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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	To: Robert Damus [partial] [CIA Act] (1 page)	12/11/1996	P3/b(3)
002. list	re: Interagency Working Group [partial] (1 page)	01/03/1997	P3/b(3)
003. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
004. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
005. fax	To Elizabeth Drye (1 page)	12/31/1996	P3/b(3)
006. fax	To Mac Reed [CIA Act] [partial, page 1 in full] (2 pages)	12/11/1996	P3/b(3)
007. list	re: comments [partial] (1 page)	n.d.	P3/b(3)
008. 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:
Comments on Directive/Classified Research

2014-0046-S
rc1439

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 :

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 recommend that all classified research projects 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;
- be approved 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 board's 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") shall, within 60 days, jointly publish in the Federal Register the following revisions to Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services 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 proposal should take 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, unless the head of the sponsoring agency 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 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.

(ii) 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 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 decision 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.

(iii) IRB's for classified research shall determine: whether the proposal has scientific merit; whether the balance of risks and benefits is acceptable; whether potential subjects have sufficient information to make a valid informed consent decision; and whether potential subjects need security clearances to be adequately informed when consent is sought and, if so, how such clearances will affect their privacy and voluntariness.

potential whether 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 12958.

6. No classified human research without Common Rule. Beginning one year after the date of this directive, 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.

Office for Protection from Research Risks

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

Date: JAN 08 1997

To: ELIZABETH DRYE

FAX: 202-456-7028
Phone: _____

From: Gary B. Ellis

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

Comments:

PLEASE RECONSIDER THE NEW LANGUAGE AT SECTION 1(e)(iii) OF THE PROPOSED PRESIDENTIAL MEMORANDUM.

COMMON RULE AT SECTION 111, STATES 8 CRITERIA FOR IRB APPROVAL OF RESEARCH. BY PARAPHRASING 3 OF THESE CRITERIA, YOU CREATE MUCH CONFUSION. ONE OF YOUR CRITERIA IS, INDEED, NEW AND DIFFERENT. SEE ATTACHED. THANKS!

Document consists of 2 pages, including cover sheet.

JAN 0 8 1997

Ellis, Gary

To: Canning, Betty
Subject: Clearance of proposed memorandum

The draft Memorandum on "Strengthened Protections for Human Subjects of Classified Research" should be revised as follows:

Section 1(e)(iii) should read:

"IRBs for classified research shall determine whether potential subjects need ~~security clearances~~ access to classified information is granted to be adequately informed when consent is sought and, ~~if so, how such clearances will affect their privacy and~~ voluntariness."

In others words, the first three clauses in the existing text (i.e., scientific merit; risks/benefits; informed consent) should be deleted. The Federal Policy for the Protection of Human Subjects, at Sections 111(a)(1),(2), and (4), currently requires IRBs to make these three determinations before approving proposed research. The existing regulatory language is specific and well-understood. Introducing new phrasing, that differs slightly from the current language, on these three IRB responsibilities is quite confusing.

With this revision, I clear the proposed Memorandum.

Gary B. Ellis
Chair
Human Subjects Research Subcommittee
Committee on Health, Safety, and Food
National Science and Technology Council

and
Director, Office for Protection from Research Risks

TO: Mac Reed
Phone: (202) 395-3563
Fax: (202) 395-7294

FROM: MaryAnn Shebek
Phone: (202) 586-1522
FAX: (202) 586-8685

SUBJECT: Proposed Executive Memorandum Entitled "Strengthened Protection For Human Subjects of Classified Research"

Comments on subject executive order are attached for your consideration.

2 pages including cover sheet

Department of Energy
Washington, DC 20585

MEMORANDUM FOR: MARYANN SHEBEK
DEPUTY ASSISTANT GENERAL COUNSEL
FOR LEGAL COUNSEL

FROM: JOAN B. ROHLFING
DIRECTOR
OFFICE OF NONPROLIFERATION AND NATIONAL SECURITY

Ron Spunol for Thomas Ryder, Resource Manager

SUBJECT: PROPOSED EXECUTIVE MEMORANDUM ENTITLED "STRENGTHENED PROTECTION FOR HUMAN SUBJECTS OF CLASSIFIED RESEARCH"

The following comments are submitted concerning the proposed Executive Memorandum:

The memorandum fails to clearly address the possible clearance requirements of the individual human subject. If the memorandum implies that only unclassified information is provided to the research subject, it should so state. As the proposal reads now there is no indication whether the human subject must have a clearance or if only "sanitized" information will be provided or if the individual will be asked to sign a non-disclosure agreement. By not addressing these issues the proposal may fall short of the attempts to strengthen the protection of human subjects research.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
Business and Administrative Law Division
Room 5362 Cohen Building
330 Independence Av., S.W.
Washington, D.C. 20201

Facsimile Transmission Sheet

TO: **Mac Reed**
OMB, OGC
_____

FROM: **Timothy M. White**
Phone: (202) 619-2155
FAX: (202) 619 2922

CALL FOR PICKUP: _____

Total Pages	Fax Number	Date
2 plus cover	395-7294	December 6, 1996

Attached is a Note providing the Food and Drug Administration comments on the proposed Presidential Memorandum on Protection of Human Subjects of Classified Research. Subject to those comments, this Department concurs in the Memorandum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 6, 1996

Note to: Leslie L. Clune

Subject: Proposed Presidential Memorandum entitled "Strengthened Protections for Human Subjects of Classified Research"

The Food and Drug Administration (FDA) has reviewed the proposed Presidential Memorandum attached to your December 4, 1996, memorandum and offers the following comments:

✓ Page 1, fourth paragraph, second line: "researches" should be "researchers"

✓ Page 1, fifth paragraph, last sentence: We believe that characterizing the approach as "less burdensome" could raise a red flag for certain individuals. It may be preferable to delete this sentence--it is not really needed. line deleted

✓ Page 2, first paragraph, last sentence: We question whether "secret" or "issuing" are the appropriate words. This sentence may be more accurate if it were to state: "It also prohibits agencies from conducting classified human subject research without first promulgating into final regulations the Federal Policy for the Protection of Human Subjects as modified by section 1 below."

Page 2, third paragraph: We question the appropriateness of "all agencies that conduct or support research involving human subjects" being required to publish the revisions pertaining to classified research. Most agencies that conduct such research do not conduct or support classified research. It may be more relevant and to the point to state that "All agencies that may conduct or support classified research...." (?) noted Discuss

Page 2, paragraph (b)(2): We suggest adding "an explanation of what 'classified' means" to the requirement to tell the subject that the project is classified.

Page 2, paragraph (c)(1), second line: delete the "a" at the end of the line.

Page 2, paragraph (c)(1), last sentence: We question whether the requirement that the member "not otherwise affiliated with the institution" be a "non-governmental member" will accomplish what is intended. As currently worded, this member could be a retired government person; a spouse of a retired government person; a Discuss

contractor to another government agency or a potential contractor or grantee (although not active at the time of membership). One could make this requirement tighter by defining "institution" as the government; and by changing "is not otherwise affiliated" to "is not and has not been at any time otherwise affiliated."

Page 3, last paragraph: This would be clearer if it were changed to read: "No agency shall conduct or support classified human subject research without proposing and promulgating a final Common Rule including the changes set forth in this memorandum and any subsequent amendments."

If you have any questions about these comments, please contact Dennis Myers, Director of FDA's Executive Secretariat, at 301-827-4450.

Mary Pendergast

Mary K. Pendergast
Deputy Commissioner
Senior Advisor to the Commissioner

DEPARTMENT OF VETERANS AFFAIRS
Washington, D.C. 20420
OFFICE OF THE GENERAL COUNSEL (023)

FAX COVER SHEET

DATE: 12/6/96

TO: Mr. Mac Reed — **PHONE:** 202-395-3563 **FAX:** 202-395-7294

FROM: Sharon M. Johnston — **PHONE:** (202)-273-6334 **FAX:** (202)-273-6403

RE: Proposed Memorandum entitled "Strengthened Protections for Human Subjects of Classified Research"

Number of pages: (including cover page) 11

Message:

TO: Mac Reed

FROM: Department of Veterans Affairs

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

The Department of Veterans Affairs wholeheartedly supports the policy underlying the proposed memorandum on classified research. We believe it is entirely appropriate to strengthen the protections for human subjects involved in classified research. We sought comments on the proposed memorandum from appropriate officials within VA. The Assistant Secretary for Congressional Affairs and the Deputy Director, Medical Research, have provided some worthwhile suggestions that should be considered. Attached to this document are their verbatim comments.

