APPENDIX 2

INFORMATION SOURCES

1. SELECTED BIBLIOGRAPHY

A. Regulations

(1) Department of Defense (DoD)

(a) Common Rule (32 CFR Part 219) (see exhibit 1).

(b) DoD Directive 3216.2, Protection of Human Subjects in DoD Supported Research, DoD Policy Memorandum, 10 June 1993.

(2) Army

(a) AR 40-7, Clinical Use of Investigational Drugs, 13 November 1964.

(b) AR 40-38, Clinical Investigation Program, 23 February 1973.

(c) AR 70-25, Use of Volunteers as Subjects of Research, 31 July 1974.

(3) Navy

(a) Secretary of the Navy Instruction 3900.39B, Protection of Human Subjects, 27 February 1984.

(4) Air Force

(a) AF Instruction 40-402, Using Human Subjects in Research, Development, Test, and Evaluation, 19 July 1994.

(b) AF Instruction 40-403, Clinical Investigations in Medical Research, Guidance and Procedures, May 1994.

(c) AF Policy Directive 40-4, Clinical Investigations and Human Use in Medical Research, 11 May 1994.

B. Executive Orders/Memoranda

(1) Executive Order 12891, Subject: Advisory Committee on Human Radiation Experiments, dated 15 January 1994 (see exhibit 2).

(2) Memorandum, from Secretary to the Cabinet, Subject: Retrieval and Inventory of Records of Human Radiation Experiments, dated 19 January 1994 (see exhibit 3).

(3) Memorandum from President Clinton, Subject: Review of Federal Policy for the Protection of Human Subjects, dated 17 February 1994 (see exhibit 4).

(4) Executive Order 12958, Subject: Classified National Security Information, dated 17 April 1995 (see exhibit 5).

(5) Executive Order 12975, Subject: Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission, dated 3 October 1995 (see exhibit 6).

C. Congressional Reports

(1) U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Energy Conservation and Power, November 1986, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens."

(2) U.S. Senate, Committee on Governmental Affairs, 11 November 1993, "Nuclear Health and Safety: Examples of Post World War II Radiation Releases at U.S. Nuclear Sites," GAO / RCED-94-51-FS.

D. Advisory Committee on Human Radiation Experiments

Final Report (Washington, D.C.: U.S. Government Printing Office, October 1995).

E. DoD Memorandums

(1) Memorandum from Secretary of Defense, Subject: DoD Human Radiation Review, dated 7 January 1994 (see exhibit 7).

(2) Memorandum from Assistant to the Secretary of Defense (Atomic Energy), Subject: Locating Records of DoD Human Radiation Experiments, dated 31 January 1994 (see exhibit 8).

(3) Memorandum from Assistant to the Secretary of Defense (Atomic Energy), Subject: Expansion of Human Radiation Research Review to Include Policy Making Activities of DoD Components, dated 14 June 1994 (see exhibit 9).

(4) Memorandum from Secretary of Defense, Subject: Response by the DoD to the Findings and Recommendations of the Advisory Committee on Human Radiation Experiments, dated 30 October 1995 (see exhibit 10).

(5) Memorandum from Assistant to the Secretary of Defense (Atomic Energy), Subject: Response by the DoD to the Findings and Recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE), dated 2 November 1995 (see exhibit 11).

F. U.S. Department of Energy (DOE)

(1) United States Nuclear Tests, DOE / NV-209 (Rev. 14) (Springfield, VA: National Technical Information Service, U.S. Department of Commerce, 1994).

(2) Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records (Springfield, VA: National Technical Information Service, U.S. Department of Commerce, February 1995).

(3) Human Radiation Experiments Associated with the Department of Energy and Its Predecessors (Springfield, VA: National Technical Information Service, U.S. Department of Commerce, July 1995).

2. Sources for Additional Information

A. DoD

(1) DoD Office of Public Affairs:

HRE records are also available to the public by submitting a request to the DoD Public Affairs Office. Before submitting a request, it is important first to determine if the information is available to the public in reading rooms provided by NARA and DOE or if the information can be retrieved from the CIC or by HREX on the Internet World Wide Web (see following). Requests may be submitted to:

Department of Defense
Office of Public Affairs
ATTN: Radiation Experiments
Command Center
1400 Defense Pentagon
Washington, DC 20301-1400

(2) Military Services.

Points of contact for human radiation projects:

Army:
Assistant Secretary of the Army
(Manpower and Reserve Affairs)
ATTN: Assistant for Health Policy
Room 2E591
111 Army Pentagon
Washington, DC 20310
(703) 697-2044

Navy (includes Marine Corps):
Chief, Bureau of Medicine and Surgery
300 E Street, NW
Washington, DC 20372
(202) 653-1182

Air Force:
HQ, Air Force Medical Operations Agency
ATTN: AFMOA/SGOT
110 Luke Avenue, Room 400
Bolling Air Force Base
Washington, DC 20332-7050
(202) 767-5078

(3) Nuclear Test Personnel Review (NTPR) Program. The NTPR program is responsible for identifying DoD personnel who participated in U.S. atmospheric nuclear tests and for determining their radiation doses. This program provides participants with confirmation of their participation, their associated radiation dose, and the availability of health care and compensation programs. The NTPR program can be contacted at the Defense Special Weapons Agency, Attn: ESN / NTPR, 6801 Telegraph Road, Alexandria, Virginia 22310-3398, or call 1-800-462-3683.

B. National Archives and Records Administration (NARA)

Documents that ACHRE cited in its Final Report are available from NARA. Submit written requests for records to:

NARA at College Park, Reference Branch
8601 Adelphi Road
College Park, MD 20740
(301) 713-7250

A public reading room is open on Mondays and Wednesdays from 8:45 a.m. to 5:00 p.m., and on Tuesdays, Thursdays, Fridays, and Saturdays from 8:45 a.m. to 9:00 p.m. After obtaining an identification card, requesters can use the finding aids to request documents. Documents are pulled at 9:30 a.m., 10:30 a.m., 11:30 a.m., 1:30 p.m., and 3:30 p.m. If the documents have been requested ahead of time, they can be reviewed any time the reading room is open. The copy fee at the reading room is $0.10 per page.

C. Coordination and Information Center (CIC)

The CIC is a DOE facility that contains:

- Historical documents, records and data dealing with off-site radioactive fallout from U.S. testing of nuclear devices and human radiation experimentation
- Policy documents dealing with conduct of tests and public safety
- Documents dealing with the development and state-of-knowledge of the health effects of radiation
- Documents dealing with public information as disseminated through the media
- Studies and reports produced by the scientific and technical field.

The CIC is open to visitors Monday through Friday from 7:30 a.m. to 4:40 p.m. and provides library services, including a staff that will make copies or do proxy research according to a fee schedule that is available on request. The location is:

CIC
2621 Losee Road
Building B-3
North Las Vegas, NV 89030
(702) 295-0731
FAX: (702) 295-0877
E-mail: cic@egg.nv.doe.gov

Written requests for services can be made to:

Bechtel
P.O. Box 98521
Las Vegas, NV 89193-8521

D. Internet Access

(1) HREX (Human Radiation Experiments) is a World Wide Web resource for documents and information on human radiation experiments. Copies of documents (approximately 10,000 records) that the DoD has collected are currently being processed for this system. The web site address for HREX is

http:\\www.ohre.doe.gov.

(2) OPENNET. OpenNet is an Internet source for recently declassified Government documents (approximately 10,000 records). The DoD has declassified many documents identified in the search for human radiation experiments, and these are planned for transfer to OpenNet. The World Wide Web address for this system is

http://www.doe.gov/html/otsi/opennet/opennet1.html.

The DoD collection is scheduled to be available in 1997.

