current number is (202) 586-8439. By calling this number, individuals who think they may have been involved in experiments can have their cases reviewed by the appropriate agency. As of December 1, 1996, DOE has answered over 20,000 information requests, and researched 3,000 cases; DOD has responded to approximately 7,000 case inquiries of which approximately 800 are currently undergoing active research; VA has responded to approximately 1,750 inquiries; and HHS, to approximately 90.

Departments are making every effort to research cases. There are several factors beyond the government's control that influence the length of time the research takes or the ultimate success in each

In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be enough identifiable subjects to allow for a follow-up study.

individual quest for information. For example, some government records are more complete than others; some individuals can provide more kinds of information (e.g., dates, place names, and other identifying information); and some private institutions will be more or less responsive to inquiries.

DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II.

Notification of NASA employees: Consistent with the effort to provide general information to the widest possible groups of people, the National Aeronautics and Space Administration (NASA) has notified approximately 110,000 current and former NASA employees, contractors, and grantees about the human radiation research review. This notification included those universities and institutions at which human radiation research was performed through NASA grants.

Notification of veterans: VA convened an expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry to review information about certain projects, and to determine whether notification of known subjects is warranted. The VA focused its attention on early radiation research projects for which at least some of the names of research subject were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. The expert committee did not identify any veterans who warranted special follow-up actions specifically because of their radiation exposure.

Nasopharyngeal irradiation with radium (NP) during military service: DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II. In April 1996, DOD discovered a Navy medical log book which lists the names of submariners who were given the NP treatment in 1945 to 1946 under an experimental protocol. Using the log book as the focal point, DOD and VA are conducting intensive research at the National Records Center and other repositories to identify other Service members who received NP treatment and, if feasible, retrieve medical data for possible cohort or epidemiological studies to notify individuals as appropriate. NP treatment was a widely used conventional therapy, particularly for children, during the 1940s and 1950s. Therefore a study could be valuable to many civilians as well as veterans.

The VA, along with the Centers for Disease Control (CDC) and Yale University, cosponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut in September 1995. Consensus did not support medical screening of asymptomatic individuals but recommended that individuals treated

with NP irradiation inform their health care providers for consideration when they are examined or evaluated. VA officials have published information on NP irradiation treatments in medical journals and provided it to veterans' newsletters.

The VA and CDC held a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP irradiation do not have special eligibility for VA care. The Administration will propose legislation that would make veterans treated with NP irradiation eligible for the VA's Ionizing Radiation Program.

Alaskan natives: A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM concerning the Iodine-131 experiments involving Native Alaskans as set forth in its recent report. Efforts are ongoing with representatives of the Native Alaskans to determine appropriate follow-up remedies.

Identifying additional subjects: DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located. In addition, DOE asked all its facilities at which human radiation experiments were identified, to provide detailed information about the availability of data, if any, relating to individual subjects, the feasibility of notification, and whether any notification process had occurred. Where employees or former employees had been involved in experiments, notification generally had taken place. Otherwise, it was determined that the available data did not warrant notification in light of the criteria outlined above. If new information or experiments come to light, the Department will review these according to the Advisory Committee criteria.

DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located.

ACHRE Findings and Recommendations Regarding Remedies

The Advisory Committee found that:

[T]he government sponsored . . . several thousand human radiation experiments. In the great majority of cases, the experiments were conducted to advance biomedical science; some experiments were conducted

to advance national interests in defense or space exploration; and some experiments served both biomedical and defense or space exploration purposes. (Finding 1)

[P]eople who were used as research subjects without their consent were wronged even if they were not harmed." In addition, the Committee was "not persuaded that even where the facts are clear and the identities of subjects known, financial compensation is necessarily a fitting remedy when people have been used as subjects without their knowledge or consent but suffered no material harm as a consequence. (Recommendation 3)

[S]ome government agencies required the consent of some research subjects well before 1944 . . . [and] government agencies did not generally take effective measures to implement their requirements and policies on consent to human radiation research. (Findings 4 and 5)

[T]he government and government officials are morally responsible in cases in which they did not take effective measures to implement the government's policies and requirements. . . .

[G]overnment officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive medical benefits (nontherapeutic research in the strict sense). By contrast, to the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices. (Findings 11a and 11c)

[S]ince the end of the Manhattan Project in 1946 human radiation experiments (even where expressly conducted for military purposes) have typically not been classified as secret by the government. Nonetheless, important discussions of human experimentation took place in secret, and information was kept secret out of concern for embarrassment to the government, potential legal liability, and concern that public misunderstanding would jeopardize government programs. In some cases, deception was employed. In the case of the

For Phil Caplan

For Dot

to
Bliz Dye

THE WHITE HOUSE

WASHINGTON

March 27, 1997

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE ATTORNEY GENERAL
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 DIRECTOR OF CENTRAL INTELLIGENCE
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION
AGENCY
THE ADMINISTRATOR OF THE AGENCY FOR INTERNATIONAL
DEVELOPMENT
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION
THE DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION
THE CHAIR OF THE NUCLEAR REGULATORY COMMISSION
THE DIRECTOR OF THE OFFICE OF SCIENCE AND
TECHNOLOGY POLICY
THE CHAIR OF THE CONSUMER PRODUCT SAFETY
COMMISSION

SUBJECT: Strengthened Protections for Human Subjects
of Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January 1994, I established the Advisory Committee on Human Radiation Experiments (the "Advisory Committee") to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed the Advisory Committee to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October 1995 final report, the Advisory Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, Final Report, Advisory Committee on Human Radiation Experiments). This memorandum sets forth policy changes in response to those recommendations.

The Advisory Committee acknowledged that it is in the Nation's interest to continue to allow the government to conduct classified research involving human subjects where such research serves important national security interests. The Advisory Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." The Advisory Committee was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." The Advisory Committee recommended that in all classified research projects the agency conducting or sponsoring the research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research;
- obtain approval by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances" that reviews scientific merit, risk-benefit tradeoffs, and ensures subjects have enough information to make informed decisions to give valid consent; and
- maintain permanent records of the panel's deliberations and consent procedures.

This memorandum implements these recommendations with some modifications. For classified research, it prohibits waiver of informed consent and requires researchers to disclose that the project is classified. For all but minimal risk studies, it requires researchers to inform subjects of the sponsoring agency. It also requires permanent recordkeeping.

The memorandum also responds to the Advisory Committee's call for a special review process for classified human subjects research. It requires that institutional review boards for secret projects include a nongovernmental member, and establishes an appeals process so that any member of a review board who believes a project should not go forward can appeal the boards' decision to approve it.

Finally, this memorandum sets forth additional steps to ensure that classified human research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by their agency. It also prohibits any agency from conducting secret human research without first promulgating a final rule applying the Federal Policy for the Protection of Human Subjects, as modified in this memorandum, to the agency.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

1. Modifications to the Federal Policy for the Protection of Human Subjects as it Affects Classified Research. All agencies that may conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") (56 Fed. Reg. 28010-28018) shall promptly jointly publish in the Federal Register the following proposed revisions to the Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services shall be the lead agency and, in consultation with the Office of Management and Budget, shall coordinate the joint rulemaking.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to prohibit the use of expedited review procedures under the Common Rule for classified research.

(c) The joint proposal should request comment on whether all research exemptions under the Common Rule should be maintained for classified research.

(d) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

- (i) the identity of the sponsoring Federal agency. Exceptions are allowed if the head of the sponsoring agency determines that providing this information could compromise intelligence sources or methods and that the research involves no more than minimal risk to subjects. The determination about sources and methods is to be made in consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs. The determination about risk is to be made in consultation with the Director of the White House Office of Science and Technology Policy.

- (ii) a statement that the project is "classified" and an explanation of what classified means.

(e) The agencies shall jointly propose to modify the institutional review board ("IRB") approval process for classified human subjects research as follows:

- (i) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a nongovernmental member with the appropriate security clearance.
- (ii) Under the Common Rule, research projects are approved by the IRB if a "majority of those (IRB) members present at a meeting" approved the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve the project to the head of the sponsoring agency. If the agency head affirms the IRB's decision to approve the project, the dissenting IRB member may appeal the IRB's decisions to the Director of OSTP. The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of nongovernmental officials, each with the appropriate security clearances, to approve or disapprove the project.
- (iii) IRBs for classified research shall determine whether potential subjects need access to classified information to make a valid informed consent decision.

2. Final Rules. Agencies shall, within 1 year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

3. Agency Head Approval of Classified Research Projects. Agencies may not conduct any classified human research project subject to the Common Rule unless the agency head has personally approved the specific project.

4. Annual Public Disclosure of the Number of Classified Research Projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that

date, the number completed in the previous 12-month period, and the number of human subjects in each project. The Director of OSTP shall report the total number of classified research projects and participating subjects to the President and shall then report to the congressional armed services and intelligence committees and further shall publish the numbers in the Federal Register.

5. Definitions. For purposes of this memorandum, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule. "Classified human research" means research involving "classified information" as defined in Executive Order 12958.

6. No Classified Human Research Without Common Rule. Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed and promulgated the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.

7. Judicial Review. This memorandum is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

8. The Secretary of Health and Human Services shall publish this memorandum in the Federal Register.

WILLIAM J. CLINTON

Office for
Protection from
Research
Risks

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Suite 3B01
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Rockville, MD 20892-7507

Date: SEP 16 1996

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From: Gary B. Ellis

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Comments:

FEDERAL POLICY FOR THE
PROTECTION OF HUMAN SUBJECTS

Document consists of 9 pages, including cover sheet.

Tuesday
June 18, 1991

Part II

Federal Policy for the Protection of Human Subjects; Notices and Rules

Office of Science and Technology Policy
Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Consumer Product Safety Commission
International Development Cooperation Agency
 Agency for International Development
Department of Housing and Urban Development
Department of Justice
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
 Office of the Secretary
 Food and Drug Administration
National Science Foundation
Department of Transportation

Federal Register / Vol. 56, No. 117 / Tuesday, June 18, 1991

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

**NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION**

14 CFR Part 1230

DEPARTMENT OF COMMERCE

15 CFR Part 27

**CONSUMER PRODUCT SAFETY
COMMISSION**

16 CFR Part 1028

**INTERNATIONAL DEVELOPMENT
COOPERATION AGENCY**

Agency for International Development

22 CFR Part 225

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

24 CFR Part 60

DEPARTMENT OF JUSTICE

28 CFR Part 46

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**DEPARTMENT OF VETERANS
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

45 CFR Part 46

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

**Federal Policy for the Protection of
Human Subjects**

AGENCIES: United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; Department of Transportation.

ACTION: Final rule.

CFR Part —Protection of Human Subjects

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§ 101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 102(e) must be reviewed and approved, in compliance

with § 101, § 102, and § 107 through § 117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

Text of the Common Rule

The text of the Common Rule as adopted by the Department and Agencies in this document appears below:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the

procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures.¹

§ 102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

¹ Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR part 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR part 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). *Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.*

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of

routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under § 101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with § 103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the

department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under § 101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § 103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § 103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 104 (Reserved)

§ 105 (Reserved)

§ 106 (Reserved)

§ 107 IRB Membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly

conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the name detail as described in

§ 103(b)(4) and, to the extent required by, § 103(b)(5).

(b) Except when an expedited review procedure is used (see § 110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 109 IRB Review of Research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 116. The IRB may require that information, in addition to that specifically mentioned in § 116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication

by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the

possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 103(b)(4) and § 103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research

covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will

involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 118. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 118 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted by the institution to the department or agency.

§ 119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution, to the department or agency.

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and final approval given to the proposed change by the department or agency.

§ ____120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ ____121 [Reserved]

§ ____122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ ____123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects

(whether or not the research was subject to federal regulation).

§ ____124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

-List

-memo

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

THE DIRECTOR

January 10, 1997

700-740

MEMORANDUM FOR THE PRESIDENT

FROM: Franklin D. Raines 
Director

SUBJECT: Proposed Memorandum Entitled "Strengthened
Protections for Human Subjects of Classified
Research"

rec'd
1-10-97
4:59pm

SUMMARY: This memorandum forwards for your consideration a proposed memorandum that was prepared by an interagency working group chaired by the White House Office of Domestic Policy. The proposed memorandum would strengthen protections for human subjects of classified research.

BACKGROUND: In January 1994, you established the Advisory Committee on Human Radiation Experiments ("Committee") to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. In its October 1995 final report, the Committee found that the government had indeed funded and conducted unethical human radiation experiments during the Cold War and recommended, among other things, certain changes to the government's policy governing classified research on human subjects. The proposed memorandum would implement the Committee's recommendations.

The proposed memorandum would direct all agencies that conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") to jointly propose certain changes in the Common Rule. Among other changes, the agencies would jointly propose to: (a) prohibit waiver of informed consent for classified research, (b) take comment on whether all research exemptions under the Common Rule should be maintained, (c) disclose, to the potential subject, the identity of the sponsoring Federal agency, unless the agency head determines that such information could compromise intelligence sources, and (d) provide, to the potential subject, a statement that the project is classified and an explanation of what classified means. The memorandum would direct the agencies to change the Common Rule to permit any member of an institutional review board to appeal a majority decision of the board to the head of the sponsoring agency and then to the Director of the White House Office of Science and Technology Policy ("OSTP"). Agencies would also inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects at their agency and the number of human subjects in each project.