Department of Veterans Affairs

Memorandum

December 5, 1996

Date:

From: Assistant Secretary for Congressional Affairs (009)

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

To: Richard Robinson (023B)

1. I am suggesting a few minor edits, mainly for grammatical purposes, as shown on the attached copy of the proposed memorandum.

2. I found the discussion of the Federal Policy for the Protection of Human Subjects and the imposition of certain new rules confusing and illogical. The last sentence of the paragraph at the top of the second page says agencies may not conduct secret human subjects research "without first issuing the Federal Policy for the Protection of Human Subjects (Emphasis added)." I do not understand how various agencies can all issue "the" federal policy on any topic. There is a problem of either semantics or logic here.

editorial
discuss

3. The memorandum sets forth six "sections." These do not seem to be proposed sections of a law, regulation, or directive, and the use of the "sections" designator half way through a memorandum seems out of place to me. I suggest that "Sec." be dropped from each numbered item.

4. The requirement that all agencies involved in human subjects research "jointly" propose to make various revisions in the "Common Rule" strikes me as an unnecessarily cumbersome approach. I believe it would be easier, and no less effective, for each to be required to revise its own regulations in the prescribed fashion.

5. The paragraph on "Final Rules" (section 2) places no restrictions on the final version of the rules that the agencies promulgate. This means that the changes that they are required to propose need not be included in the rules that actually go into effect. Is this what is intended? I think it would be more effective to designate a lead agency for purposes of these regulations and allow others to deviate only where they can demonstrate that they must follow a different course in order to carry out their mission.

discuss NO

6. In section 1(c)(1), the memorandum proposes that, for purposes of classified research, "not otherwise affiliated with the institution" be defined as "a non-governmental member with the appropriate security clearance." This places total reliance on the IRB member in question not being a government employee and would allow an employee of a private sector entity that is very closely affiliated with the institution to serve. Thus, I recommend that the second sentence of section 2(c)(1) be revised so as to provide that for purposes of classified research, all federal government employees [and certain others,

NO

such as personal services contractors and consultants?] are to be considered to be affiliated with the institution. I discuss

7. Section 6 seems to require the immediate cessation of all classified research (including ongoing projects) until new final rules are actually promulgated. If that is the intent, I recommend that section 6 say so specifically. If that is not, I recommend that section 6 specify what the status of ongoing projects is and how and when the new rules might apply to them.

Ed

Edward P. Scott

--- 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.

P = Indent

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.

3. An agency

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.

4.

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.

5.

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

6.

Sec. 6. No classified human subjects research without common rule. No agency shall conduct or support classified human subjects research without first implementing 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.

E R

Department of Veterans Affairs

Memorandum

Date: DEC 05 1996

From: Deputy Director, Medical Research (121A)

Subj: Comments on Proposed Memorandum "Strengthened Protections for Human Subjects of Classified Research"

To: Deputy Assistant General Counsel (023B)
Thru: Sharon M. Johnston

1. I have reviewed the attached draft memo and am providing comments as requested by Gene Hufford (10C1) in the Under Secretary for Health's Office.

2. Minor editorial and typographical alterations are provided directly on the draft. I want to point out that the term "human subjects research" is awkward phraseology and is a term that in my experience as a clinical researcher I have not used. I do not have the Common Rule in front of me so I don't know whether this term is used there. If not, I think the straightforward term "human research" is more appropriate.

3. My biggest concern is over the addition of only one non-government member to the responsible IRB for a classified research project. The presumption is that the non-government member will provide a disinterested view to counterweight any government interests that could impair or appear to impair the objectivity of the IRB. The effectiveness of this approach relies on the ability of the non-government member to go against the rest of the committee, in the event such a situation arises. An alternative might be to require two non-government members, one being a clinician/researcher, the other being a bioethicist.

4. Consideration should also be given to explicitly stating that any non-government member should have no substantial interest in the government agency conducting the research. For example, a non-government member should not be a contractor or grantee of the agency. This could be problem if the agency is the NIH since so many researchers are funded by NIH. However, I don't believe the NIH does classified research and therefore it may be a non-issue.

Timothy R. Gerrity, Ph.D.

cc: Gene Hufford (10C1)

VA FORM
MAR 1989 2105

--- DRAFT ---

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

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

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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.

THESE IRBs SHOULD (MUST?) BE CONSTRUED IN BACKGROUND WITH THE FEDERAL [illegible] RULE

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.

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(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.

I'M CONCERNED ABOUT A SINGLE NON-GOVT. MEMBER WITH APPROPRIATE CLEARANCES

WOULD IT BE POSSIBLE FOR THE COMM TO BE NON-GOVERNMENT? OR HAVE 2 NON-GOVT MEMBERS

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
Business and Administrative Law Division
Room 5362 Cohen Building
330 Independence Av., S.W.
Washington, D.C. 20201

Facsimile Transmission Sheet

TO: **Mac Reed**
OMB, OGC

FROM: **Leslie L. Clune**
Phone: (202) 619-0150
FAX: (202) 619-2922

CALL FOR PICKUP: 395-5600

Total Pages	Fax Number	Date
1 plus cover	395-7294	December 9, 1996

Subject: Proposed Memorandum, "Strengthened Protections for Human Subjects of Classified Research"

In addition to the comments that we faxed to you last week from the Food and Drug Administration, we have received the attached comments from the National Institutes of Health. In summary, NIH suggests that, rather than initiating a lengthy rulemaking process involving 17 agencies, the memorandum itself impose the policy changes on agencies that conduct classified research. While implementation of certain provisions of the policy may require changes in the regulations (e.g., appeal of majority IRB decisions to the OSTP), others appear to be matters that could be addressed outside of the rulemaking context (e.g., the policy against waiving informed consent).

Also, it is unclear whether the intent of section 6 of the proposed policy is to suspend until a final rule is published any classified research that may be ongoing.

Canning, Betty

From: Ellis, Gary
To: Canning, Betty
Subject: 153976
Date: Thursday, December 05, 1996 11:17AM

OPRR cannot clear the proposed Presidential Memorandum entitled "Strengthened Protections for Human Subjects of Classified Research," as it is written. OPRR recommends that DHHS clearance be given only after the revisions itemized below are incorporated in the draft.

The draft embraces a 17-agency (or more) rulemaking process that can be expected to consume several years. (The previous iteration of this process involved 16 agencies and consumed 9 years.) With classified research having ever been done, being done, or being contemplated at 3 to 4 agencies/departments at most (e.g., CIA?, DOD?, DOE?, HHS?), a more skillful and conservative approach by the President is warranted. At present, an estimated 1 to 6 classified research projects involving human subjects are conducted or supported by the Federal Government.

Section 1 should be revised to read as follows:

Sec. 1: (a) No Federal funds shall be expended to conduct or support classified research involving human subjects where an Institutional Review Board has waived informed consent (or waived documentation of informed consent) or where a determination has been made that the research is exempt from Institutional Review Board review.

(b) In all Federally funded classified research, two additional elements of information shall be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency, and 2) a statement that the project involves classified information.

(c) In all Federally funded classified research, the nonaffiliated member(s) of the responsible Institutional Review Board shall be nongovernmental individual(s) with the appropriate security clearance(s).

(d) In all Federally funded classified research, any member of the responsible Institutional Review Board may appeal a majority decision to approve the 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 nongovernmental officials, each with the appropriate security clearances, to approve or disapprove the project.

Section 2 should be omitted, as the need for it is now obviated.

Section 3 is okay.

Section 4 is okay.

Section 5 should be revised to include a definition of "classified."

Section 6 should be revised to read as follows:

Section 6. No classified human subjects research without common rule. No department or agency shall conduct or support classified human subjects research without first promulgating the Federal Policy for the Protection of Human Subjects.