E. Other Sources

Department of Energy
Office of Human Radiation Experiments
(202) 586-5195

Department of Veterans Affairs
National Service Number
1-800-827-1000

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE"

code of federal regulations

National Defense

PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

§ 219.101 To what does this policy apply?

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

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §219.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §219.102(e) must be reviewed and approved, in compliance with §219.101, §219.102, and §219.107 through §219.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

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

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

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

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

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

(i) Public benefit or service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) If wholesome foods without additives are consumed or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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

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

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

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

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

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

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

[56 FR 28012, 28021, June 18, 1991, as amended at 56 FR 29756, June 28, 1991]

§219.102 Definitions.

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

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

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

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

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

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

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

(2) Identifiable private information.

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

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

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

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

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

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

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

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §219.101 (b) or (i).

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

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §219.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

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

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

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

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

(e) On the basis of this evaluation, the department or agency head may

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

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

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §219.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §219.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §219.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under control number 9999–0020)

[56 FR 28012, 28021, June 18, 1991, as amended at 56 FR 29756, June 28, 1991]

§§ 219.104—219.106 [Reserved]

§ 219.107 IRB membership.

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

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

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

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

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

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

§ 219.108 IRB functions and operations.

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

§219.103(b)(4) and, to the extent required by, §219.103(b)(5).

(b) Except when an expedited review procedure is used (see §219.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§219.109 IRB Review of Research.

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

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §219.116. The IRB may require that information, in addition to that specifically mentioned in §219.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §219.117.

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

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

(Approved by the Office of Management and Budget under control number 9999-0020)

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

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

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

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

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

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §219.108(b).

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

§ 219.111 Criteria for IRB approval of research.

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

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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

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

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 219.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 219.117.

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

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

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

§ 219.112 Review by institution.

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

§ 219.113 Suspension or termination of IRB approval of research.

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

(Approved by the Office of Management and Budget under control number 9999-0020)

§ 219.114 Cooperative research.

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

§219.115 IRB records.

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

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

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

(3) Records of continuing review activities.

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

(5) A list of IRB members in the same detail as described is §219.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §219.103(b)(4) and §219.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §219.116(b)(5).

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

(Approved by the Office of Management and Budget under control number 9999-0020)

§219.116 General requirements for informed consent.

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

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

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

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

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

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

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

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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

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

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

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

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

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

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

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

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) Public benefit of service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs; and

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

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

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

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

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

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

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

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9999–0020)

§ 219.117 Documentation of informed consent.

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

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

(1) A written consent document that embodies the elements of informed consent required by § 219.116. This form

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §219.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

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

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

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999–0020)

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

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §219.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

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

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

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

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

EXHIBIT 1 DoD IMPLEMENTATION OF THE "COMMON RULE" (CONTINUED)

§ 219.122

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

§ 219.121 [Reserved]

§ 219.122 Use of Federal funds.

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

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

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

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 219.124 Conditions.

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

EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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

Section 1. Establishment. (a) There shall be established an Advisory Committee on Human Radiation Experiments (the "Advisory Committee" or "Committee"). The Advisory Committee shall be composed of not more than 15 members to be appointed or designated by the President. The Advisory Committee shall comply with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

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

Sec. 2. Functions. (a) There has been established a Human Radiation Interagency Working Group, the members of which include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence, and the Director of the Office of Management and Budget. As set forth in paragraph (b) of this section, the Advisory Committee shall provide to the Human Radiation Interagency Working Group advice and recommendations on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. As used herein, "human radiation experiments" means:

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

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

Consistent with the provisions set forth in paragraph (b) of this section, the Advisory Committee shall also provide advice, information, and recommendations on the following experiments:

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EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

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

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

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

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

(5) any other similar experiment that may later be identified by the Human Radiation Interagency Working Group.

The Advisory Committee shall review experiments conducted from 1944 to May 30, 1974. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education, and Welfare ("DHEW") Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into experiments is warranted. Further inquiry into experiments conducted after May 30, 1974, may be pursued if the Advisory Committee determines, with the concurrence of the Human Radiation Interagency Working Group, that such inquiry is warranted.

(b)(1) The Advisory Committee shall determine the ethical and scientific standards and criteria by which it shall evaluate human radiation experiments, as set forth in paragraph (a) of this section. The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today.

(2) The Advisory Committee shall evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards as determined by the Committee pursuant to paragraph (b)(1) of this section. If deemed necessary for such an assessment, the Committee may carry out a detailed review of experiments and associated records to the extent permitted by law.

(3) If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up.

EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

(4) The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

(5) The Advisory Committee may carry out such additional functions as the Human Radiation Interagency Working Group may from time to time request.

Sec. 3. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Advisory Committee with such information as it may require for purposes of carrying out its functions.

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

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Energy shall provide the Advisory Committee with such funds as may be necessary for the performance of its functions.

Sec. 4. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Advisory Committee, except that of reporting annually to the Congress, shall be performed by the Human Radiation Interagency Working Group, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Advisory Committee shall terminate 30 days after submitting its final report to the Human Radiation Interagency Working Group.

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

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

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EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

CHARTER

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

1. Committee's Official Designation

Advisory Committee on Human Radiation Experiments (the "Advisory Committee" or "Committee").

2. Authority

Executive Order No. 12891.

3. Objectives and Scope of Activities

There has been established a Human Radiation Interagency Working Group (the "Interagency Working Group"), the members of which include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans' Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence, and the Director of the Office of Management and Budget. As set forth in section 4 of this Charter, the Advisory Committee shall provide to the Interagency Working Group advice and recommendations on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. As used herein, "human radiation experiments" means:

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

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

EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

Consistent with the provisions set forth in section 4 of this Charter, the Advisory Committee also shall provide advice, information and recommendations on the following experiments:

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

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

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

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

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

The Advisory Committee shall review experiments conducted from 1944 to May 30, 1974, the date of issuance of the Department of Health, Education and Welfare Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into experiments is warranted. Further inquiry into experiments conducted after May 30, 1974, may be pursued if the Advisory Committee determines, with the concurrence of the Interagency Working Group, that such inquiry is warranted.

4. Description of Duties for which Committee is Responsible

The duties of the Advisory Committee are solely advisory and shall be:

a. The Advisory Committee shall determine the ethical and scientific standards and criteria by which it shall evaluate human radiation experiments, as set forth in section 3 of this Charter. The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today.

EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

b. The Advisory Committee shall evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards as determined by the Committee pursuant to paragraph (a) of this section. If deemed necessary for such an assessment, the Advisory Committee may carry out a detailed review of experiments and associated records to the extent permitted by law.

c. If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up.

d. The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

e. The Advisory Committee may carry out such additional functions as the Interagency Working Group may from time to time request.

5. To Whom the Advisory Committee Reports

The Advisory Committee shall report to the Interagency Working Group.

The Advisory Committee shall submit its final report to the Interagency Working Group within one year of the date of the first meeting of the Advisory Committee, unless such period is extended by the Interagency Working Group. The Advisory Committee shall issue an interim report not more than six months after the date of the first meeting of the Advisory Committee. That interim report shall advise the Interagency Working Group on the status of the Advisory Committee's proceedings and the likelihood that the Committee will be able to complete its duties within one year of the date of the first meeting of the Advisory Committee.

6. Duration and Termination Date

The Advisory Committee shall terminate thirty days after submission of its final report to the Interagency Working Group. This Charter shall expire one year plus thirty days after the first meeting of the Advisory Committee, subject to renewal and extension by the President.

EXHIBIT 2 EXECUTIVE ORDER 12891: ADVISORY COMMITTEE ON HREs (CONTINUED)

7. Agency responsible for providing financial and administrative support to the Advisory Committee

Financial and administrative support shall be provided by the Department of Energy.

8. Estimated Annual Operating Costs

$3 million.

9. Estimated Number and Frequency of Meetings

The Advisory Committee shall meet as it deems necessary to complete its functions.

