

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The Committee's report began by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" were then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity were also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at selected hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects

and evaluating research risks and to sample attitudes toward human subject research.

The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved, and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments were proposed as candidates by the Committee.

Summary Response: As recommended by the Advisory Committee, in coordination with the Department of Justice (DOJ), and to the extent permitted by law, subjects (or their surviving immediate family members) will be offered reasonable financial compensation for human radiation experiments in which a government agency was involved in actions falling with the Advisory Committee criteria:

1. Experiments in which excessive secrecy deprived individuals of the opportunity to pursue potential grievances;
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

A streamlined administrative process, based on Federal Tort claims Act procedures or other applicable law, will be used to consider compensation as part of a settlement of relevant claims. Maximum effort will be made to avoid unnecessary litigation, including use of alternative dispute resolution, such as mediation, where appropriate. In considering the issue of compensation, the critical factors will be the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies will seek expert advice on scientific and medical issues. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek legislative relief in appropriate cases.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment was proposed as a candidate with the indication that there may be many others.

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

Recommendation 4: Subject notification and medical follow-up unnecessary; criteria for subsequent notification if new experiments come to light. These criteria included both the level of risk from radiation exposure and the potential benefit from medical follow-up in exposed individuals.

Summary Response: The IAWG staff has generally agreed with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee are appropriate for evaluating future cases. This recommendation has generated a great deal of controversy among stakeholders, which was expressed at the Stakeholders Workshop of February 26, and 27, 1996, held by the IAWG. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally seemed to want some form of notification along with medical care provided by physicians of their own choice,

rather than medical follow-up by the government. They viewed the latter as a continuation of suspect government activities.

In addition, at hearings on human radiation experiments held by the Senate Committee on Governmental Affairs on March 12, 1996, Senator Glenn suggested that subjects may want to be notified whether or not they were harmed.

In response, the IAWG staff has further discussed and reviewed its response to this recommendation. Many staff members have pointed out that the entire human radiation experiments effort as carried out by the Federal agencies has involved a public notification process, though generally not at the level of individual participants. Lists of experiments have been made public as has a large volume of documents. The whole process has received extensive publicity.

In one example, the National Aeronautics and Space Administration (NASA) sent a detailed letter notifying all current and former NASA employees, contractors and grantees about the human research radiation review. Headquarters, the nine NASA Field Installations, and the Jet Propulsion Laboratory participated in this notification. These avenues of notification included those universities and institutions at which human radiation research was performed through NASA grants. Additional notification was accomplished through various NASA alumnae associations and professional organizations. At the same time, except for astronaut medical records, NASA did not and does not retain any administrative or individual medical records of human radiation research subjects.

In addition, through the Interagency Helpline, individuals who think they may have been involved in experiments have had their cases reviewed by the appropriate agency. In response to these inquiries, for example, DOE has notified a number of individuals that they appear to have been participants in a human radiation experiment in which DOE had some involvement.

The VA reported that it focused its attention on early radiation research projects for which at least some of the names of research subject were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if

warranted. An expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry reviewed information about these projects and no veterans were identified who were felt to warrant special follow-up actions specifically because of their radiation exposure.

Several agencies have been evaluating the issue of notification for specific categories of experiments:..

Treatment with Nasopharyngeal (NP) Radium during Military Service

The Departments of Defense (DOD) and Veterans Affairs (VA) have been considering a relatively large group which has attracted public attention: the servicemen who received NP irradiation during and immediately following World War II. Nasopharyngeal irradiation was considered accepted medical treatment at the time, and records identifying individuals receiving this treatment are difficult to locate. DOD has been able to locate names of a few servicemen who received nasopharyngeal irradiation and sent them a letter informing of this fact and providing a fact sheet about the therapy.

The VA, along with the Centers for Disease Control (CDC) and Yale University, co-sponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut in September 1995. Consensus did not support medical screening of asymptomatic individuals but recommended that individuals treated with NP radium inform their health care providers for consideration when they are examined or evaluated. VA officials have published information on NP radium treatments in medical journals and sent information to veterans' service organizations for their newsletters.