OPRR is pleased to provide any additional comment, as needed. OPRR recommends that the Office of General Counsel also review the incoming draft and OPRR comments.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20160

OFFICE OF
GENERAL COUNSEL

FAX TRANSMITTAL

CROSS-CUTTING ISSUES DIVISION

DATE: December 11, 1996

TO: Mac Reed

PHONE No: 202-395-5600

FAX No. 202-395-7294

FROM: Abigail Jordan for Craig Annear

PHONE NO: (202) 260-7622

3 Pages Sent including this cover sheet

MESSAGE:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 11 1996

OFFICE OF
GENERAL COUNSEL

MEMORANDUM

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

FROM: Robert G. Dreher
Senior Policy Advisor

TO: Mac Reed
Office of General Counsel, OMB

Thank you for soliciting our comments on the draft Presidential memorandum. We appreciate your allowing us two extra work days to respond.

Please consider the following editorial and substantive comments:

1. Page 1, 4th paragraph, "researches" should be "researchers."

2. Sec. 1, preamble, says "All agencies...shall...publish", but in subsections (a), (b), and (c), the phrases are "shall jointly propose." Also, Sections 2 and 6 make no reference to agencies' jointly promulgating the final rule. The terminology should be consistent throughout all three sections, and the memorandum should require common rulemaking.

3. A single agency should be assigned responsibility for coordinating work on the Common Rule. We recommend that NIH's Office for Protection from Research Risks, currently the overseer of the "Common Rule," be specified in the memorandum as the agency to administer and coordinate the government's common rulemaking, both at the proposed and the final stage, consistent with the draft memorandum's requirements.

4. Sec. 1(b)(2) would require that the joint rule impose an obligation on the sponsoring agency to tell potential subjects when a research project is classified. We assume that information about the purpose of the research, a required element for informed consent, might be classified. Is the intent of this provision to trigger a duty of secrecy on the potential subject, raising a possibility of future prosecution for disclosure? If so, we recommend that any such additional duties be set out explicitly.

If you have questions about these comments, you may contact Roger Cortesi of our Office of Research and Development (260-6739) or Alan Ehrlich (260-7510) or Craig Annear (260-5328) of my staff.

cc: Roger Cortesi, ORD
Alan Ehrlich, OGC
Dana Ott, OGC

THE WHITE HOUSE
WASHINGTON.

12-31-96
2:15

Elizabeth,

Attached are two redelegated commands I have received. Defense has promised to get back to me today or Thursday at the latest for any comments. If I don't hear from them by Thursday (I'll call them), then they will be deemed to not object.

I was unable to get the earlier draft to NRL for comment. After the next draft I'll send it to them for 24 hour turnaround.

We can try to get this into the White House next week. Thank you.

Mac
(453-5687)

U.S. Agency For International Development
Washington, D.C. 20523

FACSIMILE TRANSMITTAL COVER SHEET
FAX No. (703)875-4413

DATE: 12/13/96

TO:

ATTENTION: MAC REED ORGANIZATION: OMB/IC

FAX PHONE: 202.395.7291 OFFICE 202.395.5600

FROM:

ORIGINATOR 202-395-7294 ORGANIZATION: USAID/W

PHONE: OFFICE G/PHN/POP/CLM

SUBJECT: Comment on Strengthened Retention of Classified Record

NUMBER OF PAGES *(including this cover sheet)*: 2

COMMENTS:

AID 330-7 (8/94)

DEC-13-96 FRI 15:12 AID/RD/POP FAX NO. 7038754413 P.01

U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

To: Mac Reed

This is in response to your request for comment on the draft memorandum on strengthened protections for human subjects of classified research. As we discussed, as far as I know USAID conducts no classified research and I don't anticipate any. Still I have one significant comment:

I think it is important to focus and limit the memorandum and its implementation on experimental human subjects research. The "Common Rule" also applies to a wide variety of survey, epidemiologic, social science and other research and in fact can be construed to apply to a wide range of information gathering. It could actually be argued that a wide variety of classified intelligence-gathering activities constitute human subjects research, which clearly could be rendered totally impractical under such a scenario.

Limiting the memorandum to experimental human subjects research avoids this problem. I believe this is really the intent of memorandum and the Advisory Committee on Human Radiation Experiments.

James D. Shelton
Cognizant Human Subjects Officer

Jim Shelton
875-4719

320 TWENTY-FIRST STREET, N.W., WASHINGTON, D.C. 20523

CENTRAL INTELLIGENCE AGENCY

WASHINGTON, D.C. 20505

Office of General Counsel

11 DEC 1996

Mr. Robert G. Damus
Executive Office of the President
Office of Management and Budget
Office of the General Counsel
Washington, DC 20503

Dear Mr. Damus:

This is in response to your request for the views of the Central Intelligence Agency on the proposed Presidential Memorandum entitled "Strengthened Protections for Human Subjects of Classified Research," which was prepared by the Office of Domestic Policy. This Presidential Memorandum implements recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) with respect to classified research. We agree with many of the recommendations, including the requirement for informed consent. We do have concerns, however, with requiring researchers in all cases to identify the sponsoring agency, requiring agency head approval for all human research involving classified information, and imprecise language concerning the composition of the Institutional Review Board (IRB).

Identifying the sponsor of the human research could, in rare cases, jeopardize national security by alerting foreign intelligence services to possible vulnerabilities in existing security procedures or by providing foreign services with the opportunity to counter advances made as a result of the research. For example, identifying the Agency as the sponsor of research intended to improve the effectiveness and reliability of the polygraph could allow foreign intelligence services to counter new means to detect deception. In these types of cases, requiring the identity of the sponsoring agency would add little, if any, additional protection to research subjects and could seriously jeopardize a new method to detect espionage. We therefore request that the Presidential Memorandum be modified to provide an exemption from the requirement to identify the sponsoring agency where the head of the agency conducting the research determines that such an exemption is necessary for national security purposes.

Mr. Robert G. Damus

We also are concerned with the requirement that all classified human research be approved by the head of the agency. Under existing rules, an IRB has the authority to approve, modify or disapprove all covered research activities. Certain research activities, however, are exempt from even this requirement. For example, research involving the collection or study of existing data or records is exempt from the rules regarding human research if information is recorded by the investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject. In other cases, expedited review procedures are provided for certain cases involving no more than minimal risk to the subject or where the research involves nothing more than minor changes to previously approved research. The proposed Presidential Memorandum alters these rules by requiring that all human research, regardless of the level of risk, be approved by the agency head if the research is classified.

Requiring agency head approval for classified research is unnecessary and burdensome for those categories of research that pose a minimal risk. For example, numerous epidemiological studies are conducted annually by the Agency's Office of Medical Services. Most of these studies, which are classified because they contain information on covert employees, are currently exempt from review. Under the draft Presidential Memorandum, these studies will require approval by the Director of Central Intelligence (DCI). (DCI approval will in turn trigger a requirement for review by the Agency's Human Subject Research Panel.) We do not understand why such benign research, which entails nothing more than reviewing files and compiling statistical data, should require panel and DCI approval simply because files contain the names of covert employees. The proposed Presidential Memorandum should be amended to exempt from the requirement of agency head approval classified research that is now exempt from coverage under existing rules or which can be approved under an expedited review procedure.

may be OK

Finally, we are concerned with imprecise language with respect to composition of the IRB. The draft Presidential Memorandum requires that for classified research, each IRB include a non-governmental member. It is not clear whether a person who receive grants or other funding from the government may serve on a panel as the "non-governmental member." Individuals ideally suited to serve on IRB's are often themselves engaged in research that is funded by the government. This point should be clarified.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	To: Robert Damus [partial] [CIA Act] (1 page)	12/11/1996	P3/b(3)

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

FOLDER TITLE:
Comments on Directive/Classified Research

2014-0046-S
rc1439

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]

Mr. Robert G. Damus

I appreciate the opportunity to comment on this proposed Presidential Memorandum. Should OMB require additional information regarding our position on this matter, please contact me or Mr. John Pereira, the Agency's representative on the Interagency Working Group, at (b)(3)

Sincerely yours,

(b)(3)

[001]

U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

To: Mac Reed

This is in response to your request for comment on the draft memorandum on strengthened protections for human subjects of classified research. As we discussed, as far as I know USAID conducts no classified research and I don't anticipate any. Still I have one significant comment:

I think it is important to focus and limit the memorandum and its implementation on experimental human subjects research. The "Common Rule" also applies to a wide variety of survey, epidemiologic, social science and other research and in fact can be construed to apply to a wide range of information gathering. It could actually be argued that a wide variety of classified intelligence-gathering activities constitute human subjects research, which clearly could be rendered totally impractical under such a scenario.