None of the affected agencies objects to the proposed memorandum.

RECOMMENDATION: I recommend that you sign the proposed memorandum.

THE WHITE HOUSE
WASHINGTON

February 24, 1997

MEMORANDUM FOR TODD STERN

FROM: SAMUEL R. BERGER 

SUBJECT: Proposed Memorandum on Protection of Human
Subjects in Classified Research

The National Security Council staff concurs with the proposed Presidential memorandum (at Tab A) on strengthening protections for human subjects of classified research, which was transmitted by Franklin Raines in a letter dated January 10, 1997, with one change.

The wording of paragraph 1(d)(i) found on page 3 of the proposed memorandum requires clarification because it conveys the incorrect impression that the Director of the Office of Science and Technology Policy would make judgments about whether identifying the sponsoring agency of classified research would compromise intelligence sources and methods. Such determinations should be made by the head of the sponsoring agency in consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs. The Director of OSTP should be consulted to determine if the research involves more than minimal risk to subjects.

Therefore, I ask that you change paragraph 1(d)(i) on page 3 of the memorandum to read:

- (i) the identity of the sponsoring Federal agency. Exceptions are allowed if the head of the sponsoring agency determines that providing this information could compromise intelligence sources or methods and that the research involves no more than minimal risk to subjects. The determination about sources and methods is to be made in consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs. The determination about risk is to be made in consultation with the Director of the White House Office of Science and Technology Policy.

Attachment

Tab A Memorandum on Strengthened Protections for Human
Subjects of Classified Research

DRAFT

MEMORANDUM FOR:

SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF DEFENSE
SECRETARY OF ENERGY
DIRECTOR, CENTRAL INTELLIGENCE AGENCY
HEADS OF SUCH OTHER DEPARTMENTS AND AGENCIES THAT MAY
CONDUCT OR SUPPORT CLASSIFIED HUMAN RESEARCH

SUBJECT: Strengthened Protections for Human Subjects of
Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January 1994, I established the Advisory Committee on Human Radiation Experiments ("ACHRE") to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October 1995 final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, Final Report, Advisory Committee on Human Radiation Experiments). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research involving human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommended that in all classified research projects the agency conducting or sponsoring the research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;

- inform subjects that the project involves classified research;
- obtain approval by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances" that reviews scientific merit, risk-benefit tradeoffs, and ensures subjects have enough information to give valid consent; and
- maintain permanent records of the panel's deliberations and consent procedures.

This memorandum implements these recommendations with some modifications. For classified research, it prohibits waiver of informed consent and requires researchers to disclose that the project is classified. For all but minimal risk studies, it requires researchers to inform subjects of the sponsoring agency. It also requires permanent recordkeeping.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. It requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board who believes a project should not go forward can appeal the boards' decision to approve it.

Finally, this memorandum sets forth additional steps to ensure that classified human research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by their agency. It also prohibits any agency from conducting secret human research without first promulgating a final rule applying the Federal Policy for the Protection of Human Subjects, as modified in this memorandum, to the agency.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that may conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") (56 Fed. Reg. 28010-28018) shall promptly jointly publish in the Federal Register the following proposed revisions to the Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services shall be the lead agency and, in consultation with the Office of Management and Budget, shall coordinate the joint rulemaking.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to prohibit the use of expedited review procedures under the Common Rule for classified research.

(c) The joint proposal should request comment on whether all research exemptions under the Common Rule should be maintained for classified research.

(d) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

- Revised w/
NSC language
attached*
- (i) the identify of the sponsoring Federal agency, unless the head of the sponsoring agency, in consultation with the Director of the White House Office of Science and Technology Policy, determines that providing this information could compromise intelligence sources or methods and the proposed research involves no more than minimal risk to potential subjects; and
 - (ii) a statement that the project is "classified" and an explanation of what classified means.

(e) The agencies shall jointly propose to modify the institutional review board ("IRB") approval process for classified human subjects research as follows:

- (i) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.
- (ii) Under the Common Rule, research projects are approved by the IRB if a "majority of those (IRB) members present at a meeting" approved the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve the project to the head of the sponsoring agency. If the agency head affirms the IRB's decision to approve the project, the dissenting IRB member may appeal the IRB's decisions to the Director for the White House Office of Science and

Technology Policy ("OSTP"). The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of non-governmental officials, each with the appropriate security clearances, to approve or disapprove the project.

- (iii) IRBs for classified research shall determine whether potential subjects need access to classified information to make a valid informed consent decision.

2. Final rules. Agencies shall, within one year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

3. Agency head approval of classified research projects. Agencies may not conduct any classified human research project subject to the Common Rule unless the agency head has personally approved the specific project.

4. Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month period and of the number of human subjects in each project. The Director of OSTP shall report the total number of classified research projects and participating subjects to the President. The President shall transmit this number to Congressional armed services and intelligence committees and shall publish this number in the Federal Register.

5. Definitions. For purposes of this order, the terms "research" and human subject" shall have the meaning set forth in the Common Rule. "Classified human research" means research involving "classified information" as defined in Executive Order No. 12958.

6. No classified human research without Common Rule. Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed and promulgated the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.

7. Judicial Review. This memorandum is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

taxes. And what I was told was what you heard, in a very cursory way, was that an error had been made in the hiring of an illegal alien; that it had been made after consulting a lawyer who was an expert in this area, so basically they had acted on counsel's advice, but they were wrong; that they moved immediately to try to correct it, and the status had been corrected in terms of the legality of the person; and that the vector's conclusion was there would be no problem.

I have to tell you that during the course of these inquiries, I received other weightier warning, if you will, of things which had to be worked through with other potential nominees. In retrospect, what I should have done is to basically delay the whole thing for a couple of days and look into it in greater depth.

But that was—I take full responsibility for that. This process is in no way a reflection on her. We would not have known any of this had she not disclosed it to us and to the United States Senate subsequently. So I will say again what I said this morning: I'm sorry about this. I still think she is an extraordinary person and a very able person who will have a rich and successful career, and I take full responsibility for what happened in the review process.

Thank you.

NOTE: The President spoke at 3:22 p.m. in the Roosevelt Room at the White House.

Memorandum on Fetal Tissue Transplantation Research

January 22, 1993

Memorandum for the Secretary of Health and Human Services

Subject: Federal Funding of Fetal Tissue Transplantation Research

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services ("HHS") imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of

Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson's disease, Alzheimer's disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the *Federal Register*.

William J. Clinton

Memorandum on the Title X "Gag Rule"

January 22, 1993

Memorandum for the Secretary of Health and Human Services

Subject: The Title X "Gag Rule"

Title X of the Public Health Services Act provides Federal funding for family planning clinics to provide services for low-income patients. The Act specifies that Title X funds may not be used for the performance of abortions, but places no restrictions on the ability of clinics that receive Title X funds to provide abortion counseling and referrals or to perform abortions using non-Title X funds. During the first 18 years of the program, medical professionals at Title X clinics provided complete, uncensored information, including nondirective abortion counseling. In February 1988, the Department of Health and Human Services adopted regulations, which have become known as the "Gag Rule," prohibiting Title X recipients from providing their patients with information, counseling, or referrals concerning abortion. Subsequent attempts by the Bush Administration to modify the Gag Rule and ensuing litigation have created confusion and uncertainty about the current legal status of the regulations.

The Gag Rule endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that

medical professionals are otherwise ethically and legally required to provide to their patients. Furthermore, the Gag Rule contravenes the clear intent of a majority of the members of both the United States Senate and House of Representatives, which twice passed legislation to block the Gag Rule's enforcement but failed to override Presidential vetoes.

For these reasons, you have informed me that you will suspend the Gag Rule pending the promulgation of new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act. I hereby direct you to take that action as soon as possible. I further direct that, within 30 days, you publish in the *Federal Register* new proposed regulations for public comment.

You are hereby authorized and directed to publish this memorandum in the *Federal Register*.

William J. Clinton

Memorandum on the Mexico City Policy

January 22, 1993

Memorandum for the Acting Administrator of the Agency for International Development

Subject: AID Family Planning Grants/ Mexico City Policy

The Foreign Assistance Act of 1961 prohibits nongovernmental organizations ("NGO's") that receive Federal funds from using those funds "to pay for the performance of abortions as a method of family planning, or to motivate or coerce any person to practice abortions." (22 U.S.C. 2151b(f)(1)). The August 1984 announcement by President Reagan of what has become known as the "Mexico City Policy" directed the Agency for International Development ("AID") to expand this limitation and withhold AID funds from NGO's that engage in a wide range of activities, including providing advice, counseling, or information regarding abortion, or lobbying a foreign government

to legalize or make abortion available. These conditions have been imposed even where an NGO uses non-AID funds for abortion-related activities.

These excessively broad anti-abortion conditions are unwarranted. I am informed that the conditions are not mandated by the Foreign Assistance Act or any other law. Moreover, they have undermined efforts to promote safe and efficacious family planning programs in foreign nations. Accordingly, I hereby direct that AID remove the conditions not explicitly mandated by the Foreign Assistance Act or any other law from all current AID grants to NGO's and exclude them from future grants.

William J. Clinton

Memorandum on Abortions in Military Hospitals

January 22, 1993

Memorandum for the Secretary of Defense

Subject: Privately Funded Abortions at Military Hospitals

Section 1093 of title 10 of the United States Code prohibits the use of Department of Defense ("DOD") funds to perform abortions except where the life of a woman would be endangered if the fetus were carried to term. By memoranda of December 21, 1987, and June 21, 1988, DOD has gone beyond what I am informed are the requirements of the statute and has banned all abortions at U.S. military facilities, even where the procedure is privately funded. This ban is unwarranted. Accordingly, I hereby direct that you reverse the ban immediately and permit abortion services to be provided, if paid for entirely with non-DOD funds and in accordance with other relevant DOD policies and procedures.

You are hereby authorized and directed to publish this memorandum in the *Federal Register*.

William J. Clinton

Memorandum on Importation of RU-486

January 22, 1993

Memorandum for the Secretary of Health and Human Services

Subject: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristone—commonly known as RU-486—from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the *Federal Register*.

William J. Clinton

Digest of Other White House Announcements

The following list includes the President's public schedule and other items of general interest an-

nounced by the Office of the Press Secretary and not including elsewhere in this issue.

January 20

Following the Inaugural luncheon at the Capitol, President Clinton and Hillary Clinton went by motorcade along the parade route to the White House, where they viewed the Inaugural parade from the viewing stand.

In the evening, President Clinton and Hillary Clinton attended several Inaugural balls.

January 21

In the morning, President Clinton and Hillary Clinton held an open house for the American people in the Diplomatic Reception Room at the White House.

In the afternoon, President Clinton met with senior staff members in the Roosevelt Room, after which he and Hillary Clinton hosted a reception in the State Dining Room for their family and friends from Arkansas.

January 22

In the morning, President Clinton met at the White House with Thomas F. McLarty, Chief of Staff to the President; Anthony Lake, Assistant to the President for National Security Affairs; Samuel R. Berger, Deputy Assistant to the President for National Security Affairs; and members of the CIA briefing staff.

Later in the morning, after the swearing-in ceremony for Cabinet members, President Clinton attended a reception for them and held a Cabinet meeting.

Nominations Submitted to the Senate

The following list does not include promotions of members of the Uniformed Services, nominations to the Service Academies, or nominations of Foreign Service officers.

Submitted January 20

Warren Christopher, of California, to be Secretary of State.

Congressman Davis, Congressman Clinger, Congresswoman Morella, Congresswoman Norton, Mayor Barry, President Clarke, members of the City Council, and other friends of the District of Columbia, this is a very important day and a very important piece of legislation for all of us who care about our country's Capital and for all of us who love Washington as a city. I have lived here not only as President but also as a college student. I know this to be a city, not only of our national monuments and political centers but also a city of neighborhoods, of Shaw and Anacostia and Cleveland Park and Adams Morgan and so many others.

So this is a very important day for a city—a city and thousands and thousands of people who live in it, who love it, who care about it, who have lives, many of them who have nothing to do with the politics of the Nation's Capital, but who deserve to live in a city that works, that functions, and that also can symbolize the very best in America.

The health of the city and the security of its citizens have been threatened by the financial crisis. And I applaud all those who have come together to work together to begin the road back.

The purpose of the bill I am signing today is just that; it is a road back. The Financial Responsibility and Management Assistance Act will speed the District's recovery and return to fiscal health and will help over the long run to improve the delivery of services to its citizens.

For the past 2 years, I've worked hard to turn the economy of our country around. And we've seen dramatic improvements in the deficit, in the ability of this country to create jobs, and having a Government that is both smaller and more efficient.

But none of that means very much to people whose own lives are troubled with insecurity. And the citizens of the District of Columbia need to know that security, stability, growth, and opportunity will be the hallmarks of their living in our Nation's Capital.