10. Subcommittees

To facilitate functioning of the Advisory Committee, subcommittee(s) may be formed. The objectives of the subcommittee(s) are to make recommendations to the Advisory Committee with respect to matters related to the responsibilities of the Advisory Committee. Subcommittees shall meet as the Advisory Committee deems appropriate.

11. Members

Up to a maximum of fifteen Advisory Committee members shall be appointed by the President for a term of one year, which may be extended by the President. Committee members shall be compensated in accordance with federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. §§ 5701-5707).

12. Chairperson

The President shall designate a Chairperson from among the members of the Advisory Committee.

EXHIBIT 3 RETRIEVAL AND INVENTORY OF RECORDS OF HREs

THE WHITE HOUSE

WASHINGTON

January 19, 1994

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: CHRISTINE A. VARNEY
Secretary to the Cabinet

SUBJECT: Retrieval and Inventory of Records of Human Radiation Experiments

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

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

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

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

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

EXHIBIT 3 RETRIEVAL AND INVENTORY OF RECORDS OF HREs (CONTINUED)

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

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

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

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

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

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

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

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

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

EXHIBIT 3 RETRIEVAL AND INVENTORY OF RECORDS OF HREs (CONTINUED)

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

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

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

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

7. Each agency should also:

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

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

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

EXHIBIT 3 RETRIEVAL AND INVENTORY OF RECORDS OF HREs (CONTINUED)

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

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

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

EXHIBIT 4 REVIEW OF FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS

Office of the Press Secretary

For Immediate Release February 17, 1994

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT
THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

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

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

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

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

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

WILLIAM J. CLINTON

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EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION

EXECUTIVE ORDER

12958

CLASSIFIED NATIONAL SECURITY INFORMATION

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

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

PART 1 ORIGINAL CLASSIFICATION

Section 1.1. Definitions. For purposes of this order:

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

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

(c) "Classified national security information" (hereafter "classified information") means information that has been

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

determined pursuant to this order or any predecessor order to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form.

(d) "Foreign Government Information" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) the original classification authority determines that the unauthorized disclosure of the information reasonably could be expected to result in damage to the national security and the original classification authority is able to identify or describe the damage.

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

(1) amplify or modify the substantive criteria or procedures for classification; or

(2) create any substantive or procedural rights subject to judicial review.

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

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

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

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

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

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

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

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

(1) the President;

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

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

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

(c) Delegation of original classification authority.

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

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

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

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

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

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

Sec. 1.5. Classification Categories. Information may not be considered for classification unless it concerns:

(a) military plans, weapons systems, or operations;

(b) foreign government information;

(c) intelligence activities (including special activities), intelligence sources or methods, or cryptology;

(d) foreign relations or foreign activities of the United States, including confidential sources;

(e) scientific, technological, or economic matters relating to the national security;

(f) United States Government programs for safeguarding nuclear materials or facilities; or

(g) vulnerabilities or capabilities of systems, installations, projects or plans relating to the national security.

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

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

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

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

(1) reveal an intelligence source, method, or activity, or a cryptologic system or activity;

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

(3) reveal information that would impair the development or use of technology within a United States weapons system;

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

(4) reveal United States military plans, or national security emergency preparedness plans;

(5) reveal foreign government information;

(6) damage relations between the United States and a foreign government, reveal a confidential source, or seriously undermine diplomatic activities that are reasonably expected to be ongoing for a period greater than that provided in paragraph (b), above;

(7) impair the ability of responsible United States Government officials to protect the President, the Vice President, and other individuals for whom protection services, in the interest of national security, are authorized; or

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

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

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

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

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

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

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

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(A) the date or event for declassification, as prescribed in section 1.6(a) or section 1.6(c); or

(B) the date that is 10 years from the date of original classification, as prescribed in section 1.6(b); or

(C) the exemption category from declassification, as prescribed in section 1.6(d); and

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

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

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

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

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

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(f) Information assigned a level of classification under this or predecessor orders shall be considered as classified at that level of classification despite the omission of other required markings. Whenever such information is used in the derivative classification process or is reviewed for possible declassification, holders of such information shall coordinate with an appropriate classification authority for the application of omitted markings.

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

Sec. 1.8. Classification Prohibitions and Limitations.

(a) In no case shall information be classified in order to:

(1) conceal violations of law, inefficiency, or administrative error;

(2) prevent embarrassment to a person, organization, or agency;

(3) restrain competition; or

(4) prevent or delay the release of information that does not require protection in the interest of national security.

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

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

(d) Information that has not previously been disclosed to the public under proper authority may be classified or reclassified after an agency has received a request for it under the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a), or the mandatory review provisions of section 3.6 of this order only if such classification meets the requirements of this order and is accomplished on a document-by-document basis with the personal participation or

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under the direction of the agency head, the deputy agency head, or the senior agency official designated under section 5.6 of this order. This provision does not apply to classified information contained in records that are more than 25 years old and have been determined to have permanent historical value under title 44, United States Code.

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

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

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

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

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

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

(1) individuals are not subject to retribution for bringing such actions;

(2) an opportunity is provided for review by an impartial official or panel; and

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(3) individuals are advised of their right to appeal agency decisions to the Interagency Security Classification Appeals Panel established by section 5.4 of this order.

PART 2 DERIVATIVE CLASSIFICATION

Sec. 2.1. Definitions. For purposes of this order:

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

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

(c) "Classification guide" means a documentary form of classification guidance issued by an original classification authority that identifies the elements of information regarding a specific subject that must be classified and establishes the level and duration of classification for each such element.

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

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

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

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(b) Persons who apply derivative classification markings shall:

(1) observe and respect original classification decisions; and

(2) carry forward to any newly created documents the pertinent classification markings. For information derivatively classified based on multiple sources, the derivative classifier shall carry forward:

(A) the date or event for declassification that corresponds to the longest period of classification among the sources; and

(B) a listing of these sources on or attached to the official file or record copy.

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

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

(1) has program or supervisory responsibility over the information or is the senior agency official; and

(2) is authorized to classify information originally at the highest level of classification prescribed in the guide.

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

PART 3 DECLASSIFICATION AND DOWNGRADING

Sec. 3.1. Definitions. For purposes of this order:

(a) "Declassification" means the authorized change in the status of information from classified information to unclassified information.

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

(1) the occurrence of a specific date or event as determined by the original classification authority; or

(2) the expiration of a maximum time frame for duration of classification established under this order.

(c) "Declassification authority" means:

(1) the official who authorized the original classification, if that official is still serving in the same position;

(2) the originator's current successor in function;

(3) a supervisory official of either; or

(4) officials delegated declassification authority in writing by the agency head or the senior agency official.

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

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

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

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

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(h) "File series" means documentary material, regardless of its physical form or characteristics, that is arranged in accordance with a filing system or maintained as a unit because it pertains to the same function or activity.

Sec. 3.2. Authority for Declassification. (a) Information shall be declassified as soon as it no longer meets the standards for classification under this order.

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

(1) amplify or modify the substantive criteria or procedures for classification; or

(2) create any substantive or procedural rights subject to judicial review.

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

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

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Sec. 1.3. Transferred Information. (a) In the case of classified information transferred in conjunction with a transfer of functions, and not merely for storage purposes, the receiving agency shall be deemed to be the originating agency for purposes of this order.

(b) In the case of classified information that is not officially transferred as described in paragraph (a), above, but that originated in an agency that has ceased to exist and for which there is no successor agency, each agency in possession of such information shall be deemed to be the originating agency for purposes of this order. Such information may be declassified or downgraded by the agency in possession after consultation with any other agency that has an interest in the subject matter of the information.