Limiting the memorandum to experimental human subjects research avoids this problem. I believe this is really the intent of memorandum and the Advisory Committee on Human Radiation Experiments.

James D. Shelton
Cognizant Human Subjects Officer

Jim Shelton
875-4719

320 TWENTY-FIRST STREET, N.W., WASHINGTON, D.C. 20523

19 December 1996

MEMORANDUM FOR: Elizabeth Drye
White House

FROM: John Pereira
Central Intelligence Agency

SUBJECT: Radiation--Draft Presidential Memorandum

1. This is a follow-up to our discussion of 18 December, during which you asked if we could craft more specific wording concerning an exception from disclosing the identity of the sponsoring agency in classified research.

2. The Office of General Counsel and the Chairperson of the Agency's Human Subject Research Panel propose the following revision of Sec 1., (b) of the draft memorandum (new wording underlined):

(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, unless the head of the sponsoring agency 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

2) a statement that the project is classified.

3. Please let me know if you would like further information.

John Pereira

Substantive comments on Presidential Directive on Classified Human Research.
1/6/96

DOE (Shebek):

1. Fails to address the clearance needs of the individual subject.

    Redraft states that panel must consider whether subject was sufficiently informed to make a valid consent decision.

FDA (White):

Suggest narrowing to all agencies that may conduct or support classified research.

    done.

Suggest adding requirement to tell subject what classified means.

    Done.

Could further restrict defn of non-governmental.

    Left to rulemaking.

VA (Robinson)

Should designate a lead agency to coordinate regulations

    Done. Assigned to OPRR w/in HHS.

Suggests further restricting defn of non-governmental (e.g. not a contractor or grantee w/agency)

    Left to rulemaking

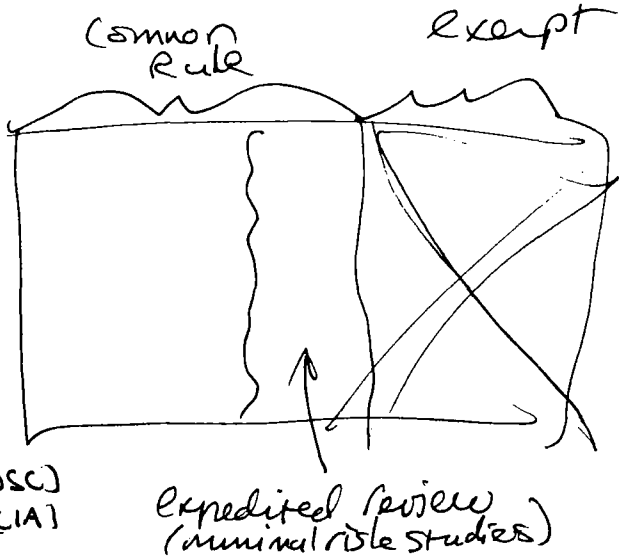
Suggests adding two non-governmental members.

    Rejected.

HHS (Clune)

OPRR suggests we not do by rulemaking

    That approach was rejected by Justice.



HHS noes Sec. 6 may interrupt on-going work.

Redrafted to apply one year after the directive.

EPA (Craig Aneer)

Section 1(b)2 may trigger a duty of secrecy on subject.

Agree, but left to rulemaking.

USAID (Jim Shelton)

Limit to "experimental human subjects research" as common rule is too broad.

Rejected. Some ethicists believe common rule already has too many exemptions.

CIA (Eilenberger and subsequent note from Periera)

Provide an exemption from the requirement to identify the sponsoring agency where minimal risk and necessary for national security purposes.

Accepted.

Exempt from the requirement of agency head approval classified research that is now exempt from coverage under existing rules or which can be approved under an expedited review procedure.

Expedited review not allowed. Won't apply to research outside Common Rule.

Defn. of non-governmental member unclear. Individuals well-suited to sit on IRB's often engaged in gov't funded research.

Agree, but some commenters want tighter defn. Left to regulation.

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.

Add. agencies shall permanently maintain. ~~Capture~~ documentation of the IRB's deliberations, the informed consent process, and the informed consent documents [and shall declassify such documents in accordance w/ EO . . .]

Add. 15 b (4) re. whether sec. clearance is needed for subjects

1 sentence defn. of classified [pendergast]

Issues — "non-gov'tl" (VA - higher; FOA - higher; 12 committees)
- prohibition on C.R. w/o commercial transition
VA, HHS
Change numbers?

CIA Exemption to identifying sponsoring agency where agency head determines necessary for national security purposes

What to do with "Expedited review" research where subjects cannot be identified.

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~~ research involving 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~~ promulgating into a final regulations the Federal Policy for the Protection of Human Subjects as modified by Section 1 below.

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.

Use Section # 1 ?

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~~

Add grandfather clause.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. list	re: Interagency Working Group [partial] (1 page)	01/03/1997	P3/b(3)

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

FOLDER TITLE:
Comments on Directive/Classified Research

2014-0046-S
rc1439

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.

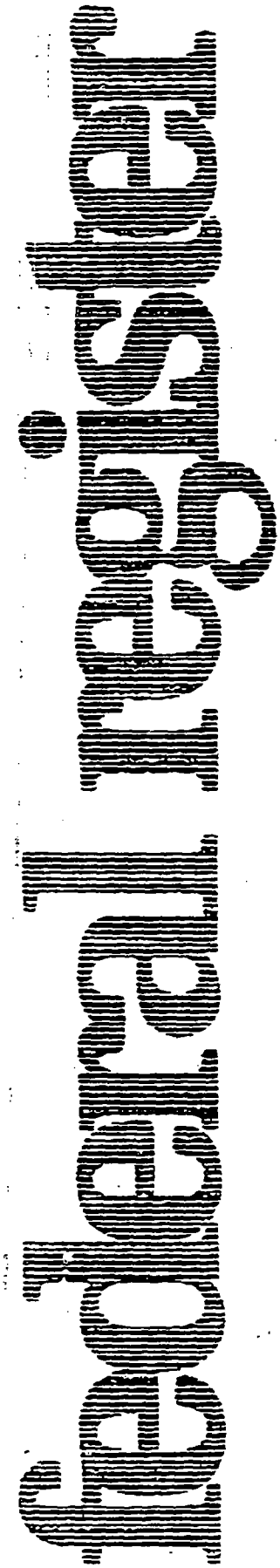
Freedom of Information Act - [5 U.S.C. 552(b)]

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)	[602]
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...	301-496-1096	[fax 402-3469]
	ELLIS, GARY.....	301-496-7005 (#205)	[fax 402-2071]
NASA:	FERGUSON, EARL.....	358-4538	[fax 358-3038]
	NICOGOSSIAN, ARNAUD	358-0215	[fax 358-4174]
	STOKLOSA, 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]
	QTCHIN, NEIL.....	273-8578	[fax 273-9078]
	CATHY Colleu	273-7226	
WH:	CAPLAN, PHIL.....	456-2702	[fax 456-2215]
	DRYE, ELIZABETH.....	456-2216	[fax 456-7028]
	~~NEUWIRTH, STEVE.....~~	~~456-7903~~	~~[fax 456-1647]~~
	REGAS, DIANE.....	456-5589	[fax 456-7028]
	David Flein	456-6219	

Updated 6-3-96



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.

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.

Add. agencies shall permanently maintain.
documentation of the IRB's deliberations, informed consent process, and the informed consent documents [and shall declassify such documents in accordance w/ EO . . .]