This effort, as Alice Rivlin has said, is proof of what we can accomplish when we work together, when we put the interests of real people first, when we ignore partisan politics, and when we get on with the job at hand.

I want to thank Alice Rivlin, as I said, for all the work that she has been doing. I want to thank the Members of the Congress here present. Congressman Davis, I think when he came to the Congress, never could have imagined that this would be his first big assignment. [Laughter] He is now, I guess, an honorary citizen of Washington, DC. Eleanor Holmes Norton, when she ran for Congress, probably never imagined that this would be one of the most important pieces of legislation which she would have to undertake. But they have worked together in good spirit, in good faith. And I thank them, along with the other Members who are present, and Congressman Walsh, and others, and also the Members of the Senate who worked so expeditiously on this legislation.

The legislation calls for the creation of the Financial Responsibility and Management Assistance Authority to monitor and certify District budgets and borrowing, to get the city back on solid financial footing.

I expect to appoint the five members of this Authority very soon. All of them will have a commitment to this city, and all of them will either live or work here.

Our goals are clear. There are tough choices in the short term, but I am confident that this legislation will lead to better services, a more responsive government, to safer streets, and to a stronger city for the citizens of this District. All of them deserve that, and America needs that.

Thank you very much.

NOTE: The President spoke at 12:35 p.m. in the Roosevelt Room at the White House. In his remarks, he referred to Mayor Marion Barry of the District of Columbia and David Clarke, District of Columbia Council president.

Statement on Signing the Executive Order on Classified National Security Information

April 17, 1995

Today I have signed an Executive order reforming the Government's system of secrecy. The order will lift the veil on millions of existing documents, keep a great many future documents from ever being classified, and still maintain necessary controls over in-

formation that legitimately needs to be guarded in the interests of national security.

In issuing this order, I am seeking to bring the system for classifying, safeguarding, and declassifying national security information into line with our vision of American democracy in the post-Cold War world.

This order strikes an appropriate balance. On the one hand, it will sharply reduce the permitted level of secrecy within our Government, making available to the American people and posterity most documents of permanent historical value that were maintained in secrecy until now.

On the other, the order enables us to safeguard the information that we must hold in confidence to protect our Nation and our citizens. We must continue to protect information that is critical to the pursuit of our national security interests. There are some categories of information—for example, the war plans we may employ or the identities of clandestine human assets—that must remain protected.

This order also will reduce the sizable costs of secrecy—the tangible costs of needlessly guarding documents and the intangible costs of depriving ourselves of the fullest possible flow of information.

This order establishes many firsts: Classifiers will have to justify what they classify; employees will be encouraged and expected to challenge improper classification and protected from retribution for doing so; and large-scale declassification won't be dependent on the availability of individuals to conduct a line-by-line review. Rather, we will automatically declassify hundreds of millions of pages of information that were classified in the past 50 years.

Similarly, we will no longer tolerate the excesses of the current system. For example, we will resolve doubtful calls about classification in favor of keeping the information unclassified. We will not permit the reclassification of information after it has been declassified and disclosed under proper authority. We will authorize agency heads to balance the public interest in disclosure against the national security interest in making declassification decisions. And, we will no longer presumptively classify certain categories of information, whether or not the specific in-

formation otherwise meets the strict standards for classification. At the same time, however, we will maintain every necessary safeguard and procedure to assure that appropriately classified information is fully protected.

Taken together, these reforms will greatly reduce the amount of information that we classify in the first place and the amount that remains classified. Perhaps most important, the reforms will create a classification system that Americans can trust to protect our national security in a reasonable, limited, and cost-effective manner.

In keeping with my goals and commitments, this order was drafted in an unprecedented environment of openness. We held open hearings and benefitted from the recommendations of interested Committees of Congress and nongovernmental organizations, groups, businesses, and individuals. The order I have signed today is stronger because of the advice we received from so many sources. I thank all those who have helped to establish this new system as a model for protecting our national security within the framework of a Government of, by, and for the people.

William J. Clinton

The White House,
April 17, 1995.

Executive Order 12958—Classified National Security Information *April 17, 1995*

This order prescribes a uniform system for classifying, safeguarding, and declassifying national security information. Our democratic principles require that the American people be informed of the activities of their Government. Also, our Nation's progress depends on the free flow of information. Nevertheless, throughout our history, the national interest has required that certain information be maintained in confidence in order to protect our citizens, our democratic institutions, and our participation within the community of nations. Protecting information critical to our Nation's security remains a priority. In recent years, however, dramatic changes have altered, although not eliminated, the

national security threats that we confront. These changes provide a greater opportunity to emphasize our commitment to open Government.

Now, Therefore, 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:

Part 1 Original Classification

Section 1.1. Definitions. For purposes of this order:

(a) "National security" means the national defense or foreign relations of the United States.

(b) "Information" means any knowledge that can be communicated or documentary material, regardless of its physical form or characteristics, that is owned by, produced by or for, or is under the control of the United States Government. "Control" means the authority of the agency that originates information, or its successor in function, to regulate access to the information.

(c) "Classified national security information" (hereafter "classified information") means information that has been determined pursuant to this order or any predecessor order to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form.

(d) "Foreign Government Information" means:

(1) information provided to the United States Government by a foreign government or governments, an international organization of governments, or any element thereof, with the expectation that the information, the source of the information, or both, are to be held in confidence;

(2) information produced by the United States pursuant to or as a result of a joint arrangement with a foreign government or governments, or an international organization of governments, or any element thereof, requiring that the information, the arrangement, or both, are to be held in confidence; or

(3) information received and treated as "Foreign Government Information" under the terms of a predecessor order.

(e) "Classification" means the act or process by which information is determined to be classified information.

(f) "Original classification" means an initial determination that information requires, in the interest of national security, protection against unauthorized disclosure.

(g) "Original classification authority" means an individual authorized in writing, either by the President, or by agency heads or other officials designated by the President, to classify information in the first instance.

(h) "Unauthorized disclosure" means a communication or physical transfer of classified information to an unauthorized recipient.

(i) "Agency" means any "Executive agency," as defined in 5 U.S.C. 105, and any other entity within the executive branch that comes into the possession of classified information.

(j) "Senior agency official" means the official designated by the agency head under section 5.6(c) of this order to direct and administer the agency's program under which information is classified, safeguarded, and declassified.

(k) "Confidential source" means any individual or organization that has provided, or that may reasonably be expected to provide, information to the United States on matters pertaining to the national security with the expectation that the information or relationship, or both, are to be held in confidence.

(l) "Damage to the national security" means harm to the national defense or foreign relations of the United States from the unauthorized disclosure of information, to include the sensitivity, value, and utility of that information.

Sec. 1.2. Classification Standards. (a) Information may be originally classified under the terms of this order only if all of the following conditions are met:

(1) an original classification authority is classifying the information;

(2) the information is owned by, produced by or for, or is under the control of the United States Government;

(3) the information falls within one or more of the categories of information listed in section 1.5 of this order; and

(4) the original classification authority determines that the unauthorized dis-

closure of the information reasonably could be expected to result in damage to the national security and the original classification authority is able to identify or describe the damage.

(b) If there is significant doubt about the need to classify information, it shall not be classified. This provision does not:

- (1) amplify or modify the substantive criteria or procedures for classification; or
- (2) create any substantive or procedural rights subject to judicial review.

(c) Classified information shall not be declassified automatically as a result of any unauthorized disclosure of identical or similar information.

Sec. 1.3. Classification Levels. (a) Information may be classified at one of the following three levels:

- (1) "Top Secret" shall be applied to information, the unauthorized disclosure of which reasonably could be expected to cause exceptionally grave damage to the national security that the original classification authority is able to identify or describe.
- (2) "Secret" shall be applied to information, the unauthorized disclosure of which reasonably could be expected to cause serious damage to the national security that the original classification authority is able to identify or describe.
- (3) "Confidential" shall be applied to information, the unauthorized disclosure of which reasonably could be expected to cause damage to the national security that the original classification authority is able to identify or describe.

(b) Except as otherwise provided by statute, no other terms shall be used to identify United States classified information.

(c) If there is significant doubt about the appropriate level of classification, it shall be classified at the lower level.

Sec. 1.4. Classification Authority. (a) The authority to classify information originally may be exercised only by:

- (1) the President;
- (2) agency heads and officials designated by the President in the *Federal Register*; or

(3) United States Government officials delegated this authority pursuant to paragraph (c), below.

(b) Officials authorized to classify information at a specified level are also authorized to classify information at a lower level.

(c) Delegation of original classification authority.

(1) Delegations of original classification authority shall be limited to the minimum required to administer this order. Agency heads are responsible for ensuring that designated subordinate officials have a demonstrable and continuing need to exercise this authority.

(2) "Top Secret" original classification authority may be delegated only by the President or by an agency head or official designated pursuant to paragraph (a)(2), above.

(3) "Secret" or "Confidential" original classification authority may be delegated only by the President; an agency head or official designated pursuant to paragraph (a)(2), above; or the senior agency official, provided that official has been delegated "Top Secret" original classification authority by the agency head.

(4) Each delegation of original classification authority shall be in writing and the authority shall not be redelegated except as provided in this order. Each delegation shall identify the official by name or position title.

(d) Original classification authorities must receive training in original classification as provided in this order and its implementing directives.

(e) Exceptional cases. When an employee, contractor, licensee, certificate holder, or grantee of an agency that does not have original classification authority originates information believed by that person to require classification, the information shall be protected in a manner consistent with this order and its implementing directives. The information shall be transmitted promptly as provided under this order or its implementing directives to the agency that has appropriate subject matter interest and classification authority with respect to this information. That agency shall decide within 30 days whether to classify this information. If it is not clear

which agency has classification responsibility for this information, it shall be sent to the Director of the Information Security Oversight Office. The Director shall determine the agency having primary subject matter interest and forward the information, with appropriate recommendations, to that agency for a classification determination.

Sec. 1.5. Classification Categories.

Information may not be considered for classification unless it concerns:

- (a) military plans, weapons systems, or operations;
- (b) foreign government information;
- (c) intelligence activities (including special activities), intelligence sources or methods, or cryptology;
- (d) foreign relations or foreign activities of the United States, including confidential sources;
- (e) scientific, technological, or economic matters relating to the national security;
- (f) United States Government programs for safeguarding nuclear materials or facilities; or
- (g) vulnerabilities or capabilities of systems, installations, projects or plans relating to the national security.

Sec. 1.6. Duration of Classification. (a) At the time of original classification, the original classification authority shall attempt to establish a specific date or event for declassification based upon the duration of the national security sensitivity of the information. The date or event shall not exceed the time frame in paragraph (b), below.

(b) If the original classification authority cannot determine an earlier specific date or event for declassification, information shall be marked for declassification 10 years from the date of the original decision, except as provided in paragraph (d), below.

(c) An original classification authority may extend the duration of classification or reclassify specific information for successive periods not to exceed 10 years at a time if such action is consistent with the standards and procedures established under this order. This provision does not apply to information contained in records that are more than 25 years old and have been determined to have permanent historical value under title 44, United States Code.

(d) At the time of original classification, the original classification authority may exempt from declassification within 10 years specific information, the unauthorized disclosure of which could reasonably be expected to cause damage to the national security for a period greater than that provided in paragraph (b), above, and the release of which could reasonably be expected to:

- (1) reveal an intelligence source, method, or activity, or a cryptologic system or activity;
- (2) reveal information that would assist in the development or use of weapons of mass destruction;
- (3) reveal information that would impair the development or use of technology within a United States weapons system;
- (4) reveal United States military plans, or national security emergency preparedness plans;
- (5) reveal foreign government information;
- (6) damage relations between the United States and a foreign government, reveal a confidential source, or seriously undermine diplomatic activities that are reasonably expected to be ongoing for a period greater than that provided in paragraph (b), above;
- (7) impair the ability of responsible United States Government officials to protect the President, the Vice President, and other individuals for whom protection services, in the interest of national security, are authorized; or
- (8) violate a statute, treaty, or international agreement.

(e) Information marked for an indefinite duration of classification under predecessor orders, for example, "Originating Agency's Determination Required," or information classified under predecessor orders that contains no declassification instructions shall be declassified in accordance with part 3 of this order.

Sec. 1.7. Identification and Markings. (a) At the time of original classification, the following shall appear on the face of each classified document, or shall be applied to other classified media in an appropriate manner:

- (1) one of the three classification levels defined in section 1.3 of this order;

(2) the identity, by name or personal identifier and position, of the original classification authority;

(3) the agency and office of origin, if not otherwise evident;

(4) declassification instructions, which shall indicate one of the following:

- (A) the date or event for declassification, as prescribed in section 1.6(a) or section 1.6(c); or
- (B) the date that is 10 years from the date of original classification, as prescribed in section 1.6(b); or
- (C) the exemption category from declassification, as prescribed in section 1.6(d); and

(5) a concise reason for classification which, at a minimum, cites the applicable classification categories in section 1.5 of this order.

(b) Specific information contained in paragraph (a), above, may be excluded if it would reveal additional classified information.