The VA and CDC are planning a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP radiation do not have special eligibility for VA care. A current bill (HR #2080), if enacted, would provide priority eligibility to veterans treated with NP radium in service. A VA legislative proposal also currently under consideration would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program.

Alaskan Natives

A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force is currently determining appropriate follow-on concerning the minors involved in the Iodine-131 study. In general, the Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM in its recent report concerning the Iodine-131 experiments involving Native Alaskans. Efforts are ongoing to locate documents about experiments involving Native Alaskans and to identify the six Native Alaskans and six soldiers whose names were omitted from the study report.

DOE Efforts

In addition to the subjects of the plutonium injection experiments, whose next-of-kin, where located, were notified, DOE is trying to identify whether there are any other subjects for whom it has information that would make notification possible. Although the agency does not currently believe that this information is available, a letter has been sent to all DOE facilities at which human radiation experiments were identified. The letter requests the facilities to provide detailed information about the availability of data, if any, relating to individual subjects, the feasibility of notification, and whether any kind of notification process has already taken place. DOE has carefully considered the issues raised by notification and the agency's continuing concerns about the value and feasibility of this process were included in the testimony of Dr. Tara O'Toole before the Senate Committee on Governmental Affairs on March 12, 1996.

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 (RECA) to cover other exposed populations, including citizens exposed around the Hanford site.

Summary Response: The IAWG staff agrees with the Advisory Committee's concern for treating exposed populations fairly. Studies that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge are underway. If these studies reveal an increase in cancer resulting from the operation of DOE facilities, the government will work with Congress to amend existing laws to cover those affected. The GAO has been provided with a list of all studies currently in process.

Recommendation 6: Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

Summary Response: The VA has established a Working Group led by the Undersecretary for Benefits to follow-up on the recommendation. Representatives from the Departments of Defense (DOD) and Health and Human Services (HHS) are included. The Task Force is also evaluating the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to radiation exposure while in military service. The report is expected to be completed in summer of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic tables; describe the administration of laws governing compensation of Atomic Veterans; and, if appropriate, recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise was established to review the provisions in RECA that relate to compensation for uranium miners. The committee also reviewed the Department of Justice's (DOJ) implementing regulations under RECA

to ensure that they are not unduly restrictive. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee report is in the process of completion.

The committee has agreed on a series of recommendations that propose significant and substantial modification to the statutory compensation criteria for lung cancer and nonmalignant respiratory diseases, and to the regulations that govern proof of these diseases. In a few instances, it has recommended that statutory criteria be modified but has not proposed specific alternative criteria. In these cases, the committee was unable to locate sufficient reliable data to review and analyze in the time allotted or because the appropriate solution ultimately depends on a purely policy judgment.

Recommendation 8: Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involving the Marshall Islanders in the design of any further medical research conducted on them; and establishing an independent panel to review the adequacy of the current monitoring and treatment program.

Summary Response: DOE plans to continue the current monitoring and treatment program. Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utrik based upon external dose measurements and on estimates of thyroid doses. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If new data is developed to indicate that residents of atolls south and east of Bikini, other than Rongelap and Utrik, are at increased health risk, Congress would need to consider expanding the current medical surveillance program.

The planned Joint Commission for Accreditation of Healthcare Organizations (JCAHO) review of the DOE Marshall Islands Program, administered by the Brookhaven National Laboratory, has recently been suspended. At the request of the Government of the Republic of the Marshall Islands (RMI), the mechanism for such a review is being reevaluated based on further input from RMI. Discussions with the RMI Ambassador to the United States have taken place and RMI has requested a broader review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

Representatives of RMI participated in the February Stakeholders Workshop and DOE is generally working with RMI representatives to determine how to enhance the program to better meet their current need and to fully involve them in the process of rethinking the program. DOE is also in the process of locating additional documentation requested by RMI and facilitating their access to material already located.

CURRENT HUMAN SUBJECT PROTECTION

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented in the near term while others will require preliminary groundwork prior to full implementation. In addition, it is expected that a National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975 on October 3, 1995 will address a number of issues raised in the recommendations.