Add. 15 b (4) re. whether sec. clearance is needed for subjects

1 sentence defn. of classified [pendergast]

Issues — "non-govt'l" [VA - higher; FOA - higher; (2 commenters)
- prohibition on C.R. w/o common rule - transition
VA, HHS

CIA Exemption to identifying sponsoring agency where agency head determines necessary for national security purposes

What to do w/ "Expedited review" research where subjects cannot be identified, minimal risk, minor changes

THE WHITE HOUSE

WASHINGTON

November 27, 1996

MEMORANDUM FOR FRANK RAINES

FROM: Carol H. Rasco
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 ~~subject~~s 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~~

Add grandfather clause.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. 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:
Comments on Directive/Classified Research

2014-0046-S
rc1439

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
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	REGAS, DIANE.....	456-5589	[fax 456-7028]
	David Fein ~~EM 213~~	456-6219	

Updated 6-3-96

--- DRAFT ---

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

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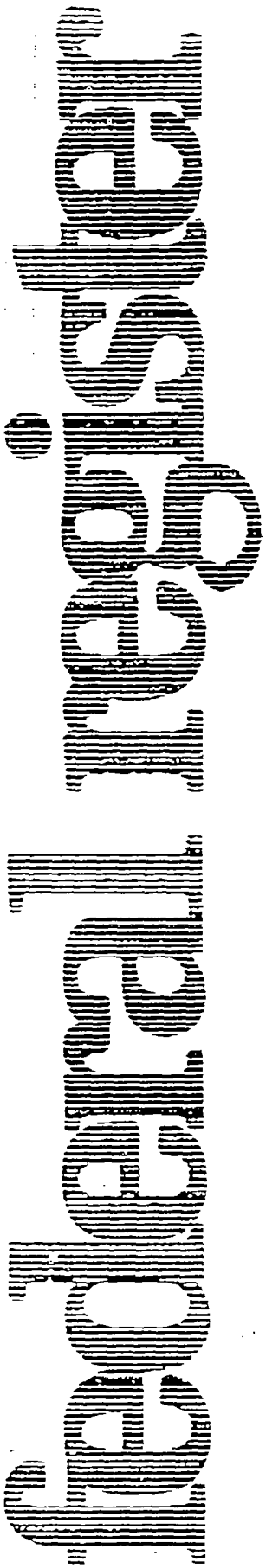

Tuesday
June 18, 1991

Part II

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

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Department of Agriculture
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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

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22 CFR Part 225

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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.

Office of General Counsel
U.S. Department of Transportation
400 Seventh Street, S.W.
C-40, Room 10100
Washington, D.C. 20590
Telephone: (202)366-4687
Telefax: (202)366-7153

TO: Mac Reed FROM: Jane DeCell

FAX #: 395-7294

Number of pages (including this page)	1
DATE AND TIME	12/16/96 - 10:30
DATE COMMENTS / RESPONSE (IF ANY) ARE DUE	—

Remarks:

Proposed E.O. "Strengthened Protections for Human Subjects of Classified Research."

DOT concurs without comment.

Jane DeCell
366-9299

Office of General Counsel
U.S. Department of Transportation
400 Seventh Street, S.W.
C-40, Room 10100
Washington, D.C. 20590
Telephone: (202)366-4687
Telefax: (202)366-7153

TO: Mac Reed FROM: Jane DeCell

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Remarks:

Proposed E.O. "Strengthened Protections for Human Subjects of Classified Research."

DOT concurs without comment.

Jane DeCell
366-9299

U.S. Agency For International Development
Washington, D.C. 20523

FACSIMILE TRANSMITTAL COVER SHEET
FAX No. (703)875-4413

DATE: 12/13/96

TO:

ATTENTION: MAC REED ORGANIZATION: OMB/IC

FAX PHONE: 202.395.7294 OFFICE 202.395.5600

FROM:

ORIGINATOR 202-395-7294 ORGANIZATION: USAID/W

PHONE: OFFICE G/PHN/POP/CLM

SUBJECT: Comment on Strengthened Retention of Classified Record

NUMBER OF PAGES *(including this cover sheet)*: 2

COMMENTS:

AID 330-7 (8/94)

U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

To: Mac Reed

This is in response to your request for comment on the draft memorandum on strengthened protections for human subjects of classified research. As we discussed, as far as I know USAID conducts no classified research and I don't anticipate any. Still I have one significant comment:

I think it is important to focus and limit the memorandum and its implementation on experimental human subjects research. The "Common Rule" also applies to a wide variety of survey, epidemiologic, social science and other research and in fact can be construed to apply to a wide range of information gathering. It could actually be argued that a wide variety of classified intelligence-gathering activities constitute human subjects research, which clearly could be rendered totally impractical under such a scenario.

Limiting the memorandum to experimental human subjects research avoids this problem. I believe this is really the intent of memorandum and the Advisory Committee on Human Radiation Experiments.

James D. Shelton
Cognizant Human Subjects Officer

Jim Shelton
875-4719

320 TWENTY-FIRST STREET, N.W., WASHINGTON, D.C. 20523

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.

THE WHITE HOUSE

WASHINGTON

November 27, 1996

MEMORANDUM FOR FRANK RAINES

FROM: Carol H. Rasco
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
004. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
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FOLDER TITLE:
Comments on Directive/Classified Research

2014-0046-S
rc1439

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]

[004]

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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]
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	NICOGOSSIAN, ARNAUD	358-0215	[fax 358-4174]
	STOKLOSA, 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]
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Updated 6-3-96

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.

> to be expected to absorb the financial, as well as the unavoidable human costs of the societal research enterprise which benefits everyone.[11]

The Advisory Committee urges not only consideration of a compensation policy for physical injuries attributable to research but also that consideration be given to appropriate remedies for subjects who have suffered dignitary harms, even in the absence of physical injury. Subjects so wronged have little recourse in the current system; litigation in the absence of physical injury is unlikely to provide relief to people who have been used as subjects without their adequate consent. If it is determined that financial compensation is not generally an appropriate remedy in the absence of physical injury, consideration should be given to other remedies that would be fitting.

Recommendations for Balancing National Security Interests and the Rights of the Public

Recommendation 15

15a: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring the informed consent of all human subjects of classified research and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring federal agency and that the project involves classified information.

15b: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives, all with the necessary security clearances. This panel should be charged with determining (1) that the proposed experiment has scientific merit; (2) that risks to subjects are acceptable and that the balance of risk and potential benefit is appropriate; (3) that the disclosure to prospective subjects is sufficiently informational and that the consent solicited from subjects is sufficiently voluntary; and (4) whether potential subjects must have security clearances in order to be sufficiently informed to make a valid consent decision, and if so, how this can be achieved without compromising the privacy and voluntariness of potential subjects. Complete documentation of the panel's deliberations and of the informed consent documents and process should be maintained permanently. These records should be made public as soon as the national security concern justifying secrecy no longer applies.

Although the Advisory Committee believes that the interests of both science and potential subjects are best served when research involving human subjects is conducted in the open, a public policy prohibiting the conduct of human subject research in secret is unwise. Important national security goals may suffer if human subjects research projects making unique and irreplaceable contributions were foreclosed. More citizens may suffer harms for lack of such information than would be harmed if adequately safeguarded human subjects research was conducted in secret.

It also is possible that a prohibition on classified human subjects research would be circumvented through redefinition of activities or disregarded outright. If this were to occur, the participants in such activities could end up less well protected than if they were bona fide research subjects.

The Advisory Committee believes, however, that the classification of human subject research ought properly to 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 does not believe that continuing with the current federal policy governing the protection of human subjects, which does not provide any special safeguards or procedures for classified research, is adequate.

In the current political context, classified human subjects research occurs relatively rarely. Existing policy may prove an inadequate safeguard of individual rights and welfare, however, if in the future national security crises occur that generate a perceived need for classified research. The history of human experimentation conducted in the interests of strengthening and protecting national security that the Advisory Committee has examined demonstrates how the rights and interests of citizens can be violated in secret research. The convergence of elements of secrecy, urgent national purposes, and the essential vulnerability of research subjects, owing to differentials in information and power between those conducting research and those serving as subjects, could again lead to abuses of individual rights and, upon subsequent revelation, the erosion of public distrust in government.