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

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

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

Sec. 1.4. Automatic Declassification. (a) Subject to paragraph (b), below, within 5 years from the date of this order, all classified information contained in records that (1) are more than 25 years old, and (2) have been determined to have permanent historical value under title 44, United States Code, shall be automatically declassified whether or not the records have been reviewed. Subsequently, all classified information in such records shall be automatically declassified no longer than 25 years from the date of its original classification, except as provided in paragraph (b), below.

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

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

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

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

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

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

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

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

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

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

(c) No later than the effective date of this order, an agency head shall notify the President through the Assistant to the President for National Security Affairs of any specific file series of records for which a review or assessment has determined that the information within those file series almost invariably falls within one or more of the exemption categories listed in paragraph (b), above, and which the agency proposes to exempt from automatic declassification. The notification shall include:

(1) a description of the file series;

(2) an explanation of why the information within the file series is almost invariably exempt from automatic declassification and why the information must remain classified for a longer period of time; and

(3) except for the identity of a confidential human source or a human intelligence source, as provided in paragraph (b), above, a specific date or event for declassification of the information.

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

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

(1) a description of the information;

(2) an explanation of why the information is exempt from automatic declassification and must remain classified for a longer period of time; and

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

(e) No later than the effective date of this order, the agency head or senior agency official shall provide the Director of the Information Security Oversight Office with a plan for compliance with the requirements of this section, including the establishment of interim target dates. Each such plan shall include the requirement that the agency declassify at least 15 percent of the records affected by this section no later than

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1 year from the effective date of this order, and similar commitments for subsequent years until the effective date for automatic declassification.

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

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

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

(1) recommendations of the Information Security Policy Advisory Council, established in section 5.5 of this order, on specific subject areas for systematic review concentration; or

(2) the degree of researcher interest and the likelihood of declassification upon review.

(b) The Archivist of the shall conduct a systematic declassification review program for classified information: (1) accessioned into the National Archives as of the effective date of this order; (2) information transferred to the Archivist pursuant to section 2203 of title 44, United States Code; and (3) information for which the National Archives and Records

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

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

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

(1) the request for a review describes the document or material containing the information with sufficient specificity to enable the agency to locate it with a reasonable amount of effort;

(2) the information is not exempted from search and review under the Central Intelligence Agency Information Act; and

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(3) the information has not been reviewed for declassification within the past 2 years. If the agency has reviewed the information within the past 2 years, or the information is the subject of pending litigation, the agency shall inform the requester of this fact and of the requester's appeal rights.

(b) Information originated by:

(1) the incumbent President;

(2) the incumbent President's White House Staff;

(3) committees, commissions, or boards appointed by the incumbent President; or

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

(c) Agencies conducting a mandatory review for declassification shall declassify information that no longer meets the standards for classification under this order. They

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shall release this information unless withholding is otherwise authorized and warranted under applicable law.

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

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

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

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

(b) When an agency receives any request for documents in its custody that contain information that was originally classified by another agency, or comes across such documents in the process of the automatic declassification or systematic review provisions of this order, it shall refer copies of any request and the pertinent documents to the originating agency

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for processing, and may, after consultation with the originating agency, inform any requester of the referral unless such association is itself classified under this order. In cases in which the originating agency determines in writing that a response under paragraph (a), above, is required, the referring agency shall respond to the requester in accordance with that paragraph.

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

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

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

PART 4 SAFEGUARDING

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

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

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

(d) "Automated information system" means an assembly of computer hardware, software, or firmware configured to collect,

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

create, communicate, compute, disseminate, process, store, or control data or information.

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

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

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

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

Sec. 4.2. General Restrictions on Access. (a) A person may have access to classified information provided that:

(1) a favorable determination of eligibility for access has been made by an agency head or the agency head's designee;

(2) the person has signed an approved nondisclosure agreement; and

(3) the person has a need-to-know the information.

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

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

(1) prevent access by unauthorized persons; and

(2) ensure the integrity of the information.

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

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

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

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

(1) the vulnerability of, or threat to, specific information is exceptional; and

(2) the normal criteria for determining eligibility for access applicable to information classified at the same level are not deemed sufficient to protect the information from unauthorized disclosure; or

(3) the program is required by statute.

(b) Requirements and Limitations. (1) Special access programs shall be limited to programs in which the number of persons who will have access ordinarily will be reasonably small and commensurate with the objective of providing enhanced protection for the information involved.

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

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

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

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

Sec. 4.5. Access by Historical Researchers and Former Presidential Appointees. (a) The requirement in section 4.2(a)(3) of this order that access to classified information may be granted only to individuals who have a need-to-know the information may be waived for persons who:

(1) are engaged in historical research projects; or

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

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

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

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

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

PART 5 IMPLEMENTATION AND REVIEW

Sec. 5.1. Definitions. For purposes of this order:

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

(b) "Violation" means:

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

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

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

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

(1) classification and marking principles;

(2) agency security education and training programs;

(3) agency self-inspection programs; and

(4) classification and declassification guides.

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

Sec. 5.1. Information Security Oversight Office.

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

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

(1) develop directives for the implementation of this order;

(2) oversee agency actions to ensure compliance with this order and its implementing directives;

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

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

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

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

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

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

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

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

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

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

(b) Functions. The Panel shall:

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

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

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

(c) Rules and Procedures. The Panel shall issue bylaws, which shall be published in the Federal Register no later than 120 days from the effective date of this order. The bylaws shall establish the rules and procedures that the Panel will follow in accepting, considering, and issuing decisions on appeals. The rules and procedures of the Panel shall provide that the Panel will consider appeals only on actions in which: (1) the appellant has exhausted his or her administrative remedies within the responsible agency; (2) there is no current

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

action pending on the issue within the federal courts; and (3) the information has not been the subject of review by the federal courts or the Panel within the past 2 years.

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

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

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

(b) Functions. The Council shall:

(1) advise the President, the Assistant to the President for National Security Affairs, the Director of the Office of Management and Budget, or such other executive branch officials as it deems appropriate, on

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

policies established under this order or its implementing directives, including recommended changes to those policies;

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

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

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

(d) Administration.

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

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

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

(4) Notwithstanding any other Executive order, the

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

Sec. 5.6. General Responsibilities. Heads of agencies that originate or handle classified information shall:

(a) demonstrate personal commitment and commit senior management to the successful implementation of the program established under this order;

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

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

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

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

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

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

(5) establishing procedures to prevent unnecessary access to classified information, including procedures that: (i) require that a need for access to

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

classified information is established before initiating administrative clearance procedures; and (ii) ensure that the number of persons granted access to classified information is limited to the minimum consistent with operational and security requirements and needs;

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

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

(8) accounting for the costs associated with the implementation of this order, which shall be reported to the Director of the Information Security Oversight Office for publication; and

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

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

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

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

(1) disclose to unauthorized persons information properly classified under this order or predecessor orders;

(2) classify or continue the classification of information in violation of this order or any implementing directive;

(3) create or continue a special access program contrary to the requirements of this order; or

(4) contravene any other provision of this order or its implementing directives.

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

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

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

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

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

PART 6 GENERAL PROVISIONS

Sec. 6.1. General Provisions. (a) Nothing in this order shall supersede any requirement made by or under the Atomic Energy Act of 1954, as amended, or the National Security Act of 1947, as amended. "Restricted Data" and "Formerly Restricted

EXHIBIT 5 EXECUTIVE ORDER 12958: CLASSIFIED NATIONAL SECURITY INFORMATION (CONTINUED)

Data" shall be handled, protected, classified, downgraded, and declassified in conformity with the provisions of the Atomic Energy Act of 1954, as amended, and regulations issued under that Act.

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

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

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

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

THE WHITE HOUSE,

April 17, 1995.