(c) Each classified document shall, by marking or other means, indicate which portions are classified, with the applicable classification level, which portions are exempt from declassification under section 1.6(d) of this order, and which portions are unclassified. In accordance with standards prescribed in directives issued under this order, the Director of the Information Security Oversight Office may grant waivers of this requirement for specified classes of documents or information. The Director shall revoke any waiver upon a finding of abuse.

(d) Markings implementing the provisions of this order, including abbreviations and requirements to safeguard classified working papers, shall conform to the standards prescribed in implementing directives issued pursuant to this order.

(e) Foreign government information shall retain its original classification markings or shall be assigned a U.S. classification that provides a degree of protection at least equivalent to that required by the entity that furnished the information.

(f) Information assigned a level of classification under this or predecessor orders shall be considered as classified at that level of classification despite the omission of other required markings. Whenever such informa-

tion is used in the derivative classification process or is reviewed for possible declassification, holders of such information shall coordinate with an appropriate classification authority for the application of omitted markings.

(g) The classification authority shall, whenever practicable, use a classified addendum whenever classified information constitutes a small portion of an otherwise unclassified document.

Sec. 1.8. Classification Prohibitions and Limitations. (a) In no case shall information be classified in order to:

- (1) conceal violations of law, inefficiency, or administrative error;
- (2) prevent embarrassment to a person, organization, or agency;
- (3) restrain competition; or
- (4) prevent or delay the release of information that does not require protection in the interest of national security.

(b) Basic scientific research information not clearly related to the national security may not be classified.

(c) Information may not be reclassified after it has been declassified and released to the public under proper authority.

(d) Information that has not previously been disclosed to the public under proper authority may be classified or reclassified after an agency has received a request for it under the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a), or the mandatory review provisions of section 3.6 of this order only if such classification meets the requirements of this order and is accomplished on a document-by-document basis with the personal participation or under the direction of the agency head, the deputy agency head, or the senior agency official designated under section 5.6 of this order. This provision does not apply to classified information contained in records that are more than 25 years old and have been determined to have permanent historical value under title 44, United States Code.

(e) Compilations of items of information which are individually unclassified may be classified if the compiled information reveals an additional association or relationship that:

- (1) meets the standards for classification under this order; and

(2) is not otherwise revealed in the individual items of information.

As used in this order, "compilation" means an aggregation of pre-existing unclassified items of information.

Sec. 1.9. Classification Challenges. (a) Authorized holders of information who, in good faith, believe that its classification status is improper are encouraged and expected to challenge the classification status of the information in accordance with agency procedures established under paragraph (b), below.

(b) In accordance with implementing directives issued pursuant to this order, an agency head or senior agency official shall establish procedures under which authorized holders of information are encouraged and expected to challenge the classification of information that they believe is improperly classified or unclassified. These procedures shall assure that:

- (1) individuals are not subject to retribution for bringing such actions;
- (2) an opportunity is provided for review by an impartial official or panel; and
- (3) individuals are advised of their right to appeal agency decisions to the Inter-agency Security Classification Appeals Panel established by section 5.4 of this order.

Part 2 Derivative Classification

Sec. 2.1. Definitions. For purposes of this order: (a) "Derivative classification" means the incorporating, paraphrasing, restating or generating in new form information that is already classified, and marking the newly developed material consistent with the classification markings that apply to the source information. Derivative classification includes the classification of information based on classification guidance. The duplication or reproduction of existing classified information is not derivative classification.

(b) "Classification guidance" means any instruction or source that prescribes the classification of specific information.

(c) "Classification guide" means a documentary form of classification guidance issued by an original classification authority that identifies the elements of information regarding a specific subject that must be clas-

sified and establishes the level and duration of classification for each such element.

(d) "Source document" means an existing document that contains classified information that is incorporated, paraphrased, restated, or generated in new form into a new document.

(e) "Multiple sources" means two or more source documents, classification guides, or a combination of both.

Sec. 2.2. Use of Derivative Classification. (a) Persons who only reproduce, extract, or summarize classified information, or who only apply classification markings derived from source material or as directed by a classification guide, need not possess original classification authority.

(b) Persons who apply derivative classification markings shall:

- (1) observe and respect original classification decisions; and
- (2) carry forward to any newly created documents the pertinent classification markings. For information derivatively classified based on multiple sources, the derivative classifier shall carry forward:
 - (A) the date or event for declassification that corresponds to the longest period of classification among the sources; and
 - (B) a listing of these sources on or attached to the official file or record copy.

Sec. 2.3. Classification Guides. (a) Agencies with original classification authority shall prepare classification guides to facilitate the proper and uniform derivative classification of information. These guides shall conform to standards contained in directives issued under this order.

(b) Each guide shall be approved personally and in writing by an official who:

- (1) has program or supervisory responsibility over the information or is the senior agency official; and
- (2) is authorized to classify information originally at the highest level of classification prescribed in the guide.

(c) Agencies shall establish procedures to assure that classification guides are reviewed and updated as provided in directives issued under this order.

Part 3 Declassification and Downgrading

Sec. 3.1. Definitions. For purposes of this order: (a) "Declassification" means the authorized change in the status of information from classified information to unclassified information.

(b) "Automatic declassification" means the declassification of information based solely upon:

- (1) the occurrence of a specific date or event as determined by the original classification authority; or
- (2) the expiration of a maximum time frame for duration of classification established under this order.

(c) "Declassification authority" means:

- (1) the official who authorized the original classification, if that official is still serving in the same position;
- (2) the originator's current successor in function;
- (3) a supervisory official of either; or
- (4) officials delegated declassification authority in writing by the agency head or the senior agency official.

(d) "Mandatory declassification review" means the review for declassification of classified information in response to a request for declassification that meets the requirements under section 3.6 of this order.

(e) "Systematic declassification review" means the review for declassification of classified information contained in records that have been determined by the Archivist of the United States ("Archivist") to have permanent historical value in accordance with chapter 33 of title 44, United States Code.

(f) "Declassification guide" means written instructions issued by a declassification authority that describes the elements of information regarding a specific subject that may be declassified and the elements that must remain classified.

(g) "Downgrading" means a determination by a declassification authority that information classified and safeguarded at a specified level shall be classified and safeguarded at a lower level.

(h) "File series" means documentary material, regardless of its physical form or characteristics, that is arranged in accordance with a filing system or maintained as a unit

because it pertains to the same function or activity.

Sec. 3.2. Authority for Declassification.

(a) Information shall be declassified as soon as it no longer meets the standards for classification under this order.

(b) It is presumed that information that continues to meet the classification requirements under this order requires continued protection. In some exceptional cases, however, the need to protect such information may be outweighed by the public interest in disclosure of the information, and in these cases the information should be declassified. When such questions arise, they shall be referred to the agency head or the senior agency official. That official will determine, as an exercise of discretion, whether the public interest in disclosure outweighs the damage to national security that might reasonably be expected from disclosure. This provision does not:

- (1) amplify or modify the substantive criteria or procedures for classification; or
- (2) create any substantive or procedural rights subject to judicial review.

(c) If the Director of the Information Security Oversight Office determines that information is classified in violation of this order, the Director may require the information to be declassified by the agency that originated the classification. Any such decision by the Director may be appealed to the President through the Assistant to the President for National Security Affairs. The information shall remain classified pending a prompt decision on the appeal.

(d) The provisions of this section shall also apply to agencies that, under the terms of this order, do not have original classification authority, but had such authority under predecessor orders.

Sec. 3.3. Transferred Information. (a) In the case of classified information transferred in conjunction with a transfer of functions, and not merely for storage purposes, the receiving agency shall be deemed to be the originating agency for purposes of this order.

(b) In the case of classified information that is not officially transferred as described in paragraph (a), above, but that originated in an agency that has ceased to exist and for

which there is no successor agency, each agency in possession of such information shall be deemed to be the originating agency for purposes of this order. Such information may be declassified or downgraded by the agency in possession after consultation with any other agency that has an interest in the subject matter of the information.

(c) Classified information accessioned into the National Archives and Records Administration ("National Archives") as of the effective date of this order shall be declassified or downgraded by the Archivist in accordance with this order, the directives issued pursuant to this order, agency declassification guides, and any existing procedural agreement between the Archivist and the relevant agency head.

(d) The originating agency shall take all reasonable steps to declassify classified information contained in records determined to have permanent historical value before they are accessioned into the National Archives. However, the Archivist may require that records containing classified information be accessioned into the National Archives when necessary to comply with the provisions of the Federal Records Act. This provision does not apply to information being transferred to the Archivist pursuant to section 2203 of title 44, United States Code, or information for which the National Archives and Records Administration serves as the custodian of the records of an agency or organization that goes out of existence.

(e) To the extent practicable, agencies shall adopt a system of records management that will facilitate the public release of documents at the time such documents are declassified pursuant to the provisions for automatic declassification in sections 1.6 and 3.4 of this order.

Sec. 3.4. Automatic Declassification. (a) Subject to paragraph (b), below, within 5 years from the date of this order, all classified information contained in records that (1) are more than 25 years old, and (2) have been determined to have permanent historical value under title 44, United States Code, shall be automatically declassified whether or not the records have been reviewed. Subsequently, all classified information in such records shall be automatically declassified no

longer than 25 years from the date of its original classification, except as provided in paragraph (b), below.

(b) An agency head may exempt from automatic declassification under paragraph (a), above, specific information, the release of which should be expected to:

(1) reveal the identity of a confidential human source, or reveal information about the application of an intelligence source or method, or reveal the identity of a human intelligence source when the unauthorized disclosure of that source would clearly and demonstrably damage the national security interests of the United States;

(2) reveal information that would assist in the development or use of weapons of mass destruction;

(3) reveal information that would impair U.S. cryptologic systems or activities;

(4) reveal information that would impair the application of state of the art technology within a U.S. weapon system;

(5) reveal actual U.S. military war plans that remain in effect;

(6) reveal information that would seriously and demonstrably impair relations between the United States and a foreign government, or seriously and demonstrably undermine ongoing diplomatic activities of the United States;

(7) reveal information that would clearly and demonstrably impair the current ability of United States Government officials to protect the President, Vice President, and other officials for whom protection services, in the interest of national security, are authorized;

(8) reveal information that would seriously and demonstrably impair current national security emergency preparedness plans; or

(9) violate a statute, treaty, or international agreement.

(c) No later than the effective date of this order, an agency head shall notify the President through the Assistant to the President for National Security Affairs of any specific file series of records for which a review or assessment has determined that the information within those file series almost invariably falls within one or more of the exemption

categories listed in paragraph (b), above, and which the agency proposes to exempt from automatic declassification. The notification shall include:

- (1) a description of the file series;
- (2) an explanation of why the information within the file series is almost invariably exempt from automatic declassification and why the information must remain classified for a longer period of time; and
- (3) except for the identity of a confidential human source or a human intelligence source, as provided in paragraph (b), above, a specific date or event for declassification of the information.

The President may direct the agency head not to exempt the file series or to declassify the information within that series at an earlier date than recommended.

(d) At least 180 days before information is automatically declassified under this section, an agency head or senior agency official shall notify the Director of the Information Security Oversight Office, serving as Executive Secretary of the Interagency Security Classification Appeals Panel, of any specific information beyond that included in a notification to the President under paragraph (c), above, that the agency proposes to exempt from automatic declassification. The notification shall include:

- (1) a description of the information;
- (2) an explanation of why the information is exempt from automatic declassification and must remain classified for a longer period of time; and
- (3) except for the identity of a confidential human source or a human intelligence source, as provided in paragraph (b), above, a specific date or event for declassification of the information. The Panel may direct the agency not to exempt the information or to declassify it at an earlier date than recommended. The agency head may appeal such a decision to the President through the Assistant to the President for National Security Affairs. The information will remain classified while such an appeal is pending.

(e) No later than the effective date of this order, the agency head or senior agency offi-

cial shall provide the Director of the Information Security Oversight Office with a plan for compliance with the requirements of this section, including the establishment of interim target dates. Each such plan shall include the requirement that the agency declassify at least 15 percent of the records affected by this section no later than 1 year from the effective date of this order, and similar commitments for subsequent years until the effective date for automatic declassification.

(f) Information exempted from automatic declassification under this section shall remain subject to the mandatory and systematic declassification review provisions of this order.

(g) The Secretary of State shall determine when the United States should commence negotiations with the appropriate officials of a foreign government or international organization of governments to modify any treaty or international agreement that requires the classification of information contained in records affected by this section for a period longer than 25 years from the date of its creation, unless the treaty or international agreement pertains to information that may otherwise remain classified beyond 25 years under this section.

Sec. 3.5. Systematic Declassification Review. (a) Each agency that has originated classified information under this order or its predecessors shall establish and conduct a program for systematic declassification review. This program shall apply to historically valuable records exempted from automatic declassification under section 3.4 of this order. Agencies shall prioritize the systematic review of records based upon:

- (1) recommendations of the Information Security Policy Advisory Council, established in section 5.5 of this order, on specific subject areas for systematic review concentration; or
- (2) the degree of researcher interest and the likelihood of declassification upon review.