In general, agency activities in response to these recommendations fall into the following categories:

- Referring specific Advisory Committee recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-Federally funded research with the ethical considerations in conducting research involving human subjects;
- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research;
- Reminding institutions conducting Federally funded research of their ongoing responsibilities with respect to Institutional Review Board (IRB) review;
- Pooling resources across agencies to enhance understanding of the informed consent process;

- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects.
- Implementing educational workshops and an active dialogue with international partners with whom Federal agencies cooperate in human research to develop common ethical principles and to ensure the rights of human subjects are protected, e.g. specific activities proposed by NASA.

NBAC Update: NBAC was established by the President to provide guidance to all Federal agencies on the ethical conduct of human behavioral and clinical research, and the applications of that research. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its establishment was catalyzed by the Advisory Committee report, NBAC in fact represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these Committee recommendations based on their merits, as judged by NBAC.

The President is expected to appoint the NBAC membership soon, with meetings to begin later in 1996. Reports provided to NBAC by agencies that carry out current human research will permit NBAC to begin a critical assessment of the implementation of the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule"). Such independent analysis is critically needed, five years after the promulgation of the regulations.

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Summary Response: NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate government entities in the areas of bioethical issues arising from research on human biology and behavior and the applications, including clinical applications, of that research. NBAC will also identify broad principles to govern the ethical conduct of research. The IAWG staff has identified activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these activities that will be carried out by HHS, DOE, DOD, and NASA. Some of these are discussed below.

In addition, the National Institutes of Health (NIH) is leading an interagency initiative to fund the development of new knowledge related to the informed consent process. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent, and NIH, NASA, DOE, and DOD are committed to supporting research that will more fully illuminate the process. A Request for Applications (RFA) is in preparation, and Fiscal Year 1997 monies are intended to support this RFA.

DOE ensures the centrality of ethics in human subject research by many methods including: education, oversight and compliance activities, public access via Internet, and control of funds. The newly initiated site visit program as well as the internet database (updated annually), educational meetings, newsletters, e-mail updates, local guest lectures, and DOE-wide brochures make this issue a very visible one at DOE. Attention does not diminish because the activities are ongoing; new activities are always added and the DOE system provides for sharing site specific accomplishments such as development of local Homepages and programmed texts for use by principal investigators.

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explain benefits, and clearly describe the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and

purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk.

Summary Response: The ACHRE offered detailed guidance -- all within the ambit of the existing Federal Policy for the Protection of Human Subjects -- directly to IRBs on their operations. The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and will provide oversight and review to ensure compliance. The IAWG staff will work with NBAC and the National Science and Technology Council in carrying out these recommendations.

The Office of Protection from Research Risks (OPRR), National Institutes of Health, leads a national educational effort to showcase the Advisory Committee's message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the Advisory Committee recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, and Houston. The November 1996 PRIM&R annual conference in San Diego is expected to address IRB implementation of the recommendations. The recent placement of the Advisory Committee report on the World Wide Web makes it possible for IRBs to examine its full text.

In October 1995, the Food and Drug Administration (FDA) issued a major, 154-page revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take into account the latest thinking and to provide guidance to IRBs.

OPRR and FDA make extensive use of public meetings, forums, hearings, FAX call, and electronic media to address evolving issues on human subjects protection. OPRR and FDA actively identify and mail to IRBs and other interested parties copies of Federal Register notices and "Dear Colleague" letters regarding human subjects protection.

In response to ACHRE concerns about IRB focus on more-than-minimal risk studies, one OPRR "Dear Colleague" letter to 5,500 addresses in the worldwide IRB community restated and explicated the existing regulatory provisions for

- 1) exemption from IRB review of six categories of low-risk research, and
- 2) expedited IRB review of 10 other kinds of research when it is judged by IRBs to be of minimal risk. Proper use of these time-saving mechanisms permits IRBs to devote greater effort to the areas of concern to the ACHRE.

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum.

Summary Response: It is expected that NBAC deliberations will provide and opportunity for public participation in the continuing review and interpretation of ethical rules.