EXHIBIT 6 EXECUTIVE ORDER 12975: PROTECTION OF HUMAN RESEARCH SUBJECTS

THE WHITE HOUSE

Office of the Press Secretary

12975

For Immediate Release October 3, 1995

EXECUTIVE ORDER

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

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

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

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

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

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

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

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

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EXHIBIT 6 EXECUTIVE ORDER 12975: PROTECTION OF HUMAN RESEARCH SUBJECTS (CONTINUED)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EXHIBIT 6 EXECUTIVE ORDER 12975: PROTECTION OF HUMAN RESEARCH SUBJECTS (CONTINUED)

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

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

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

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

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

WILLIAM J. CLINTON

THE WHITE HOUSE,
October 3, 1995.

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EXHIBIT 7 DoD HUMAN RADIATION RESEARCH REVIEW

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MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
COMPTROLLER
GENERAL COUNSEL
DIRECTOR, OPERATIONAL TEST AND EVALUATION
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTOR OF ADMINISTRATION AND MANAGEMENT
DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: DoD Human Radiation Research Review

I have appointed Dr. Harold P. Smith, Assistant to the Secretary of Defense (Atomic Energy), as the DoD-wide focal point for the compilation and review of all Defense Department data or information related to ionizing radiation research with human subjects. He will work with the Interagency Working Group on this issue and coordinate our efforts with those of the other relevant agencies. I want to move quickly and thoroughly on this matter -- it should be given high priority.

The ATSD(AE) will chair a DoD working group to structure the process for data collection and analysis and development of a DoD overall plan of action. He will also be responsible for determining the outside organizations with which the Department has worked that might have such records, and the best way to preserve those records and obtain them for review. This ATSD(AE) led effort will be under the overall guidance of John Deutch, who is the senior department official responsible for this matter.

I request you take immediate steps to ensure that any documents or records in your office related to human ionizing radiation research are retained and not destroyed. This includes all letters, memoranda, reports, logs, handwritten notes, written procedures, and all other writings, as well as photographs, maps, and machine-readable materials. Your search should include all file indices of records retired to the Federal Records Center at Suitland, MD, or a search of those files at Suitland as appropriate. Please advise all persons responsible for routine document disposal procedures of the need to preserve these records.

EXHIBIT 7 DoD HUMAN RADIATION RESEARCH REVIEW (CONTINUED)

Veterans who participated in atmospheric nuclear testing and the occupation of Hiroshima and Nagasaki are already included in the national Nuclear Test Personnel Review (NTPR) program and are not part of this effort.

Inquiries regarding this matter should be directed to Dr. Gordon K. Soper, Principal Deputy, ATSD(AE), (703) 697-5161.

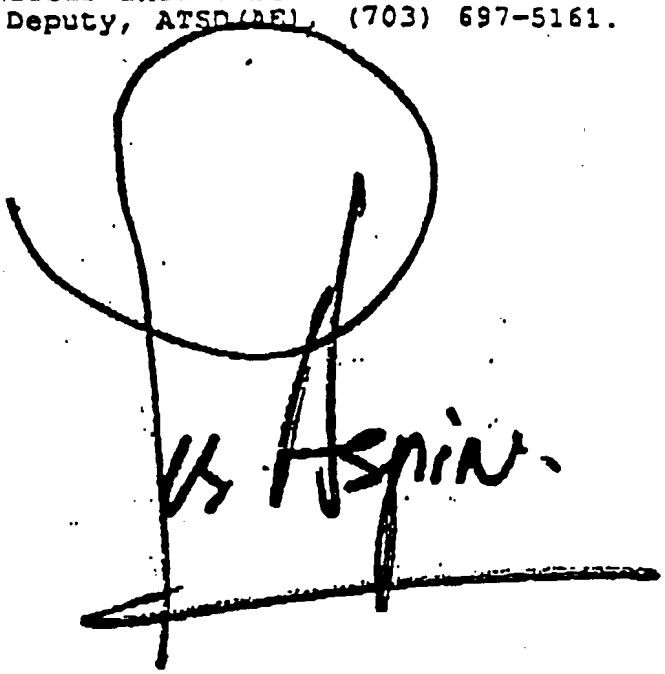


EXHIBIT 8 LOCATING RECORDS OF DOD HUMAN RADIATION EXPERIMENTS

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

January 31, 1994

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDERSECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
COMPTROLLER
GENERAL COUNSEL
DIRECTOR, OPERATIONAL TEST AND EVALUATION
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTOR OF ADMINISTRATION AND MANAGEMENT
DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Locating Records of DoD Human Radiation Experiments

On January 7, 1994, Secretary Aspin informed you that he had appointed me as the DoD-wide focal point for the review of human radiation experiments, and noted the high priority this task will require. He also directed that no records of human radiation experiments be destroyed. Based on the recommendations of the DoD working group, which I chair, this memorandum provides specific procedures for locating records of DoD human radiation experiments.

In the coming months, we will have requirements to carry out a number of important tasks, including: retrieval and inventory of all records of DoD human radiation experiments; provision of information to the Advisory Committee on Human Radiation Experiments, established by the President January 18; notification to subjects or next-of-kin of human radiation experiments; response to inquiries from citizens to the Department of Energy telephone hotline; release of information to the public; and others. To carry out these tasks, a Command Center has been established and other ground work begun. We are now ready to proceed with the formal information gathering process. Our objective in this is to "just get the facts" and our strategy is to fully arm the Command Center with as many of the facts as possible in order to minimize repeated queries to the field.

With this as the guide, I request from each addressee, by February 14, 1994, an initial report, and by February 28, a complete report, each consisting of two parts. Part I is the identification of DoD organizations under the authority of each addressee that, based on their missions and activities, might have conducted or sponsored human radiation experiments, together with an identification of the archives or records centers where records concerning such experiments might exist and a description of the steps taken to search those records. This information is needed both to document the completeness of the search and to establish a

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

base for resolving inquiries received through the Energy Department's hotline. Part II is an identification of each possible human radiation experiment and the location of records regarding each such experiment. Guidance will later be provided, after consultation with the Human Radiation Interagency Working Group, concerning procedures for actual retrieval of the records. At present, the requirement is only to identify them in the requested reports and to assure their preservation.

The attached guidance provides a definition of the scope of the records search, the requested format for the reports, and other specifics.

Inquiries regarding this matter should be directed to Dr. Gordon K. Soper, Principal Deputy, ATSD(AE), at (703) 697-5161. Thank you for your attention to this important matter.

Harold P. Smith, Jr.

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

SPECIFIC DIRECTION FOR LOCATING RECORDS OF DOD HUMAN RADIATION EXPERIMENTS

A. Scope of Records Search.

1. Definition of "human radiation experiments".

The Interagency Working Group has adopted the following definition of "human radiation experiments:"

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

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

2. Other specific experiments.

The Interagency Working Group has also identified several specific experiments for inclusion within the scope of the records search. They are:

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

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

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

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

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

3. Dates of experiments.

For purposes of the identification process, the scope of the search includes all human

EXHIBIT 8 LOCATING RECORDS OF DOD HUMAN RADIATION EXPERIMENTS (CONTINUED)

radiation experiments conducted from 1944 to present. However, experiments conducted after May 20, 1974 (the date of issuance of the Department of Health, Education and Welfare Regulations for the Protection of Human Subjects, 45 CFR Part 46), must be clearly identified as having occurred after that date. This is because records retrieval requirements with respect to experiments conducted after May 20, 1974, will probably be different than requirements regarding experiments from 1944 until May 20, 1974. The differences in requirements will be explained when guidance on records retrieval procedures is provided.

4. Radiation exposure from atmospheric nuclear tests and Hiroshima and Nagasaki occupation excluded from scope.

Former military personnel exposed to ionizing radiation incident to the atmospheric nuclear test program and/or the occupation of Hiroshima and Nagasaki are covered by the existing Nuclear Test Personnel Review (NTPR) program and by existing compensation mechanisms. They are not included in the scope of this records identification process.