(b) The Archivist shall conduct a systematic declassification review program for classified information: (1) accessioned into the National Archives as of the effective date of this order; (2) information transferred to the

Archivist pursuant to section 2203 of title 44, United States Code; and (3) information for which the National Archives and Records Administration serves as the custodian of the records of an agency or organization that has gone out of existence. This program shall apply to pertinent records no later than 25 years from the date of their creation. The Archivist shall establish priorities for the systematic review of these records based upon the recommendations of the Information Security Policy Advisory Council; or the degree of researcher interest and the likelihood of declassification upon review. These records shall be reviewed in accordance with the standards of this order, its implementing directives, and declassification guides provided to the Archivist by each agency that originated the records. The Director of the Information Security Oversight Office shall assure that agencies provide the Archivist with adequate and current declassification guides.

(c) After consultation with affected agencies, the Secretary of Defense may establish special procedures for systematic review for declassification of classified cryptologic information, and the Director of Central Intelligence may establish special procedures for systematic review for declassification of classified information pertaining to intelligence activities (including special activities), or intelligence sources or methods.

Sec. 3.6. Mandatory Declassification Review. (a) Except as provided in paragraph (b), below, all information classified under this order or predecessor orders shall be subject to a review for declassification by the originating agency if:

- (1) the request for a review describes the document or material containing the information with sufficient specificity to enable the agency to locate it with a reasonable amount of effort;
- (2) the information is not exempted from search and review under the Central Intelligence Agency Information Act; and
- (3) the information has not been reviewed for declassification within the past 2 years. If the agency has reviewed the information within the past 2 years, or the information is the subject of pending litigation, the agency shall in-

form the requester of this fact and of the requester's appeal rights.

(b) Information originated by:

- (1) the incumbent President;
- (2) the incumbent President's White House Staff;
- (3) committees, commissions, or boards appointed by the incumbent President; or

(4) other entities within the Executive Office of the President that solely advise and assist the incumbent President is exempted from the provisions of paragraph (a), above. However, the Archivist shall have the authority to review, downgrade, and declassify information of former Presidents under the control of the Archivist pursuant to sections 2107, 2111, 2111 note, or 2203 of title 44, United States Code. Review procedures developed by the Archivist shall provide for consultation with agencies having primary subject matter interest and shall be consistent with the provisions of applicable laws or lawful agreements that pertain to the respective Presidential papers or records. Agencies with primary subject matter interest shall be notified promptly of the Archivist's decision. Any final decision by the Archivist may be appealed by the requester or an agency to the Interagency Security Classification Appeals Panel. The information shall remain classified pending a prompt decision on the appeal.

(c) Agencies conducting a mandatory review for declassification shall declassify information that no longer meets the standards for classification under this order. They shall release this information unless withholding is otherwise authorized and warranted under applicable law.

(d) In accordance with directives issued pursuant to this order, agency heads shall develop procedures to process requests for the mandatory review of classified information. These procedures shall apply to information classified under this or predecessor orders. They also shall provide a means for administratively appealing a denial of a mandatory review request, and for notifying the requester of the right to appeal a final agency

decision to the Interagency Security Classification Appeals Panel.

(e) After consultation with affected agencies, the Secretary of Defense shall develop special procedures for the review of cryptologic information, the Director of Central Intelligence shall develop special procedures for the review of information pertaining to intelligence activities (including special activities), or intelligence sources or methods, and the Archivist shall develop special procedures for the review of information accessioned into the National Archives.

Sec. 3.7. Processing Requests and Reviews. In response to a request for information under the Freedom of Information Act, the Privacy Act of 1974, or the mandatory review provisions of this order, or pursuant to the automatic declassification or systematic review provisions of this order:

(a) An agency may refuse to confirm or deny the existence or nonexistence of requested information whenever the fact of its existence or nonexistence is itself classified under this order.

(b) When an agency receives any request for documents in its custody that contain information that was originally classified by another agency, or comes across such documents in the process of the automatic declassification or systematic review provisions of this order, it shall refer copies of any request and the pertinent documents to the originating agency for processing, and may, after consultation with the originating agency, inform any requester of the referral unless such association is itself classified under this order. In cases in which the originating agency determines in writing that a response under paragraph (a), above, is required, the referring agency shall respond to the requester in accordance with that paragraph.

Sec. 3.8. Declassification Database. (a) The Archivist in conjunction with the Director of the Information Security Oversight Office and those agencies that originate classified information, shall establish a Governmentwide database of information that has been declassified. The Archivist shall also explore other possible uses of technology to facilitate the declassification process.

(b) Agency heads shall fully cooperate with the Archivist in these efforts.

(c) Except as otherwise authorized and warranted by law, all declassified information contained within the database established under paragraph (a), above, shall be available to the public.

Part 4 Safeguarding

Sec. 4.1. Definitions. For purposes of this order: (a) "Safeguarding" means measures and controls that are prescribed to protect classified information.

(b) "Access" means the ability or opportunity to gain knowledge of classified information.

(c) "Need-to-know" means a determination made by an authorized holder of classified information that a prospective recipient requires access to specific classified information in order to perform or assist in a lawful and authorized governmental function.

(d) "Automated information system" means an assembly of computer hardware, software, or firmware configured to collect, create, communicate, compute, disseminate, process, store, or control data or information.

(e) "Integrity" means the state that exists when information is unchanged from its source and has not been accidentally or intentionally modified, altered, or destroyed.

(f) "Network" means a system of two or more computers that can exchange data or information.

(g) "Telecommunications" means the preparation, transmission, or communication of information by electronic means.

(h) "Special access program" means a program established for a specific class of classified information that imposes safeguarding and access requirements that exceed those normally required for information at the same classification level.

Sec. 4.2. General Restrictions on Access.

(a) A person may have access to classified information provided that:

- (1) a favorable determination of eligibility for access has been made by an agency head or the agency head's designee;
- (2) the person has signed an approved nondisclosure agreement; and
- (3) the person has a need-to-know the information.

(b) Classified information shall remain under the control of the originating agency or its successor in function. An agency shall not disclose information originally classified by another agency without its authorization. An official or employee leaving agency service may not remove classified information from the agency's control.

(c) Classified information may not be removed from official premises without proper authorization.

(d) Persons authorized to disseminate classified information outside the executive branch shall assure the protection of the information in a manner equivalent to that provided within the executive branch.

(e) Consistent with law, directives, and regulation, an agency head or senior agency official shall establish uniform procedures to ensure that automated information systems, including networks and telecommunications systems, that collect, create, communicate, compute, disseminate, process, or store classified information have controls that:

- (1) prevent access by unauthorized persons; and
- (2) ensure the integrity of the information.

(f) Consistent with law, directives, and regulation, each agency head or senior agency official shall establish controls to ensure that classified information is used, processed, stored, reproduced, transmitted, and destroyed under conditions that provide adequate protection and prevent access by unauthorized persons.

(g) Consistent with directives issued pursuant to this order, an agency shall safeguard foreign government information under standards that provide a degree of protection at least equivalent to that required by the government or international organization of governments that furnished the information. When adequate to achieve equivalency, these standards may be less restrictive than the safeguarding standards that ordinarily apply to United States "Confidential" information, including allowing access to individuals with a need-to-know who have not otherwise been cleared for access to classified information or executed an approved nondisclosure agreement.

(h) Except as provided by statute or directives issued pursuant to this order, classified information originating in one agency may not be disseminated outside any other agency to which it has been made available without the consent of the originating agency. An agency head or senior agency official may waive this requirement for specific information originated within that agency. For purposes of this section, the Department of Defense shall be considered one agency.

Sec. 4.3. Distribution Controls. (a) Each agency shall establish controls over the distribution of classified information to assure that it is distributed only to organizations or individuals eligible for access who also have a need-to-know the information.

(b) Each agency shall update, at least annually, the automatic, routine, or recurring distribution of classified information that they distribute. Recipients shall cooperate fully with distributors who are updating distribution lists and shall notify distributors whenever a relevant change in status occurs.

Sec. 4.4. Special Access Programs. (a) Establishment of special access programs. Unless otherwise authorized by the President, only the Secretaries of State, Defense and Energy, and the Director of Central Intelligence, or the principal deputy of each, may create a special access program. For special access programs pertaining to intelligence activities (including special activities, but not including military operational, strategic and tactical programs), or intelligence sources or methods, this function will be exercised by the Director of Central Intelligence. These officials shall keep the number of these programs at an absolute minimum, and shall establish them only upon a specific finding that:

- (1) the vulnerability of, or threat to, specific information is exceptional; and
- (2) the normal criteria for determining eligibility for access applicable to information classified at the same level are not deemed sufficient to protect the information from unauthorized disclosure; or

(3) the program is required by statute.

(b) *Requirements and Limitations.* (1) Special access programs shall be limited to programs in which the number of persons who will have access ordinarily will be reasonably

small and commensurate with the objective of providing enhanced protection for the information involved.

(2) Each agency head shall establish and maintain a system of accounting for special access programs consistent with directives issued pursuant to this order.

(3) Special access programs shall be subject to the oversight program established under section 5.6(c) of this order. In addition, the Director of the Information Security Oversight Office shall be afforded access to these programs, in accordance with the security requirements of each program, in order to perform the functions assigned to the Information Security Oversight Office under this order. An agency head may limit access to a special access program to the Director and no more than one other employee of the Information Security Oversight Office; or, for special access programs that are extraordinarily sensitive and vulnerable, to the Director only.

(4) The agency head or principal deputy shall review annually each special access program to determine whether it continues to meet the requirements of this order.

(5) Upon request, an agency shall brief the Assistant to the President for National Security Affairs, or his or her designee, on any or all of the agency's special access programs.

(c) Within 180 days after the effective date of this order, each agency head or principal deputy shall review all existing special access programs under the agency's jurisdiction. These officials shall terminate any special access programs that do not clearly meet the provisions of this order. Each existing special access program that an agency head or principal deputy validates shall be treated as if it were established on the effective date of this order.

(d) Nothing in this order shall supersede any requirement made by or under 10 U.S.C. 119.

Sec. 4.5. Access by Historical Researchers and Former Presidential Appointees. (a) The requirement in section 4.2(a)(3) of this order that access to classified information may be

granted only to individuals who have a need-to-know the information may be waived for persons who:

(1) are engaged in historical research projects; or

(2) previously have occupied policy-making positions to which they were appointed by the President.

(b) Waivers under this section may be granted only if the agency head or senior agency official of the originating agency:

(1) determines in writing that access is consistent with the interest of national security;

(2) takes appropriate steps to protect classified information from unauthorized disclosure or compromise, and ensures that the information is safeguarded in a manner consistent with this order; and

(3) limits the access granted to former Presidential appointees to items that the person originated, reviewed, signed, or received while serving as a Presidential appointee.

Part 5 Implementation and Review

Sec. 5.1. Definitions. For purposes of this order: (a) "Self-inspection" means the internal review and evaluation of individual agency activities and the agency as a whole with respect to the implementation of the program established under this order and its implementing directives.

(b) "Violation" means:

(1) any knowing, willful, or negligent action that could reasonably be expected to result in an unauthorized disclosure of classified information;

(2) any knowing, willful, or negligent action to classify or continue the classification of information contrary to the requirements of this order or its implementing directives; or

(3) any knowing, willful, or negligent action to create or continue a special access program contrary to the requirements of this order.

(c) "Infraction" means any knowing, willful, or negligent action contrary to the requirements of this order or its implementing directives that does not comprise a "violation," as defined above.

Sec. 5.2. Program Direction. (a) The Director of the Office of Management and Budget, in consultation with the Assistant to the President for National Security Affairs and the co-chairs of the Security Policy Board, shall issue such directives as are necessary to implement this order. These directives shall be binding upon the agencies. Directives issued by the Director of the Office of Management and Budget shall establish standards for:

- (1) classification and marking principles;
- (2) agency security education and training programs;
- (3) agency self-inspection programs; and
- (4) classification and declassification guides.

(b) The Director of the Office of Management and Budget shall delegate the implementation and monitorship functions of this program to the Director of the Information Security Oversight Office.

(c) The Security Policy Board, established by a Presidential Decision Directive, shall make a recommendation to the President through the Assistant to the President for National Security Affairs with respect to the issuance of a Presidential directive on safeguarding classified information. The Presidential directive shall pertain to the handling, storage, distribution, transmittal, and destruction of and accounting for classified information.

Sec. 5.3. Information Security Oversight Office. (a) There is established within the Office of Management and Budget an Information Security Oversight Office. The Director of the Office of Management and Budget shall appoint the Director of the Information Security Oversight Office, subject to the approval of the President.