The Advisory Committee is particularly concerned about two aspects of current policy--exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified. The current requirement for the informed consent of research participants is not absolute, leaving open the possibility that subjects may serve as mere tools of the state in the interests of national security if consent is waived. A strengthened requirement for the informed consent of research subjects in classified research should safeguard against the merely instrumental use of individual people to serve national purposes.

Institutional review boards of government agencies are not sufficiently independent of the interests of the organizations of which they are a part to set

aside considerations of organizational mission when considering research construed as having the greatest national priority. Thus, determination by an agency IRB that a waiver of informed consent is warranted, or that sufficient information about a study remains in a censored protocol description for a potential subject's review, inadequately protects subjects' interests and rights and does not adequately safeguard the public's trust. By contrast, an independent panel should be less subject to unintended bias than that of an IRB of a federal agency whose mission is to protect and promote national security.

Although the Advisory Committee acknowledges that both the formation of an independent review panel and an absolute informed consent requirement create opportunities for information leaks or security breaches and delays in the progress of urgent research, these disadvantages are surmountable and are more than balanced by the increased vigilance afforded the rights and interests of citizens and the safeguarding of the public's trust in government.

Recommendation 16

The Advisory Committee recommends to the Human Radiation Interagency Working Group that improvements be made in the protections of the public's rights and interests with respect to intentional releases.

16a. The Advisory Committee recommends to the Human Radiation Interagency Working Group that an independent review panel review any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

In conducting its review, the independent panel should ensure that (1) secrecy is limited to that required for reasons of national security; (2) records will be kept on the nature and purpose of the release, the rationale for not informing the public (including workers and service personnel, as well as affected citizens), and alternative means of gathering data that were considered; (3) actions to mitigate risk were considered and will be taken; and (4) actions will be taken to measure the actual effect of the release on the environment and human health and safety, to the extent that measurements are deemed needed and feasible. The panel should also review the conditions on which any information kept secret should be made public, with a view toward ensuring the release of information as soon as practicable, consistent with any legitimate national security restrictions. The panel should report to Congress periodically on the number and nature of releases it has reviewed.

--- 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."
- require permanent records of Panel's deliberations, consent and research procedures

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. It also requires permanent record-keeping

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.

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(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.

> to be expected to absorb the financial, as well as the unavoidable human costs of the societal research enterprise which benefits everyone.[11]

The Advisory Committee urges not only consideration of a compensation policy for physical injuries attributable to research but also that consideration be given to appropriate remedies for subjects who have suffered dignitary harms, even in the absence of physical injury. Subjects so wronged have little recourse in the current system; litigation in the absence of physical injury is unlikely to provide relief to people who have been used as subjects without their adequate consent. If it is determined that financial compensation is not generally an appropriate remedy in the absence of physical injury, consideration should be given to other remedies that would be fitting.

Recommendations for Balancing National Security Interests and the Rights of the Public

Recommendation 15

15a: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring the informed consent of all human subjects of classified research and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring federal agency and that the project involves classified information.

15b: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives, all with the necessary security clearances. This panel should be charged with determining (1) that the proposed experiment has scientific merit; (2) that risks to subjects are acceptable and that the balance of risk and potential benefit is appropriate; (3) that the disclosure to prospective subjects is sufficiently informational and that the consent solicited from subjects is sufficiently voluntary; and (4) whether potential subjects must have security clearances in order to be sufficiently informed to make a valid consent decision, and if so, how this can be achieved without compromising the privacy and voluntariness of potential subjects. Complete documentation of the panel's deliberations and of the informed consent documents and process should be maintained permanently. These records should be made public as soon as the national security concern justifying secrecy no longer applies.

Although the Advisory Committee believes that the interests of both science and potential subjects are best served when research involving human subjects is conducted in the open, a public policy prohibiting the conduct of human subject research in secret is unwise. Important national security goals may suffer if human subjects research projects making unique and irreplaceable contributions were foreclosed. More citizens may suffer harms for lack of such information than would be harmed if adequately safeguarded human subjects research was conducted in secret.

It also is possible that a prohibition on classified human subjects research would be circumvented through redefinition of activities or disregarded outright. If this were to occur, the participants in such activities could end up less well protected than if they were bona fide research subjects.

The Advisory Committee believes, however, that the classification of human subject research ought properly to 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 does not believe that continuing with the current federal policy governing the protection of human subjects, which does not provide any special safeguards or procedures for classified research, is adequate.

In the current political context, classified human subjects research occurs relatively rarely. Existing policy may prove an inadequate safeguard of individual rights and welfare, however, if in the future national security crises occur that generate a perceived need for classified research. The history of human experimentation conducted in the interests of strengthening and protecting national security that the Advisory Committee has examined demonstrates how the rights and interests of citizens can be violated in secret research. The convergence of elements of secrecy, urgent national purposes, and the essential vulnerability of research subjects, owing to differentials in information and power between those conducting research and those serving as subjects, could again lead to abuses of individual rights and, upon subsequent revelation, the erosion of public distrust in government.

The Advisory Committee is particularly concerned about two aspects of current policy--exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified. The current requirement for the informed consent of research participants is not absolute, leaving open the possibility that subjects may serve as mere tools of the state in the interests of national security if consent is waived. A strengthened requirement for the informed consent of research subjects in classified research should safeguard against the merely instrumental use of individual people to serve national purposes.

Institutional review boards of government agencies are not sufficiently independent of the interests of the organizations of which they are a part to set

aside considerations of organizational mission when considering research construed as having the greatest national priority. Thus, determination by an agency IRB that a waiver of informed consent is warranted, or that sufficient information about a study remains in a censored protocol description for a potential subject's review, inadequately protects subjects' interests and rights and does not adequately safeguard the public's trust. By contrast, an independent panel should be less subject to unintended bias than that of an IRB of a federal agency whose mission is to protect and promote national security.

Although the Advisory Committee acknowledges that both the formation of an independent review panel and an absolute informed consent requirement create opportunities for information leaks or security breaches and delays in the progress of urgent research, these disadvantages are surmountable and are more than balanced by the increased vigilance afforded the rights and interests of citizens and the safeguarding of the public's trust in government.

Recommendation 16

The Advisory Committee recommends to the Human Radiation Interagency Working Group that improvements be made in the protections of the public's rights and interests with respect to intentional releases.

16a. The Advisory Committee recommends to the Human Radiation Interagency Working Group that an independent review panel review any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

In conducting its review, the independent panel should ensure that (l) secrecy is limited to that required for reasons of national security; (2) records will be kept on the nature and purpose of the release, the rationale for not informing the public (including workers and service personnel, as well as affected citizens), and alternative means of gathering data that were considered; (3) actions to mitigate risk were considered and will be taken; and (4) actions will be taken to measure the actual effect of the release on the environment and human health and safety, to the extent that measurements are deemed needed and feasible. The panel should also review the conditions on which any information kept secret should be made public, with a view toward ensuring the release of information as soon as practicable, consistent with any legitimate national security restrictions. The panel should report to Congress periodically on the number and nature of releases it has reviewed.

--- 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
005. fax	To Elizabeth Drye (1 page)	12/31/1996	P3/b(3)

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

FOLDER TITLE:
Comments on Directive/Classified Research

2014-0046-S
rc1439

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]
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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]

19 December 1996

MEMORANDUM FOR: Elizabeth Drye
White House

FROM: John Pereira
Central Intelligence Agency

SUBJECT: Radiation--Draft Presidential Memorandum

1. This is a follow-up to our discussion of 18 December, during which you asked if we could craft more specific wording concerning an exception from disclosing the identity of the sponsoring agency in classified research.

2. The Office of General Counsel and the Chairperson of the Agency's Human Subject Research Panel propose the following revision of Sec 1., (b) of the draft memorandum (new wording underlined):

(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, unless the head of the sponsoring agency 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

2) a statement that the project is classified.

