

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE ATTORNEY GENERAL
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF COMMERCE
THE SECRETARY OF LABOR
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF ENERGY
THE SECRETARY OF EDUCATION
THE SECRETARY OF VETERANS AFFAIRS
THE DIRECTOR OF CENTRAL INTELLIGENCE
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION
AGENCY
THE ADMINISTRATOR OF THE AGENCY FOR INTERNATIONAL
DEVELOPMENT
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION
THE DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION
THE CHAIR OF THE NUCLEAR REGULATORY COMMISSION
THE DIRECTOR OF THE OFFICE OF SCIENCE AND
TECHNOLOGY POLICY
THE CHAIR OF THE CONSUMER PRODUCT SAFETY
COMMISSION

SUBJECT: Strengthened Protections for Human Subjects
of Classified Research

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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