(b) Under the direction of the Director of the Office of Management and Budget acting in consultation with the Assistant to the President for National Security Affairs, the Director of the Information Security Oversight Office shall:

- (1) develop directives for the implementation of this order;
- (2) oversee agency actions to ensure compliance with this order and its implementing directives;

(3) review and approve agency implementing regulations and agency guides for systematic declassification review prior to their issuance by the agency;

(4) have the authority to conduct on-site reviews of each agency's program established under this order, and to require of each agency those reports, information, and other cooperation that may be necessary to fulfill its responsibilities. If granting access to specific categories of classified information would pose an exceptional national security risk, the affected agency head or the senior agency official shall submit a written justification recommending the denial of access to the Director of the Office of Management and Budget within 60 days of the request for access. Access shall be denied pending a prompt decision by the Director of the Office of Management and Budget, who shall consult on this decision with the Assistant to the President for National Security Affairs;

(5) review requests for original classification authority from agencies or officials not granted original classification authority and, if deemed appropriate, recommend Presidential approval through the Director of the Office of Management and Budget;

(6) consider and take action on complaints and suggestions from persons within or outside the Government with respect to the administration of the program established under this order;

(7) have the authority to prescribe, after consultation with affected agencies, standardization of forms or procedures that will promote the implementation of the program established under this order;

(8) report at least annually to the President on the implementation of this order; and

(9) convene and chair interagency meetings to discuss matters pertaining to the program established by this order.

Sec. 5.4. Interagency Security Classification Appeals Panel. (a) Establishment and Administration.

(1) There is established an Interagency Security Classification Appeals Panel

("Panel"). The Secretaries of State and Defense, the Attorney General, the Director of Central Intelligence, the Archivist of the United States, and the Assistant to the President for National Security Affairs shall each appoint a senior level representative to serve as a member of the Panel. The President shall select the Chair of the Panel from among the Panel members.

(2) A vacancy on the Panel shall be filled as quickly as possible as provided in paragraph (1), above.

(3) The Director of the Information Security Oversight Office shall serve as the Executive Secretary. The staff of the Information Security Oversight Office shall provide program and administrative support for the Panel.

(4) The members and staff of the Panel shall be required to meet eligibility for access standards in order to fulfill the Panel's functions.

(5) The Panel shall meet at the call of the Chair. The Chair shall schedule meetings as may be necessary for the Panel to fulfill its functions in a timely manner.

(6) The Information Security Oversight Office shall include in its reports to the President a summary of the Panel's activities.

(b) *Functions.* The Panel shall:

(1) decide on appeals by persons who have filed classification challenges under section 1.9 of this order;

(2) approve, deny, or amend agency exemptions from automatic declassification as provided in section 3.4 of this order; and

(3) decide on appeals by persons or entities who have filed requests for mandatory declassification review under section 3.6 of this order.

(c) *Rules and Procedures.* The Panel shall issue bylaws, which shall be published in the *Federal Register* no later than 120 days from the effective date of this order. The bylaws shall establish the rules and procedures that the Panel will follow in accepting, considering, and issuing decisions on appeals. The rules and procedures of the Panel shall provide that the Panel will consider appeals only

on actions in which: (1) the appellant has exhausted his or her administrative remedies within the responsible agency; (2) there is no current action pending on the issue within the federal courts; and (3) the information has not been the subject of review by the federal courts or the Panel within the past 2 years.

(d) Agency heads will cooperate fully with the Panel so that it can fulfill its functions in a timely and fully informed manner. An agency head may appeal a decision of the Panel to the President through the Assistant to the President for National Security Affairs. The Panel will report to the President through the Assistant to the President for National Security Affairs any instance in which it believes that an agency head is not cooperating fully with the Panel.

(e) The Appeals Panel is established for the sole purpose of advising and assisting the President in the discharge of his constitutional and discretionary authority to protect the national security of the United States. Panel decisions are committed to the discretion of the Panel, unless reversed by the President.

Sec. 5.5. Information Security Policy Advisory Council. (a) *Establishment.* There is established an Information Security Policy Advisory Council ("Council"). The Council shall be composed of seven members appointed by the President for staggered terms not to exceed 4 years, from among persons who have demonstrated interest and expertise in an area related to the subject matter of this order and are not otherwise employees of the Federal Government. The President shall appoint the Council Chair from among the members. The Council shall comply with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

(b) *Functions.* The Council shall:

(1) advise the President, the Assistant to the President for National Security Affairs, the Director of the Office of Management and Budget, or such other executive branch officials as it deems appropriate, on policies established under this order or its implementing directives, including recommended changes to those policies;

(2) provide recommendations to agency heads for specific subject areas for systematic declassification review; and

(3) serve as a forum to discuss policy issues in dispute.

(c) *Meetings.* The Council shall meet at least twice each calendar year, and as determined by the Assistant to the President for National Security Affairs or the Director of the Office of Management and Budget.

(d) *Administration.*

(1) Each Council member may be compensated at a rate of pay not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the general schedule under section 5376 of title 5, United States Code, for each day during which that member is engaged in the actual performance of the duties of the Council.

(2) While away from their homes or regular place of business in the actual performance of the duties of the Council, members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5703(b)).

(3) To the extent permitted by law and subject to the availability of funds, the Information Security Oversight Office shall provide the Council with administrative services, facilities, staff, and other support services necessary for the performance of its functions.

(4) Notwithstanding any other Executive order, the functions of the President under the Federal Advisory Committee Act, as amended, that are applicable to the Council, except that of reporting to the Congress, shall be performed by the Director of the Information Security Oversight Office in accordance with the guidelines and procedures established by the General Services Administration.

Sec. 5.6. General Responsibilities. Heads of agencies that originate or handle classified information shall: (a) demonstrate personal commitment and commit senior management to the successful implementation of the program established under this order;

(b) commit necessary resources to the effective implementation of the program established under this order; and

(c) designate a senior agency official to direct and administer the program, whose responsibilities shall include:

(1) overseeing the agency's program established under this order, provided, an agency head may designate a separate official to oversee special access programs authorized under this order. This official shall provide a full accounting of the agency's special access programs at least annually;

(2) promulgating implementing regulations, which shall be published in the *Federal Register* to the extent that they affect members of the public;

(3) establishing and maintaining security education and training programs;

(4) establishing and maintaining an ongoing self-inspection program, which shall include the periodic review and assessment of the agency's classified product;

(5) establishing procedures to prevent unnecessary access to classified information, including procedures that: (i) require that a need for access to classified information is established before initiating administrative clearance procedures; and (ii) ensure that the number of persons granted access to classified information is limited to the minimum consistent with operational and security requirements and needs;

(6) developing special contingency plans for the safeguarding of classified information used in or near hostile or potentially hostile areas;

(7) assuring that the performance contract or other system used to rate civilian or military personnel performance includes the management of classified information as a critical element or item to be evaluated in the rating of: (i) original classification authorities; (ii) security managers or security specialists; and (iii) all other personnel whose duties significantly involve the creation or handling of classified information;

(8) accounting for the costs associated with the implementation of this order;

which shall be reported to the Director of the Information Security Oversight Office for publication; and

(9) assigning in a prompt manner agency personnel to respond to any request, appeal, challenge, complaint, or suggestion arising out of this order that pertains to classified information that originated in a component of the agency that no longer exists and for which there is no clear successor in function.

Sec. 5.7. Sanctions. (a) If the Director of the Information Security Oversight Office finds that a violation of this order or its implementing directives may have occurred, the Director shall make a report to the head of the agency or to the senior agency official so that corrective steps, if appropriate, may be taken.

(b) Officers and employees of the United States Government, and its contractors, licensees, certificate holders, and grantees shall be subject to appropriate sanctions if they knowingly, willfully, or negligently:

- (1) disclose to unauthorized persons information properly classified under this order or predecessor orders;
- (2) classify or continue the classification of information in violation of this order or any implementing directive;
- (3) create or continue a special access program contrary to the requirements of this order; or
- (4) contravene any other provision of this order or its implementing directives.

(c) Sanctions may include reprimand, suspension without pay, removal, termination of classification authority, loss or denial of access to classified information, or other sanctions in accordance with applicable law and agency regulation.

(d) The agency head, senior agency official, or other supervisory official shall, at a minimum, promptly remove the classification authority of any individual who demonstrates reckless disregard or a pattern of error in applying the classification standards of this order.

(e) The agency head or senior agency official shall:

(1) take appropriate and prompt corrective action when a violation or infraction under paragraph (b), above, occurs; and

(2) notify the Director of the Information Security Oversight Office when a violation under paragraph (b)(1), (2) or (3), above, occurs.

Part 6 General Provisions

Sec. 6.1. General Provisions. (a) Nothing in this order shall supersede any requirement made by or under the Atomic Energy Act of 1954, as amended, or the National Security Act of 1947, as amended. "Restricted Data" and "Formerly Restricted Data" shall be handled, protected, classified, downgraded, and declassified in conformity with the provisions of the Atomic Energy Act of 1954, as amended, and regulations issued under that Act.

(b) The Attorney General, upon request by the head of an agency or the Director of the Information Security Oversight Office, shall render an interpretation of this order with respect to any question arising in the course of its administration.

(c) Nothing in this order limits the protection afforded any information by other provisions of law, including the exemptions to the Freedom of Information Act, the Privacy Act, and the National Security Act of 1947, as amended. This order is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees. The foregoing is in addition to the specific provisos set forth in sections 1.2(b), 3.2(b) and 5.4(e) of this order.

(d) Executive Order No. 12356 of April 6, 1982, is revoked as of the effective date of this order.

Sec. 6.2. Effective Date. This order shall become effective 180 days from the date of this order.

William J. Clinton

The White House,
April 17, 1995.

[Filed with the Office of the Federal Register, 2:04 p.m., April 18, 1995]

NOTE: This Executive order was published in the *Federal Register* on April 20.

THE WHITE HOUSE
WASHINGTON

November 27, 1996

MEMORANDUM FOR FRANK RAINES

FROM: Carol H. Rasco *CHR*
Assistant to the President
for Domestic Policy

SUBJECT: POTUS Draft Memorandum to Agency Heads on Classified
Human Subjects Research

Attached is a draft memorandum from the President to heads of federal agencies strengthening protections for human subjects of classified research. I am requesting that OMB circulate the draft to affected departments and agencies for formal comment. We would like to receive agency comments by December 6, 1996.

Background

The Presidential memorandum responds to a key recommendation of the President's Advisory Committee on Human Radiation Experiments (ACHRE). The President convened ACHRE in January, 1994 to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War, to uncover the truth, to recommend steps to right past wrongs, and to propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects to better protect citizens' rights.¹

ACHRE expressed concern about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." Accordingly, ACHRE recommend that all classified research projects:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

¹ "Recommendations for Balancing National Security Interests and the Rights of the Public (Recommendation 15)," *Final Report, Advisory Committee on Human Radiation Experiments*.

Purpose of the Memorandum

This memorandum directs departments and agencies to jointly propose the following revisions to the Federal Policy for the Protection of Human Subjects as it applies to classified research:

- prohibit waiver of informed consent;
- require disclosure that the project is classified;
- require researchers to inform subjects of the sponsoring agency;
- require that institutional review boards for secret projects include a non-governmental member;
- establish an appeals process so that any member of a review board who believes a project should not go forward can appeal the board's decision to the Director of the Office of Science and Technology Policy;
- require that heads of agencies approve every classified research project that uses human subjects.

In addition, this memorandum requires each agency to disclose annually the number of secret human subjects research projects conducted or supported by the agency. It also prohibits any agency from conducting secret human subjects research without first promulgating the Federal Policy for the Protection of Human Subjects as amended.

The draft Presidential memo reflects policy decisions made by the Interagency Working Group on Human Radiation Experiments (IAWG) - the government-wide group charged with developing the Administration's response to the ACHRE report. This directive addresses one of 18 recommendations made by ACHRE, and would be announced in conjunction with a report summarizing the Administration's response to ACHRE, scheduled for completion in the coming weeks. I therefore ask that you request agency comments by December 6, 1996.

Your staff may contact Elizabeth Drye (x6-5573) or Diane Regas (x6-5589) of my staff with any questions. Thank you for your assistance. Please do not hesitate to contact me with any questions (x6-2216).

--- DRAFT ---

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES THAT CONDUCT
OR SUPPORT HUMAN SUBJECTS RESEARCH

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January, 1994 I established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, *Final Report, Advisory Committee on Human Radiation Experiments*). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research using human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified."

ACHRE recommend that all classified research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

This memorandum implements the first three recommendations. For classified research, it prohibits waiver of informed consent, requires researches to disclose that the project is classified, and requires researchers to inform subjects of the sponsoring agency.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. The memorandum requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board that believes a project should not go forward can appeal the board's decision to approve it. This approach is less burdensome than that recommended by ACHRE but addresses ACHRE's underlying concerns.

Finally, this memorandum sets forth additional steps to ensure that classified human subjects research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human subjects research projects undertaken by the agency. It also prohibits agencies from conducting secret human subjects research without first issuing the Federal Policy for the Protection of Human Subjects.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

Sec 1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that conduct or support research involving human subjects shall, within 60 days, publish in the Federal Register the following revisions to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") as it affects classified research.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

- 1) the identity of the sponsoring Federal agency; and
- 2) a statement that the project is classified.

(c) The agencies shall jointly propose to modify the institutional review board (IRB) approval process for classified human subjects research as follows:

(1) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the a immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.

(2) Under the Common Rule, research projects are approved by the IRB if a "majority of those [IRB] members present at a meeting" approve the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve that project to the Director of the White House Office of Science and Technology Policy ("OSTP"). The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of non-governmental officials, each with the appropriate security clearances, to approve or disapprove the project.