B. Component Search Coordinator.

Each DoD component requested to submit a report must identify an individual in the component as the component's coordinator for the effort to locate records of human radiation experiments. This individual will be responsible for the accuracy and completeness of the required reports, and will serve as the contact person for the Command Center. Each report must identify the name, title, address, telephone number, and telefax number of the reporting organization's search coordinator.

C. Identification of Organizations that Might Have Conducted or Sponsored Human Radiation Experiments.

Part I of the requested report requires the identification of DoD organizations that might have conducted or sponsored by contract or grant human radiation experiments. Guidelines for this task include the following.

1. Include predecessor organizations. Each organization identified as one that might have conducted or sponsored human radiation experiments must consider, if the organization is new since 1944, the activities of any predecessor organization.

2. Identify archives. Each organization identified as one that might have conducted or sponsored human radiation experiments must identify archives or records centers where records of such experiments, if conducted, might be located. This must include any archives where such records of any predecessor organizations might be located.

EXHIBIT 8 LOCATING RECORDS OF DOD HUMAN RADIATION EXPERIMENTS (CONTINUED)

D. Document Search Activities by Each Organization That Might Have Conducted or Sponsored Human Radiation Experiments.

Also under Part I of the requested report, each organization identified as one that might have conducted or sponsored human radiation experiments must, for itself and for any predecessor organization, document that it attempted to determine whether it has conducted or sponsored any such experiments. Specific methods for searching may vary based on organization practices and records systems. Methods might include: search for all published and unpublished reports of research findings; review of the organization's contracts and/or grants records; queries to current or former employees with knowledge of historical activities. Each step of the process should be documented and described in Part I of the organization's report. In addition, each organization must maintain a complete file of all relevant memoranda, meeting notes, electronic mail messages, notes of telephone conversations and all other materials that document the search activities of the organization.

E. Identification of Specific Experiments Possibly Within the Scope of the Search.

As described further below, Part II of the requested report identifies specific experiments possibly within the scope of the search and begins the reporting of key facts regarding the experiments. Guidelines regarding this part of the process follow.

1. Err on the side of inclusion.

For purposes of this initial identification of possible experiments, organizations submitting reports should err on the side of inclusion. Reported activities that are outside the scope of the records search can then be excluded prior to actual records retrieval. (Knowledge of related activities, although outside the scope, will help the Command Center deal with inquiries expected from the public through the Energy Department hotline.)

2. Experiments conducted or sponsored by a DoD organization.

Experiments to be included in the identification process are all those conducted by a DoD organization, or predecessor organization, or sponsored in whole or in part by a DoD organization or predecessor organization through a contract or grant. For this purpose, a "contract" should be understood as including any cooperative agreement, memorandum of understanding, or other similar document establishing an agreement between a DoD organization and another party concerning a human radiation experiment.

3. Identify lead agency when more than one is involved.

In cases in which more than one DoD organization was involved, or an agency outside

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

DoD was involved, it is important to identify which agency should be considered the lead agency. This will help avoid duplication of effort in records retrieval activities. If it is not clear which organization was the lead agency, respective activities of the involved agencies should be described so that an appropriate assignment of lead responsibility for records retrieval activities can be made.

F. Identification of Records Regarding Possible Human Radiation Experiments.

Part II of the requested report also identifies existing records pertaining to the possible human radiation experiments that have been identified. Guidelines regarding this part of the process follow.

1. Definition of "records".

"Records" includes a wide range of materials, including reports, letters, memoranda, notes, drafts, logs, handwritten notes, written procedures, medical records, and any other writings and documents, as well as photographs, charts, drawings, machine readable materials, video tape, audio tape, computerized information, and any other source of physically retrievable information.

2. Focus on existing records.

The effort to locate records is restricted to records that currently exist. In the event of an experiment for which some or all records that may have at one time existed cannot now be found, the task of locating records does not require an effort to recreate records regarding individual experiments. If there is a need to reconstruct additional information regarding particular experiments, that will be undertaken separately, pursuant to instructions governing such a task.

3. Prepare to submit records.

Pending further guidance on records retrieval procedures, DoD organizations should make initial preparations for submission of documents to a central repository. These initial preparations include identification of any classification issues that need to be considered, determinations regarding the existence of any other records relating to the experiment, organization of the records, and steps to assure the safekeeping of the records. It is anticipated that when records retrieval procedures are established, the organization will be requested to make two copies of the records, one for submission and one for retention by the organization for purposes of any necessary follow-up activities, and to return the original documents to the proper archives or records repository. However, pending instructions on records retrieval procedures, records are not to be forwarded to the Command Center or other repository. Rather, the records must be maintained by the organization in the original records series in accordance with the organization's established records management system.

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

G. Preservation of Records.

As instructed in Secretary Aspin's January 7 memorandum, each organization must assure that records relating to human radiation research are preserved and not destroyed. Persons responsible for routine records disposal procedures must be advised of the need to preserve these records.

H. Classification and Declassification Issues.

1. Policy of maximum declassification.

The Interagency Working Group has established the policy that agencies should, upon locating records of human radiation experiments within the scope of this records search, review the records for national security classification and should declassify such records as soon as practicable and to the maximum extent possible.

2. Classification review procedures.

Classified information must be reviewed by the appropriate classification authorities before it can be declassified. Consult DoD Directive 5200.1-R, Chapter III, for guidance on declassification procedures. If there are documents within DoD's possession for which another agency is the original classification authority, that agency must make the determination to declassify the information. Every effort should be made to expedite this declassification process.

I. Contractor and Grantee Records.

When an organization determines that records of a human radiation experiment may be in the possession of a contractor or grantee of the organization, the organization must document the nature of those records and make plans to pursue retrieval. The organization should attempt to find the governing contract or grant documents pertaining to the research project or program involved and should obtain the assistance of the organization's Staff Judge Advocate or legal counsel to determine rights and obligations pursuant to the governing documents. These activities should proceed on an expedited basis.

J. Restrictions on the Release of Records.

1. Release of records outside Freedom of Information Act channels.

Because there may be personal privacy, security classification, or other restrictions on the release of records of human radiation experiments, it is essential that DoD organizations not

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

release records to the public, unless the release has been approved by the Command Center.

2. Freedom of Information Act procedures.

Guidance will be provided in the very near future through Freedom of Information Act (FOIA) office channels regarding the handling of FOIA requests pertaining to human radiation experiments.

K. Format for Part I of Report.

The following format will assist in the compilation of the information requested. In any case in which the reporting organization has no information to report, a negative report is required.

1. Identify each organization that, based on mission or activities, might have conducted or sponsored human radiation experiments. Give name and location(s) of the organization and name(s) and location(s) of any predecessor organizations that might have conducted or sponsored such experiments.

2. For each organization identified in item 1, identify the location(s) of records of the organization where records of human radiation experiments, if conducted or sponsored, might be located (or have been located).

3. For each organization identified in item 1 and each records repository identified in item 2, describe in detail the efforts undertaken to determine if records exist of human radiation experiments. List all files and file systems searched and all individuals consulted.

4. Based on the results of the search described in item 3, state whether any records of possible human radiation experiments were found, and, if so, identify the experiments.

L. Format for Part II of Report.

For each possible human radiation experiment identified in item 4 of Part I, provide as much of the following information as is presently possible. Start each separate experiment on a separate page.

1. Identify the possible human radiation experiment.

2. State where and when it took place.

3. Identify the primary researcher(s).

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

4. Identify the organizations and entities involved in the experiment. Include all DoD organizations, any other federal agency involved in conducting or sponsoring the project, and any contractors, grantees, or other parties. Identify the DoD organization and/or the other agency that was the lead agency.

5. Indicate the number of human subjects of the experiment. Indicate any available information on known characteristics of the class of subjects, such as: active duty members, researchers, a racial or ethnic group, prisoners, institutionalized persons, medical patients, children, pregnant women. Indicate whether available information includes names or other identifying information concerning the subjects.