3. Please let me know if you would like further information.

John Pereira

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006. fax	To Mac Reed [CIA Act] [partial, page 1 in full] (2 pages)	12/11/1996	P3/b(3)

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CENTRAL INTELLIGENCE AGENCY

WASHINGTON, D.C. 20505

Office of General Counsel

11 DEC 1996

Mr. Robert G. Damus
Executive Office of the President
Office of Management and Budget
Office of the General Counsel
Washington, DC 20503

Dear Mr. Damus:

This is in response to your request for the views of the Central Intelligence Agency on the proposed Presidential Memorandum entitled "Strengthened Protections for Human Subjects of Classified Research," which was prepared by the Office of Domestic Policy. This Presidential Memorandum implements recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) with respect to classified research. We agree with many of the recommendations, including the requirement for informed consent. We do have concerns, however, with requiring researchers in all cases to identify the sponsoring agency, requiring agency head approval for all human research involving classified information, and imprecise language concerning the composition of the Institutional Review Board (IRB).

Identifying the sponsor of the human research could, in rare cases, jeopardize national security by alerting foreign intelligence services to possible vulnerabilities in existing security procedures or by providing foreign services with the opportunity to counter advances made as a result of the research. For example, identifying the Agency as the sponsor of research intended to improve the effectiveness and reliability of the polygraph could allow foreign intelligence services to counter new means to detect deception. In these types of cases, requiring the identity of the sponsoring agency would add little, if any, additional protection to research subjects and could seriously jeopardize a new method to detect espionage. We therefore request that the Presidential Memorandum be modified to provide an exemption from the requirement to identify the sponsoring agency where the head of the agency conducting the research determines that such an exemption is necessary for national security purposes.

Mr. Robert G. Damus

We also are concerned with the requirement that all classified human research be approved by the head of the agency. Under existing rules, an IRB has the authority to approve, modify or disapprove all covered research activities. Certain research activities, however, are exempt from even this requirement. For example, research involving the collection or study of existing data or records is exempt from the rules regarding human research if information is recorded by the investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject. In other cases, expedited review procedures are provided for certain cases involving no more than minimal risk to the subject or where the research involves nothing more than minor changes to previously approved research. The proposed Presidential Memorandum alters these rules by requiring that all human research, regardless of the level of risk, be approved by the agency head if the research is classified.

Requiring agency head approval for classified research is unnecessary and burdensome for those categories of research that pose a minimal risk. For example, numerous epidemiological studies are conducted annually by the Agency's Office of Medical Services. Most of these studies, which are classified because they contain information on covert employees, are currently exempt from review. Under the draft Presidential Memorandum, these studies will require approval by the Director of Central Intelligence (DCI). (DCI approval will in turn trigger a requirement for review by the Agency's Human Subject Research Panel.) We do not understand why such benign research, which entails nothing more than reviewing files and compiling statistical data, should require panel and DCI approval simply because files contain the names of covert employees. The proposed Presidential Memorandum should be amended to exempt from the requirement of agency head approval classified research that is now exempt from coverage under existing rules or which can be approved under an expedited review procedure.

May be OK

Finally, we are concerned with imprecise language with respect to composition of the IRB. The draft Presidential Memorandum requires that for classified research, each IRB include a non-governmental member. It is not clear whether a person who receive grants or other funding from the government may serve on a panel as the "non-governmental member." Individuals ideally suited to serve on IRB's are often themselves engaged in research that is funded by the government. This point should be clarified.

Mr. Robert G. Damus

I appreciate the opportunity to comment on this proposed Presidential Memorandum. Should OMB require additional information regarding our position on this matter, please contact me or Mr. John Pereira, the Agency's representative on the Interagency Working Group, at (b)(3)

Sincerely yours,

(b)(3)

[006]

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
007. list	re: comments [partial] (1 page)	n.d.	P3/b(3)

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(b)(3) [007]

Elizabeth — Please give me Language Changes for pp. 16-17

CIA Comments re: LRM EHF7 *(Proposed Report on Actions to Respond to the Advisory Committee on Human Radiation Experiments)*

- Although CIA agrees with many of the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE), CIA has concerns regarding ACHRE's Recommendation #15 (p. 16), which would require: researchers to identify an agency sponsoring classified research projects, and agency heads to approve all human subjects research involving classified information.

- As CIA noted in its letter to Robert Dumas, dated 11 December 1996, identification of an agency sponsoring classified human research could, in rare cases, jeopardize national security, while adding little, if any, additional protection to research subjects. **The proposed Presidential Memorandum, which will implement ACHRE's recommendations, should be modified to provide an exemption from the requirement to identify an agency sponsoring classified research if the head of the agency determines that such an exemption is necessary for national security purposes. The proposed report's description of the actions directed by the Presidential Memorandum concerning this matter should be changed to reflect this modification.**

- The proposed requirement that all classified human subjects research be approved by the head of the agency is not required under existing rules. It is burdensome and unnecessary for those categories of research that pose a minimal risk. **The proposed Presidential Memorandum should be amended so that heads of agencies sponsoring classified research would not be required to approve research that is exempt from coverage under existing rules or which can be approved under an expedited review procedure. The proposed report's description of the actions directed by the Presidential Memorandum concerning this matter should also be changed to reflect this modification.**

work out w/ CIA

- CIA is concerned with imprecise language in the last draft of the proposed Presidential Memorandum that it reviewed concerning the composition of the Institutional Review Board (IRB). The proposed Presidential Memorandum that CIA reviewed would require each IRB to include a "non-governmental member". However, the term "non-governmental member" is not clearly defined, leaving a question as to whether a person who receives grants or other funding from the government may serve on a panel as the "non-governmental member." This point should be clarified.

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.

THE WHITE HOUSE

WASHINGTON

November 27, 1996

MEMORANDUM FOR FRANK RAINES

FROM: Carol H. Rasco
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.

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008. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)

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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)	[006]
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...	301-496-1096	[fax 402-3469]
	ELLIS, GARY.....	301-496-7005 (#205)	[fax 402-2071]
NASA:	FERGUSON, EARL.....	358-4538	[fax 358-3038]
	NICOGOSSIAN, ARNAUD	358-0215	[fax 358-4174]
	STOKLOSA, 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]
	CATHY Collier	273-7226	
WH:	CAPLAN, PHIL.....	456-2702	[fax 456-2215]
	DRYE, ELIZABETH.....	456-2216	[fax 456-7028]
	~~NEUWIRTH, STEVE.....~~	~~456-7903~~	~~[fax 456-1647]~~
	REGAS, DIANE.....	456-5589	[fax 456-7028]
	David Fein	456-6219	

Updated 6-3-96

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.

Jon Foster

Elizabeth –

The NBAC charter has been revised to change the termination date. Keep the attached copy with your files and toss the one I sent you a week ago.

Jon

NATIONAL BIOETHICS ADVISORY COMMISSION CHARTER

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications, including the clinical applications, of that research.

Authority

Executive Order 12975. This Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory committees, and implementing regulations (41 C.F.R. § 101-6.10).

Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council, Federal agencies, and other appropriate entities, and also make available to the public the Commission's advice and recommendations. The Commission's purview includes 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 applications, including the clinical applications, of that research. The Commission shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. The Commission shall not be responsible for the review and approval of individual projects.

As a first priority, the Commission will direct its attention to consideration of:

A. Protection of the rights and welfare of human research subjects; and
B. Issues in the management and use of genetic information including but not limited to human gene patenting.

In addition to responding to requests for advice and recommendations from the National Science and Technology Council, the Commission also may accept suggestions for issues for consideration from both the Congress and the public. The Commission also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council. The Commission shall consider four criteria in establishing priority for its activities:

A. The public health or public policy urgency of the bioethical issue.
B. The relation of the bioethical issue to the goals for Federal investment in science and technology.
C. The absence of another body able to deliberate fruitfully on the bioethical issue.
D. The extent of interest in the issue across the government. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

Structure

The National Bioethics Advisory Commission shall consist of not more than 18 members including the Chairperson. Appointments shall be made by the President, who shall select from knowledgeable non-Government experts and community representatives with special qualifications and competence to deal effectively with bioethical issues. At least one member shall be selected from each of the following categories of primary expertise: (i) philosophy/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.

Members shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. The Chairperson shall be appointed by the President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.

If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office.