Sec 2. Final rules Agencies shall, within one year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

Sec 3. Agency head approval of classified research projects. Agencies may not conduct a classified human subjects research project unless the agency head has personally approved the specific project.

Sec 4. Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month period. The Director of OSTP shall report the total number of classified research projects in each category to the President. The President shall transmit this number to Congressional armed services and intelligence committees and shall publish this number in the Federal Register.

Sec 5. Definitions. For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule.

Sec 6. No classified human subjects research without common rule. No agency shall conduct or support classified human subjects research without first proposing the Common Rule, including the changes set forth in this memorandum and any subsequent amendments, and promulgating a final rule on the protection of human subjects of classified research.

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Executive Order on Classified Research

2014-0046-S

rc1443

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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David Fein

RM 213

456-6217

Tuesday
June 18, 1991

Part II

Federal Policy for the Protection of Human Subjects; Notices and Rules

Office of Science and Technology Policy
Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Consumer Product Safety Commission
International Development Cooperation Agency
 Agency for International Development
Department of Housing and Urban Development
Department of Justice
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
 Office of the Secretary
 Food and Drug Administration
National Science Foundation
Department of Transportation

Federal Register / Vol. 56, No. 117 / Tuesday, June 18, 1991

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

**NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION**

14 CFR Part 1230

DEPARTMENT OF COMMERCE

16 CFR Part 27

**CONSUMER PRODUCT SAFETY
COMMISSION**

16 CFR Part 1028

**INTERNATIONAL DEVELOPMENT
COOPERATION AGENCY**

Agency for International Development

22 CFR Part 225

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

24 CFR Part 60

DEPARTMENT OF JUSTICE

28 CFR Part 46

DEPARTMENT OF DEFENSE

32 CFR Part 219

DEPARTMENT OF EDUCATION

34 CFR Part 97

**DEPARTMENT OF VETERANS
AFFAIRS**

38 CFR Part 16

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Part 26

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

45 CFR Part 46

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

**Federal Policy for the Protection of
Human Subjects**

AGENCIES: United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; Department of Transportation.

ACTION: Final rule.

From David Fein —

Rosemary Hall — DoJ will call
514-2627 tomorrow.

→ Fax — 514 0563

On The Working Group and is EO
person

Col. Bailey — Commander English should be included
703-
Fax 847-0890 202-767-5078 Amara Brown
703-697-1494

Proposed rules
in 1988

Established in 1979.

June 18, 1994 (and) 1991
1980-83
US Code 42 USC 300v Congress established a
President's Commission for the Study of Ethical
Problems in Medicine, Biomedical, and
Behavioral Research. — 300v(c)(b) duties —

Commission started in 79-

If President has authority to issue reg. —

^ Fax 514-0563

* Query — where did authority to issue these reg. come from

300 v-1 Commission will come up w/ Fed Agencies
w/ 60 days. — Agency take action w/ respect
to FR —

VERO responsibilities in Fed Agencies.

December 2, 1996

NOTE TO MAC REED

FROM: Elizabeth Drye

SUBJECT: Presidential Directive on Classified Human Subjects
Research

Attached are:

- 1) Memo from Carol Rasco to Frank Raines asking OMB to circulate draft directive.
- 2) Draft memorandum.
- 3) List of agencies and departments that have issued the Federal Policy for the Protection of Human Subjects. As we've discussed, additional agencies, including the Dept. of Labor and the NRC, should review the draft.
- 4) Staff contacts at agencies participating in the Interagency Working Group on Human Radiation Experiments -- the group that put this policy together.

Please let me know if you need any additional information or have any questions.

December 2, 1996

NOTE TO MAC REED

FROM: Elizabeth Drye *464 0506* *EEF*

SUBJECT: Presidential Directive on Classified Human Subjects
Research

Attached are:

- 1) Memo from Carol Rasco to Frank Raines asking OMB to circulate draft directive.
- 2) Draft memorandum.
- 3) List of agencies and departments that have issued the Federal Policy for the Protection of Human Subjects. As we've discussed, additional agencies, including the Dept. of Labor and the NRC, should review the draft.
- 4) Staff contacts at agencies participating in the Interagency Working Group on Human Radiation Experiments -- the group that put this policy together.

Please let me know if you need any additional information or have any questions.

THE WHITE HOUSE
WASHINGTON

November 27, 1996

MEMORANDUM FOR FRANK RAINES

FROM: Carol H. Rasco *CHR*
Assistant to the President
for Domestic Policy

SUBJECT: POTUS Draft Memorandum to Agency Heads on Classified
Human Subjects Research

Attached is a draft memorandum from the President to heads of federal agencies strengthening protections for human subjects of classified research. I am requesting that OMB circulate the draft to affected departments and agencies for formal comment. We would like to receive agency comments by December 6, 1996.

Background

The Presidential memorandum responds to a key recommendation of the President's Advisory Committee on Human Radiation Experiments (ACHRE). The President convened ACHRE in January, 1994 to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War, to uncover the truth, to recommend steps to right past wrongs, and to propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects to better protect citizens' rights.¹

ACHRE expressed concern about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." Accordingly, ACHRE recommend that all classified research projects:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

¹ "Recommendations for Balancing National Security Interests and the Rights of the Public (Recommendation 15)," *Final Report, Advisory Committee on Human Radiation Experiments*.

Purpose of the Memorandum

This memorandum directs departments and agencies to jointly propose the following revisions to the Federal Policy for the Protection of Human Subjects as it applies to classified research:

- prohibit waiver of informed consent;
- require disclosure that the project is classified;
- require researchers to inform subjects of the sponsoring agency;
- require that institutional review boards for secret projects include a non-governmental member;
- establish an appeals process so that any member of a review board who believes a project should not go forward can appeal the board's decision to the Director of the Office of Science and Technology Policy;
- require that heads of agencies approve every classified research project that uses human subjects.

In addition, this memorandum requires each agency to disclose annually the number of secret human subjects research projects conducted or supported by the agency. It also prohibits any agency from conducting secret human subjects research without first promulgating the Federal Policy for the Protection of Human Subjects as amended.

The draft Presidential memo reflects policy decisions made by the Interagency Working Group on Human Radiation Experiments (IAWG) - the government-wide group charged with developing the Administration's response to the ACHRE report. This directive addresses one of 18 recommendations made by ACHRE, and would be announced in conjunction with a report summarizing the Administration's response to ACHRE, scheduled for completion in the coming weeks. I therefore ask that you request agency comments by December 6, 1996.

Your staff may contact Elizabeth Drye (x6-5573) or Diane Regas (x6-5589) of my staff with any questions. Thank you for your assistance. Please do not hesitate to contact me with any questions (x6-2216).

--- DRAFT ---

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES THAT CONDUCT
OR SUPPORT HUMAN SUBJECTS RESEARCH

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January, 1994 I established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, *Final Report, Advisory Committee on Human Radiation Experiments*). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research using human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommend that all classified research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

This memorandum implements the first three recommendations. For classified research, it prohibits waiver of informed consent, requires researchers to disclose that the project is classified, and requires researchers to inform subjects of the sponsoring agency.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. The memorandum requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board that believes a project should not go forward can appeal the board's decision to approve it. This approach is less burdensome than that recommended by ACHRE but addresses ACHRE's underlying concerns.

Finally, this memorandum sets forth additional steps to ensure that classified human subjects research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human subjects research projects undertaken by the agency. It also prohibits agencies from conducting secret human subjects research without first issuing the Federal Policy for the Protection of Human Subjects.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

Sec 1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that conduct or support research involving human subjects shall, within 60 days, publish in the Federal Register the following revisions to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") as it affects classified research.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

- 1) the identity of the sponsoring Federal agency; and
- 2) a statement that the project is classified.

(c) The agencies shall jointly propose to modify the institutional review board (IRB) approval process for classified human subjects research as follows:

(1) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.

(2) Under the Common Rule, research projects are approved by the IRB if a "majority of those [IRB] members present at a meeting" approve the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve that project to the Director of the White House Office of Science and Technology Policy ("OSTP"). The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of non-governmental officials, each with the appropriate security clearances, to approve or disapprove the project.

Sec 2. Final rules Agencies shall, within one year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

Sec 3. Agency head approval of classified research projects. Agencies may not conduct a classified human subjects research project unless the agency head has personally approved the specific project.

Sec 4. Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month period. The Director of OSTP shall report the total number of classified research projects in each category to the President. The President shall transmit this number to Congressional armed services and intelligence committees and shall publish this number in the Federal Register.

Sec 5. Definitions. For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule.

Sec 6. No classified human subjects research without common rule. No agency shall conduct or support classified human subjects research without first proposing the Common Rule, including the changes set forth in this memorandum and any subsequent amendments, and promulgating a final rule on the protection of human subjects of classified research.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Executive Order on Classified Research

2014-0046-S

rc1443

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

INTERAGENCY WORKING GROUP

CIA: PEREIRA, JOHN.....

(b)(3)

(002)

DEFENSE: BAILEY, CLAUD.....

703-442-5675

[fax 847-0890] ✓

PIERRE, JOAN MA.....

703-325-7302

[fax 325-2959] ✓

SOPER, GORDON.....

703-697-5561

[fax 695-0476] ✓

ENERGY: AZIM, LORI.....

586-5319

[fax 586-0956] ✓

GALSON, STEVEN.....

586-7700

[fax 586-9626] ✓

MELAMED, ELLY.....

586-6857

[fax 586-2268] ✓

NORDHAUS, BOB.....

586-5966

[fax 586-1499] ✓

O'TOOLE, TARA.....

586-6151

[fax 586-0956] ✓

SCHIAVO, LISA.....

586-5289

[fax 586-1499] ✓

EPA: FRANK, BILL.....

564-2584

[fax 501-0069] ✓

JUSTICE: GLYNN, PAT.....

616-4200

[fax 616-4473] ✓

PLAZA, EVA.....

514-3309

[fax 514-8071] ✓

HHS: BALDWIN, WENDY...

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[fax 402-3459] ✓

ELLIS, GARY.....

301-496-7005 (#205)

[fax 402-2071] ✓

NASA: FERGUSON, EARL.....

358-4538

[fax 358-3038] ✓

NICOGLOSSIAN, ARNAUD

358-0215

[fax 358-4174] ✓

STOKLOS, JANIS...

358-2209

[fax 358-3038] ✓

OMB: GLAUTHIER, T.J.....

395-4561

[fax 395-4639] ✓

MACRIS, ERIC.....

395-4706

[fax 395-4817] ✓

OSTP: LEVINSON, RACHEL..

456-6137

[fax 456-6027] ✓

VA: DEVESTY, BOB.....

273-8453

[fax 273-9080] ✓

MATHER, SUSAN.....

273-8575

[fax 273-9079] ✓

OTCHIN, NEIL.....

273-8578

[fax 273-9078] ✓

GARY Collier

273-7226

WH: CAPLAN, PHIL.....

456-2702

[fax 456-2215] ✓

DREY, ELIZABETH.....

456-2216

[fax 456-7028] ✓

NEUWIRTH, STEVE.....

456-7903

[fax 456-1647] ✓

REGAS, DIANE.....

456-5589

[fax 456-7028] ✓

David Fein

RM 213

456-6217

Tuesday
June 18, 1991

Part II

Federal Policy for the Protection of Human Subjects; Notices and Rules

Office of Science and Technology Policy
Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Consumer Product Safety Commission
International Development Cooperation Agency
 Agency for International Development
Department of Housing and Urban Development
Department of Justice
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
 Office of the Secretary
 Food and Drug Administration
National Science Foundation
Department of Transportation

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

**NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION**

14 CFR Part 1230

DEPARTMENT OF COMMERCE

15 CFR Part 27

**CONSUMER PRODUCT SAFETY
COMMISSION**

16 CFR Part 1028

**INTERNATIONAL DEVELOPMENT
COOPERATION AGENCY**

Agency for International Development

22 CFR Part 225

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

24 CFR Part 60

DEPARTMENT OF JUSTICE

28 CFR Part 46

DEPARTMENT OF DEFENSE

32 CFR Part 219

DEPARTMENT OF EDUCATION

34 CFR Part 97

**DEPARTMENT OF VETERANS
AFFAIRS**

38 CFR Part 16

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Part 26

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

45 CFR Part 46

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

Federal Policy for the Protection of
Human Subjects

AGENCIES: United States Department of
Agriculture; Department of Energy;
National Aeronautics and Space
Administration; Department of
Commerce; Consumer Product Safety
Commission; International Development
Cooperation Agency; Agency for
International Development; Department
of Housing and Urban Development;
Department of Justice; Department of
Defense; Department of Education;
Department of Veterans Affairs;
Environmental Protection Agency;
Department of Health and Human
Services; National Science Foundation;
Department of Transportation.

ACTION: Final rule.

Purpose of the Memorandum

This memorandum directs departments and agencies to jointly propose the following revisions to the Federal Policy for Protection of Human Subjects as it applies to classified research:

- prohibit waiver of informed consent;
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- require researchers to inform subjects of the sponsoring agency;
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Your staff may contact Elizabeth Drye (x6-5573) or Diane Regas (x6-5589) of my staff with any questions. Thank you for your assistance. Please do not hesitate to contact me with any questions (x6-2216).