6. Summarize the experiment, including an identification of the purpose of the experiment and the nature of the use of ionizing radiation. As examples of the types of information that would be helpful, if available information permits, preliminarily classify the possible human radiation experiment into one of the following categories. (Note that these categories are solely for the purpose of obtaining preliminary information about the experiment that may facilitate organization of the records retrieval process. These are not official classifications for any purpose. In addition, not all of these categories are necessarily within the actual scope of the records search activity, but might be involved in the initial identification because of the guidance to err on the side of inclusion of all possible human radiation experiments.)

(a) Clear purpose radiation research -- the purpose of the experiment was to test the human health effects of ionizing radiation. Example: subjects exposed to radiation for the purpose of measuring adverse reactions.

(b) Therapeutic research involving radiation -- the purpose of the experiment was to test the safety and efficacy of using ionizing radiation to diagnose or treat a disease or medical condition. Example: clinical research on bone marrow transplantation.

(c) Other research -- the experiment was for another purpose (i.e., other than categories (a) or (b)), but in the course of the research project, ionizing radiation was used in accordance with a routine, diagnostic procedure. Example: research of effects of dental coating to prevent cavities, monitored through periodic dental X-rays.

(d) Treatment use of radiation -- the use of radiation was for a medical treatment purpose, not a research purpose, but data were maintained on results or side effects. Example: radiation used as cancer treatment, with data reported on side effects.

(e) Unknown/uncertain -- available information does not indicate classification into a category.

7. Identify the location(s) of records regarding this experiment. Indicate whether any records are in the possession of a contractor or grantee, and, if so, what action will be initiated to

EXHIBIT 8 LOCATING RECORDS OF DOD HUMAN RADIATION EXPERIMENTS (CONTINUED)

retrieve them. Indicate the name of the individual responsible for the maintenance of the records.

8. Indicate the estimated nature and quantity of the records.

9. Indicate whether the records are classified, and, if so, what action has been or will be initiated to consider the classification.

M. Initial and Follow-Up Reports.

The initial report on locating records of human radiation experiments is due February 14. It is anticipated that the identification of organizations that might have conducted or sponsored human radiation experiments (Part I of the report) will be complete or substantially complete by that date. It is also expected that the identification of all specific experiments possibly within the scope of the search will not be complete, but that Part II of the February 14 report will be an interim report. A complete report, consisting of both Parts, is due February 28. Any reporting organization that is unable to give a complete report by February 28 must nonetheless report by that date and provide the necessary supplements as soon thereafter as possible. Even after an organization provides its complete report, if any new information is discovered regarding the matters covered in the reports submitted, the organization has a duty to supplement its reports to assure their completeness and accuracy.

N. Resolution of Questions.

Every effort should be made to avoid the need to repeat any of the steps involved in the records location task. Therefore, organizations should be encouraged to resolve any questions or uncertainties at the earliest possible time. This should be done through the organization's chain of authority and up to the Command Center.

O. Command Center Address and Telephone.

The address and telephone number of the Command Center, to which the requested reports are to be sent and to which inquiries may be made, are:

DoD Radiation Experiments Command Center
1211 S. Fern St., Room 217
Arlington, Va. 22202

Telephone: (703) 602-1365

EXHIBIT 8 LOCATING RECORDS OF DoD HUMAN RADIATION EXPERIMENTS (CONTINUED)

HUMAN RADIATION EXPERIMENTS IDENTIFICATION

1. **NAME.** Identify the possible human radiation experiment.

2. **WHERE/WHEN.** State where and when it took place.

3. **RESEARCHER.** Identify the primary researcher(s).

4. **AGENCY.** Identify the organizations involved. Include all DoD organizations, any other agencies, and any contractors, or other parties. Identify the lead agency.

5. **SUBJECTS.** Indicate the number of human subjects of the experiment. Indicate any available information on known characteristics of the class of subjects, such as: active duty members, a racial or ethnic group, prisoners, medical patients. Indicate whether available information includes names or other identifying information concerning the subjects.

6. **SUMMARY.** Summarize the experiment, including an identification of the purpose of the experiment and the nature of the use of ionizing radiation. As examples of the types of information that would be helpful, if available information permits, preliminarily classify the possible human radiation experiment into one of the following categories.

(a) Clear purpose radiation research -- the purpose of the experiment was to test the human health effects of ionizing radiation. Example: subjects exposed to radiation for the purpose of measuring adverse reactions.

(b) Therapeutic research involving radiation -- the purpose of the experiment was to test the safety and efficacy of using ionizing radiation to diagnose or treat a disease or medical condition. Example: clinical research on bone marrow transplantation.

(c) Other research -- the experiment was for another purpose (i.e., other than categories (a) or (b)), but in the course of the research project, ionizing radiation was used in accordance with a routine, diagnostic procedure. Example: research of effects of dental coating to prevent cavities, monitored through periodic dental X-rays.

(d) Unknown/uncertain -- available information does not indicate classification into a category.

7. **RECORDS LOCATION.** Identify the location(s) of records regarding this experiment. Indicate whether any records are in the possession of a contractor or grantee. Indicate the name of the individual responsible for the maintenance of the records.

8. **RECORDS DESCRIPTION.** Indicate estimated nature and quantity of the records.

9. **CLASSIFICATION.** Indicate whether the records are classified, and, if so, what action has been or will be initiated to consider the classification.

EXHIBIT 9 EXPANSION OF HUMAN RADIATION RESEARCH REVIEW

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

ATOMIC ENERGY

June 14, 1994

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN, JOINT CHIEFS OF STAFF
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
DIRECTOR OF ADMINISTRATION AND MANAGEMENT
DIRECTOR, DEFENSE NUCLEAR AGENCY

SUBJECT: Expansion of Human Radiation Research Review to Include Policy Making Activities of DoD Components

On January 18, 1994, the White House asked each agency to "establish forthwith an initial procedure for locating records of human radiation experiments" conducted or sponsored by the agency as a prelude to the "retrieval and inventory" of such records. In my January 31 memorandum, I established a process, consisting of two phases, for DoD's response to this request. Phase 1, which is now nearing completion, consists of the identification of all records of possible DoD human radiation experiments. Phase 2, following further guidance from the Interagency Working Group and the Presidential Advisory Committee, will entail the actual retrieval of pertinent records.

As part of, and in addition to, the process of retrieving records of actual experiments, the Advisory Committee has launched a major effort to compile records regarding the DoD policy making, dating back to 1944, relating to human radiation research. I agree with the Advisory Committee that this is a useful line of inquiry, and I have pledged DoD's support. To assure that support, I am modifying our process to establish what we might call phase 1-B, to compile records of policy making activities of DoD relating to human radiation experimentation. I am also supplementing the DoD Steering Committee specifically to include representatives of offices needed to assist in this review of policy making activities.

Specifically, I ask that the Secretaries of the Army, Navy, and Air Force include in your respective review groups, if you have not already done so, a representative of the historical office and the records management office responsible for the Office of the Secretary of each respective service. The Secretary of the Army's review should include records of the former War Department, including the Medical Research Committee of the Office of Scientific Research and Development. For the Office of the Secretary of Defense, I request the active participation of a representative of: (1) the OSD Historian (DA&M) regarding OSD relevant policy development activities; (2) the Records Management Division (DA&M) regarding identification and retrieval of records of policy making activities; (3) the Director of Defense Research and Engineering (already on the Steering Committee) regarding DoD policy on human subject research, including activities of the former DoD Research and Development Board; (4) the Assistant Secretary of

EXHIBIT 9 EXPANSION OF HUMAN RADIATION RESEARCH REVIEW (CONTINUED)

Defense (Health Affairs) regarding medical research policy, including activities of the former Armed Forces Medical Policy Council; and (5) the Assistant to the Secretary of Defense (Atomic Energy) (already on the Steering Committee) regarding DoD policy on atomic energy related research.