The heads of executive departments and agencies shall, to the extent permitted by law, provide the Commission with such information as it may require for purposes of carrying out its functions.

The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary.

The Commission is authorized to solicit information from relevant human research subject groups.

The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Secretary of Health and Human Services is also authorized to contract for the services of non-governmental consultants who may conduct analyses, prepare reports and background papers or prepare other materials for consideration by the Commission, as appropriate.

In order to avoid duplication of effort, the Commission is encouraged to review the deliberations of other entities. The Commission may incorporate or otherwise use the results of the deliberations of other entities as it deems appropriate.

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 of the subcommittee, and estimated frequency of meetings.

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

Meetings

Meetings of the Commission shall be held up to 10 times a year at the call of the Chairperson. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Assistant to the President for Science and Technology and the Secretary of Health and Human Services. Advance notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Federal regulations.

Compensation

Members may be compensated at a rate not to exceed the maximum pay authorized by 5 U.S.C. 3109, plus per diem and travel expenses as in accordance with standard government travel regulations.

Annual Cost Estimate

The estimated annual cost for operating the National Bioethics Advisory Commission is $500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, the appropriate committees of Congress, and other appropriate entities. The Commission may specifically identify the Federal department, agency or other entity to which particular recommendations are directed and request a response from the Federal department, agency or other entity within 180 days of publication of such recommendation.

Executive summaries of each report of the Commission shall be promulgated in the Federal Register. Such summaries shall specifically list the department, agency, or other entity to which any recommendations are directed and the date by which such responses are expected.

An annual report shall be submitted to the National Science and Technology Council and the appropriate committees of Congress. It shall contain, at a minimum, (i) the Commission's function; (ii) a list of members and their business addresses; (iii) the dates and places of meetings; (iv) a summary of the Commission's activities during the year; (v) a summary of the Commission's recommendations made during the year; and (vi) a summary of responses made by departments, agencies, or other entities to the Commission's recommendations during the year.

General Provisions

Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Commission, 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.

Termination Date

Unless extended by appropriate action prior to its expiration, this National Bioethics Advisory Commission will terminate October 3, 1997.

Approved:

John H. Gibbons

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

Date 26 July 1996

U.S. DEPARTMENT OF JUSTICE
OFFICE OF LEGAL COUNSEL
WASHINGTON, D.C. 20530

FACSIMILE TRANSMISSION SHEET

DATE: NOVEMBER 29, 1996

FROM: ROSEMARY HART
SENIOR COUNSEL
OFFICE PHONE: 202/514-2027

TO: ELIZABETH DRYE
WHITE HOUSE DOMESTIC POLICY
OFFICE PHONE:456-5573

FACSIMILE NUMBER: 456-7028

NUMBER OF PAGES: 3 (PLUS COVER SHEET)

REMARKS: HERE ARE OUR COMMENTS ON THE NOVEMBER 27TH DRAFT. GIVEN THE SHORT TIMEFRAME FOR ISSUANCE OF THIS MEMORANDUM, HOWEVER, WE HAVE REACHED NO CONCLUSION AS TO WHETHER INDEPENDENT AGENCIES ARE LEGALLY REQUIRED TO ADHERE TO THE REQUIREMENTS OF THE MEMORANDUM. WE WILL RE-VISIT THAT ISSUE IF SUCH AN AGENCY TAKES THE POSITION THAT IT IS NOT SUBJECT TO THE MEMORANDUM'S DIRECTIVES.

--- 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 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 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 recommendations 1-3. 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.

[Rosemary, in Sec. 1, is there a way to indicate that we're asking agencies to propose a common rule as was done in 1991, i.e. a single proposal from 17 agencies? Should we say, agencies shall jointly propose?" Also, we'd like to direct agencies to promulgate final rule within one year. Can you suggest language on that? thanks.]

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, jointly 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.

I disagree but did it lower case

Sec 2.3 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.

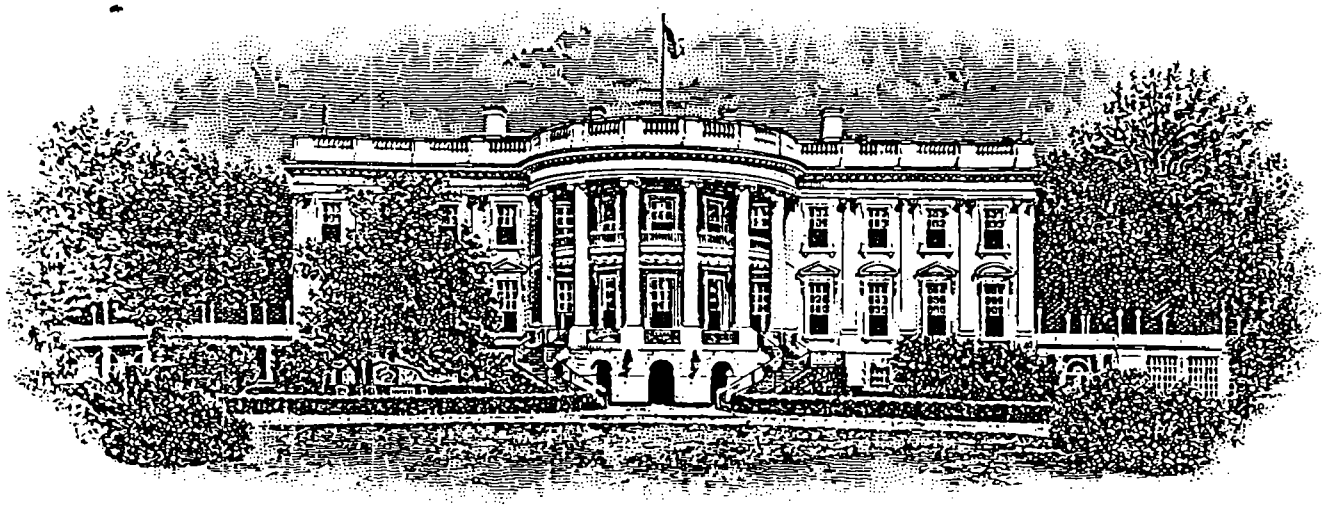
Sec 2.4 Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month 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 2.5 Definitions. For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule.

Sec 2.6 No Classified Human Subjects Research Without Common Rule. No agency shall conduct or support classified human subjects research without first proposing ~~and promulgating~~ 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.

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

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Roseman Hart

FAX NUMBER: 514-0563 (514-0539)

TELEPHONE NUMBER: 514-2027

FROM: Elizabeth Drye

TELEPHONE NUMBER: (*I am faxing again on Friday.)

PAGES (INCLUDING COVER): 4

COMMENTS: For your review.
Please Fax comments to Dorothy Crafts on Friday. Fax 456-7028, and call and let her know fax is coming 456-5571 (phone)
Thanks so much for your help

--- DRAFT ---

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

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

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- 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 recommendations 1-3. 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.

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(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 define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.

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Sec 2. 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.

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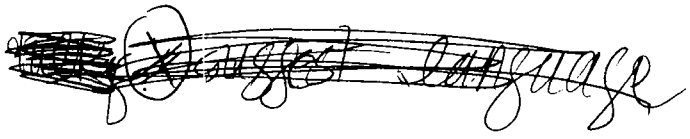
Sec 4. Definitions. For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule.

Sec 5. No Classified Human Subjects Research Without Common Rule. No agency shall conduct or support classified human subjects research without first proposing and promulgating the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.



CEA HHS
DoD
DoE

--- DRAFT ---

And such OTHER

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES THAT CONDUCT OR SUPPORT HUMAN ~~SUBJECTS~~ Classified 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 recommend that all classified research projects 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;
- be approved 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 that believes a project should not go forward can appeal the board's 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 involving human subjects shall, within 60 days, jointly 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. The Office for Protection from Research Risks in the Department of Health and Human Services 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 not exempt from the Common Rule.

(c) The proposal should take 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, unless the head of the sponsoring agency 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:

(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 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 decision 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.

(3) The Panel shall consider -

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. [Ellis, add def'n of classified]

6. No classified human research without Common Rule. Beginning one year after the date of this directive, 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 Procedures.

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 person.

MJZ 1-6-96