Office for
Protection from
Research
Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

Date: JUL 16 1996

Sopr - msg 9

John Ferreira - Exec Director Nora Sorkin
- Based on recommendation of
the General Counsel
← policy to close Agency - reserve
← is classified research.

To: DIANE REGAS DPC

FAX: 202-456-7028
Phone: 202-456-2216

To: ELLY MELAMED DOE

FAX 202-586-3552

From: Gary B. Ellis

FAX 301-402-2071
Phone 301-496-7005 x205

Comments:

HERE IS DRAFT LANGUAGE FOR THE
EXECUTIVE ORDER DISCUSSED THIS MORNING.
THE OPERATIVE PARAGRAPH IS IN BOLD.

(RESPONSE TO ACHRE RECOMMENDATION 15 a.)

DON - Gordon Sopr 202-586-6857

CEA - John Ferreira 703-351-2698 351-2802

Document consists of 2 pages, including cover sheet.

DRAFT

1 Research investigators and institutions are the stewards of a trust agreement with the
2 people who volunteer to be research subjects. We have a system in place that to the
3 greatest degree possible minimizes the potential for harm to research subjects;
4 enables and protects individual, autonomous choice by subjects; and promotes the
5 pursuit of new knowledge.

6
7 The report of the Advisory Committee on Human Radiation Experiments identifies
8 the need for certain additional protections when research is classified.

9
10 **I hereby direct that no Federal funds be expended to conduct or support**
11 **classified research involving human subjects where an Institutional Review**
12 **Board has waived informed consent or where a determination has been made**
13 **that the research is exempt from Institutional Review Board review. I hereby**
14 **direct that in all Federally funded classified research, two additional elements**
15 **of information will henceforth be provided when consent is sought from**
16 **potential human subjects: 1) the identity of the sponsoring Federal agency,**
17 **and 2) a statement that the project involves classified information.**

18
19 The Federal Government maintains an enduring commitment to ensuring that
20 research involving human subjects is undertaken in accord with the highest ethical
21 standards. By doing so, we protect the rights and welfare of our fellow citizens who
22 make a remarkable contribution to the common good by electing to volunteer for
23 research studies. We owe them our best effort.

24
25
26 William J. Clinton

— Add anything —

DRAFT

Sen up mfg.

- CIA - added a bioethicist - uniformed services
Randy Howe. -

- At least one outside

Requirement - 5 people, at least 1 ~~is~~ not affiliated with
the institution

Purest sense - not affiliated -

- Variably interpreted -

Air Force / Army -

- Local committee at a research
site.

- NOT specified in regulations -

- Interpreted variably no guidance
in the rule itself. -

"No IRB member should have a conflict."

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

13-Nov-1996 08:44am

TO: (See Below)

FROM: Carol H. Rasco
 Domestic Policy Council

SUBJECT: Meeting on NGA Early Childhood initiative

Please work with Ray Scheppach's office at NGA upon their return from the New Governor's Seminar next Monday to set up a time in the first week in December for Ray to come and meet with Elaine, Nancy, John, Jeremy and myself about the plans for NGA early childhood activities under Governor Miller's initiative as chair. One hour set aside, my office is fine.

Distribution:

TO: Jill Pizzuto

CC: Nancy.Hoit@npr.gsa.gov@INET@EOPMRX
CC: Elaine C. Kamarck
CC: Jeremy D. Benami
CC: Elizabeth E. Drye
CC: John B. Emerson

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. note	re: Questions on EO [partial] (1 page)	n.d.	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Executive Order on Classified Research

2014-0046-S

rc1443

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Steve Garbuttle

Questions on EO



- Disclosure of Agency - why not?
- Defn. of "not affiliated with the institution."
- approval of majority - adequate independence?
- add'l protection?

Call Joan Ma Pierre? DoD

Call Phil Caplan - format

- Phil
- TJ - "Diane and are"
- Elaine Kagan

E Mac Reed **53563**

- Staff sect to OMB - Counsel's Office - HHS Counsel's
- Office draft format.

Carly Hunsdon - Colleague of Rachael

David Fern - Mtg. 2:30

Rosemary Hart DOJ 514-2027

Rachael Levenson 6-6137

Tara O'Toole 586-6151

Gary Ellis

~~Gordon Soper~~

John Pereira

Col. Gland Bailey

Tina W. Weger - DoD

31-496-7005
703-697-5561

Col. Bailey - ~~gale~~ ^{date}
Command - ^{English} ~~703-697-1994~~
(Manston) 695-0476

(b)(3)

703-4212-5615 / 703-556-7300 [003]

Informed Consent

Follow

Filed a request approve one products
~~products~~ p.o.b. #;
other was vaccine for m

- Didn't like warning their informed
Consent -

- Didn't work well -
- weren't comfortable with it -
- they weren't thorough since -

EXECUTIVE ORDER

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. *Done already*

(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. *James*

(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.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004. fax	To Elizabeth Drye (1 page)	n.d.	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Executive Order on Classified Research

2014-0046-S

rc1443

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

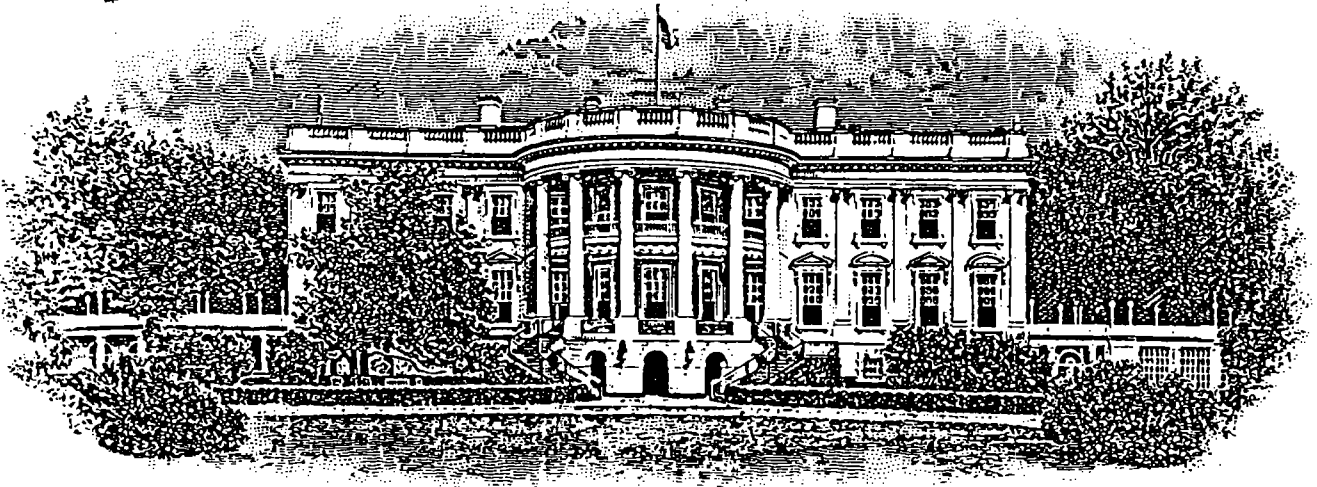
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Dr. Gordon Soper

FAX NUMBER: 703-695-0476

TELEPHONE NUMBER: 703-697-5561

FROM: Elizabeth Drye

TELEPHONE NUMBER: 202-456-5573

PAGES (INCLUDING COVER): 4

COMMENTS: Please ~~to~~ review today by 5:00

and let me know if you have any major

problems. I am putting into OMB review this evening

so you will have a chance to make ^{substantive and} editorial changes

in that process. Thanks. (Col. Bailey may be

going home early, so I'd appreciate your getting
this to Commander English if he needs to see).

EO draft -

- Common rule

- Part 21 CFR 312.86 FDA ^{research involving} products regulated by FDA

Goes once every 5 years to each IRB

Commitment:
DOE - on 3 year basis, all sites will have audits

"landlord or owner" for some sites

support academic research

broader def'n of human subjects

database on research projects

Transcript p. 286 - need for better lay membership on
institutional review boards

to DO: Jonathan, Rachael re. appeals process for
classified research

Rosemary - EO / Reg change determination

- Reporting of ^{# of} classified studies in
gov't. to POTUS, ^{Cong.} committees

10/21

~~Notemay~~ ~~Have~~

- Classified research -

Policy Federal Gov't - Examples - ^{Gag rule was} If where we have said no \$ can be spent on such and such.

Herby direct agencies to review their regos.

- Repropose the following policy -
- deadline -

- not affiliated -

Add something - any board member on his or her initiative will appeal -
< decision to proceed

M. Rellinger - Concurrent reporting provisions - to President and to Congress -

Mac Reed - Gen. Counsel's office at OMB -
Gen Counsel's get the executive orders.

(EO issued 10/3/95 - Protection of Human Subjects)

- ① - Statement
- ② - EO on how things are classified + Statement
~~1994~~ 12958 April 17, 1995
- Whether or not people get a clearance -
- ③ EO 12968 Aug 2, 1995 + Statement
- ④ - ~~EO~~ Directive to Donna Shalala -
Memo to her. -

~ 23rd Jan. 1993

Presidential Papers -

- Crag order
- reversed policy abortion in military
for hospitals.

3 things

- EO when talking to several agencies. -



EO - put into review -

- Mac should know it goes to every affected
agencies - All agencies

Steve Carfinke, ⁶²⁷⁵² 395-7450 - Office of Information Security Oversight
^{OMP} did previous EO - ⁷⁵⁰¹⁷²
Bruce McConnell - 5-3787

John Burklow 301-496-6631

MEMORANDUM FOR:

**SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF DEFENSE
SECRETARY OF ENERGY
DIRECTOR, CENTRAL INTELLIGENCE AGENCY
HEADS OF SUCH OTHER DEPARTMENTS AND AGENCIES THAT MAY
CONDUCT OR SUPPORT CLASSIFIED HUMAN RESEARCH**

**SUBJECT: Strengthened Protections for Human Subjects of
Classified Research**

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January 1994, I established the Advisory Committee on Human Radiation Experiments ("ACHRE") to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October 1995 final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, Final Report, Advisory Committee on Human Radiation Experiments). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research involving human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommended that in all classified research projects the agency conducting or sponsoring the research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;

- inform subjects that the project involves classified research;
- obtain approval by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances" that reviews scientific merit, risk-benefit tradeoffs, and ensures subjects have enough information to give valid consent; and
- maintain permanent records of the panel's deliberations and consent procedures.

This memorandum implements these recommendations with some modifications. For classified research, it prohibits waiver of informed consent and requires researchers to disclose that the project is classified. For all but minimal risk studies, it requires researchers to inform subjects of the sponsoring agency. It also requires permanent recordkeeping.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. It requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board who believes a project should not go forward can appeal the boards' decision to approve it.

Finally, this memorandum sets forth additional steps to ensure that classified human research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by their agency. It also prohibits any agency from conducting secret human research without first promulgating a final rule applying the Federal Policy for the Protection of Human Subjects, as modified in this memorandum, to the agency.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that may conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") (56 Fed. Reg. 28010-28018) shall promptly jointly publish in the Federal Register the following proposed revisions to the Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services shall be the lead agency and, in consultation with the Office of Management and Budget, shall coordinate the joint rulemaking.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to prohibit the use of expedited review procedures under the Common Rule for classified research.

(c) The joint proposal should request comment on whether all research exemptions under the Common Rule should be maintained for classified research.

(d) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

(i) the identify of the sponsoring Federal agency, unless the head of the sponsoring agency, in consultation with the Director of the White House Office of Science and Technology Policy, determines that providing this information could compromise intelligence sources or methods and the proposed research involves no more than minimal risk to ~~potential~~ subjects; and

(ii) a statement that the project is "classified" and an explanation of what classified means.

(e) The agencies shall jointly propose to modify the institutional review board ("IRB") approval process for classified human subjects research as follows:

(i) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.

(ii) Under the Common Rule, research projects are approved by the IRB if a "majority of those (IRB) members present at a meeting" approved the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve the project to the head of the sponsoring agency. If the agency head affirms the IRB's decision to approve the project, the dissenting IRB member may appeal the IRB's decisions to the Director for the White House Office of Science and

Technology Policy ("OSTP"). The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of non-governmental officials, each with the appropriate security clearances, to approve or disapprove the project.

- (iii) IRBs for classified research shall determine whether potential subjects need access to classified information to make a valid informed consent decision.

2. Final rules. Agencies shall, within one year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

3. Agency head approval of classified research projects. Agencies may not conduct any classified human research project subject to the Common Rule unless the agency head has personally approved the specific project.

4. Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month period and of the number of human subjects in each project. The Director of OSTP shall report the total number of classified research projects and participating subjects to the President. The President shall transmit this number to Congressional armed services and intelligence committees and shall publish this number in the Federal Register.

5. Definitions. For purposes of this order, the terms "research" and human subject" shall have the meaning set forth in the Common Rule. "Classified human research" means research involving "classified information" as defined in Executive Order No. 12958.

6. No classified human research without Common Rule. Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed and promulgated the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.

7. Judicial Review. This memorandum is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.