To provide additional context for this "phase 1-B" task, attached are excerpts from the Advisory Committee staff's Preliminary Report on the DoD review process and additional details regarding the needed search effort. I ask the OSD addressees of this memorandum to designate their respective representatives by June 17 to my Principal Deputy, Gordon Soper, room 3E1074. (703) 697-5561.

Thank you for your continued support.

Harold P. Smith, Jr.

Attachments
Copy to: Honorable John Deutch, Deputy Secretary of Defense
Ruth Faden, M.D., M.P.H., Chairperson,
Advisory Committee on Human Radiation Experiments

EXHIBIT 9 EXPANSION OF HUMAN RADIATION RESEARCH REVIEW (CONTINUED)

RESPONSIBILITIES OF DoD COMPONENTS FOR "PHASE 1-B" –
COMPILATION OF RECORDS OF POLICY MAKING ACTIVITIES
CONCERNING HUMAN RADIATION EXPERIMENTS

A. Scope of search.

1. Records covered.

Records covered by this search include any regulations, directives, memoranda, policy statements, letters of instruction, or any other expression of policy or procedure regarding human radiation experiments conducted or sponsored by DoD. This includes any policy or procedures regarding development or evaluation of proposed human radiation experiments, as well as the conduct or oversight of such experiments and the reporting or use of results of the experiments. Records covered by this search also include all records relating to the development, implementation and oversight of any expression of policy or procedure. This includes any proposed policies and procedures, the rationale and records of deliberations on proposals, commentary on implementation, and reviews of results.

2. Dates covered.

The dates of records are 1944 until 1974, with priority on the earliest records. A similar search may subsequently be required for post-1974 records.

3. Definitions.

For this purpose, the definitions of "human radiation experiments" and "records" are the same as in the January 31, 1994, attachment to Dr. Smith's memorandum.

B. Report requested.

Each addressee is asked to submit a report regarding the search effort of the component and the results of the search. The Radiation Experiments Command Center (RECC) will coordinate the search effort through the DoD Steering Committee and assist in conducting archives records searches.

C. Records repository.

The central repository for all records regarding DoD human radiation experiments is the RECC. All records regarding policy making activities are to be forwarded to:

DoD Radiation Experiments Command Center
6801 Telegraph Road
Alexandria, Va. 22310-3398

Telephone: (703) 602-1365

EXHIBIT 10 RESPONSE BY THE DoD TO THE FINDINGS AND RECOMMENDATIONS OF THE ACHRE

THE SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1000

C/back

30 OCT 1995

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN, JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Response by the DoD to the Findings and Recommendations of the Advisory Committee on Human Radiation Experiments.

I am aware of your commendable efforts in support of the Advisory Committee on Human Radiation Experiments. Your hard work resulted in the Department leading the way in the timely declassification of 1,200 documents requested by the Committee, retrieval of 10,000 key documents related to policy and experiments and DoD responding to more than 7,000 public inquiries. Thank you all for a job well done.

Now that the Advisory Committee has completed its Final Report, we must continue to build on the excellent progress that the Department has made in the first phase of this important project. I want to ensure that we continue to respond in a timely manner to Congressional and public inquiries, intensify public access initiatives and, when appropriate, declassify relevant documents. Protecting the rights and interests of human subjects will continue to have the utmost priority within the Department. Accordingly, under the direction of the Director, Defense Research and Engineering, responsible agencies must take prompt action on the President's charge to review human subject protection policies based on the findings and recommendations of the Advisory Committee and provide input to the National Bioethics Advisory Commission.

I am reappointing Dr. Harold P. Smith, Jr., Assistant to the Secretary of Defense (Atomic Energy), as the DoD-wide focal point for the continuation of the tasks remaining from phase one of this activity and the timely follow-up to the findings and recommendations of the Final Report of the Advisory Committee. He will work with the Interagency Working Group and coordinate our efforts with those of the other relevant agencies.

Inquiries regarding this matter should be directed to Dr. Gordon K. Soper, Principal Deputy, ATSD(AE), (703)697-5561.

William J. Perry

EXHIBIT 11 RESPONSE BY THE DOD TO THE FINDINGS AND RECOMMENDATIONS OF THE ACHRE

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NOV 2 1995

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDERSECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Response by the DoD to the Findings and Recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE)

On January 7, 1994, Secretary Aspin appointed me as the DoD-wide focal point for the Department's review of human subjects radiation experiments. On January 18, 1994, the President established the Advisory Committee on Human Radiation Experiments to conduct a government-wide review of such experiments and submit a final report to the President within one year (later six month extension). In support of the ACHRE, DoD and seven other Departments/Agencies conducted extensive record reviews to determine our involvement in conducting or sponsoring human subject experiments during the past 50 years. DoD was a key contributor in the overall success of this review (enclosure 1).

On October 3, 1995, almost 18 months after the project started, Dr. Ruth Faden, a bioethicist at John Hopkins University and Chair of the Advisory Committee on Human Radiation Experiments, presented the Final Report to the President. Concurrently, the President, via Executive Order, (enclosure 2) established a National Bioethics Advisory Commission (NBAC) and charged each responsible agency to immediately review its human research policy and procedures relative to the findings and recommendations of the Advisory Committee and submit a report to the NBAC within 120 days from the effective date of the executive order.

To ensure continuity in completing the final phase of this important project, Secretary Perry has reappointed me as the DoD-wide focal point (Enclosure 3). In reassuming the lead in this matter, I join the Secretary in thanking you and those from your agency who participated in this effort for the great support during the first phase.

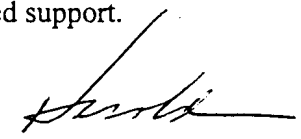
EXHIBIT 11 RESPONSE BY THE DOD TO THE FINDINGS AND RECOMMENDATIONS OF THE ACHRE (CONT.)

Within the Department, the DoD Human Radiation Experiments Steering Committee, which I chair, will continue, with members from Defense Research and Engineering (DDRE), the Services, the Defense Nuclear Agency, the Radiation Experiments Command Center (RECC), and OSD General Counsel. Our primary attention will be on three implementation issues. First, it is essential that we work promptly and effectively in developing appropriate responses to the NBAC no later than February 3, 1996. To this end, the DoD will work closely with the Interagency Working Group to ensure a coordinated effort in responding to the NBAC concerning informed consent and policy matters regarding the protection of human subjects in research. DDRE has primary oversight in this matter.

Second, as concerns other ACHRE follow-on issues, the RECC has the lead in completing several actions that will require your support. Project officers must continue to work closely with the RECC to ensure timely responses to Congressional and public inquiries and Freedom of Information Act requests. Also, the RECC has begun initial work to publish a book to reflect DoD's commitment to openness by summarizing what DoD found during its human radiation experiments records review. The proposed book is targeted for completion in March 1996 and will have chapters specific to the research efforts of the Services and DoD agencies. Therefore, the RECC will need the help of project officers to review both near final and final drafts for substantive and factual accuracy. Particulars about the book and final draft reviews will be provided via separate correspondence. Additionally, the Services and responsible DoD agencies in coordination with the RECC must take action to ensure that any documents that the Advisory Committee requested to be declassified that are still being processed are declassified and forwarded via the RECC to the National Records Center. Such action is necessary to ensure the continued integrity of our records review.

The third major implementation issue is remedies and compensation actions. On this, OSD General Counsel will continue to have the lead to ensure appropriate DoD input.

Inquiries regarding this matter should be directed to Dr. Gordon K. Soper, Principal Deputy, ATSD (AE) at (703) 697-5561 or Colonel Claud Bailey, Jr., at (703) 442-5675. Thank you for your continued support.



Harold P. Smith, Jr.