Private organizations, such as Public Responsibility in Medicine & Research (PRIM&R) and the Applied Research Ethics National Association (ARENA), and periodicals such as IRB, serve a pronounced role in the continuing interpretation of ethical rules in public.

Within the Department of Health and Human Services, the Office of Protection from Research Risk is the day-to-day interpreter of the regulations for protection of human subjects. OPRR answers more than 175 telephone calls each day, maintains an information-by-FAX service and a World Wide Web site to disseminate information, and respond to inquiries by mail.

A major aspect of the DOE human genome program's Ethical, Legal, and Social Issues (ELSI) program is the sponsorship of a wide variety of educational programs, including meetings and seminars. DOE has recently sponsored two highly acclaimed public television programs on genome issues. DOE has also sponsored a judges' workshop for trial judges to receive information on and discuss the use of DNA evidence in the courtroom. The genome program has also sponsored conferences or workshops (1) that considered discrimination that could result from the use of genetic information about ethnic and other groups, (2) that discussed

genetics, religion, and ethics, (3) that provided public officials and other nonscientist policy makers and opinion leaders hands-on experience with genome-related technologies, and (4) that give hands-on genome experience to high school teachers.

Materials produced with funding from DOE's genome program have had significant impact. By far the most successful has been the Primer on Molecular Biology, which has been sent to every high school biology teacher in the country. More than 30,000 copies have been distributed by DOE, and the number in use, given individual copies made by individuals and schools, is far greater. This primer is also available electronically on-line, and has been used to teach high school students, graduate students, and physicians at institutions like Harvard and Stanford. Additional materials that have been or are being produced and distributed include a judge's desk reference on the use of DNA evidence, a high school curriculum on the human genome project in both English and Spanish, and museum exhibits.

Recommendation 12: Improving the rights and interests of military personal with respect to human subject research by reviewing policies and procedures, educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revision of directives or Military Department regulations to meet these proposals and incorporation of appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research. In the summer of 1996, DOD will publish a revised human subjects protection regulation that will include policy changes recommended by the Advisory Committee. For example, the new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence.

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: Federal agencies are already undertaking specific activities in response to this recommendation, some of which are described below. It is expected that NBAC will fully address this recommendation in carrying out its charge.

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally-funded research should be compensated.

Summary Response: The Department of Justice, with input from other agencies, will address the recommendation, which may ultimately require legislation. Despite being addressed twice before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of the long-standing social policy issue remains elusive.

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies represented on the IAWG) were required to review this research in the light of the Advisory Committee recommendations and report to NBAC. DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (along with many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995 Executive Order. The following are some specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Revised and updated the DOE Resource Manual on protecting human subjects. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research as well as all other areas of human subjects protections and provides regulations, resources and models.
- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited

approximately once every three years. Five laboratories and three field offices were visited by a team in 1996.

- Requested all DOE laboratories to provide a sample of current informed consent documents. These are being reviewed to improve and monitor the quality of these documents.
- Has begun drafting three model informed consent documents that will be sent to all sites to adapt and use, one for genetic research, one for biomedical research, and one for engineering research..
- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.
- Put DOE's FY 95 Human Subjects Database on the Internet.
- Updated the DOE Human Subjects Research Homepage with access to all DOE information, contacts, resources, etc.
- Continued the twice yearly meetings of DOE-wide human subjects working group.
- Sponsored a large, interagency human subjects workshop to highlight the ACHRE report and other bioethical issues. This ongoing series is undertaken every other year.

The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human research subjects and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:

- Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule, and related requirements;
- Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
- Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
- Require education in human subjects regulations at the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
- Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration:

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jawarski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's final report. NASA Headquarters has also established a process

for oversight and assurance. An Agency Authorizing Official has been named for the authorization of human research and the protection of human subjects. Documentation of assurance of human subjects protection is required every five years, from all nine NASA Field Installations and the Jet Propulsion Laboratory, if the Center is conducting human subjects research. Centers not conducting such research must recertify by letter every year.

- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the international space station was agreed upon and will undergo periodic review.
- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a

research proposal before it can proceed; final approval rests with the Agency Director.

- Disseminated an agency bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Coordinates interagency Request for Applications from researchers, to develop new knowledge related to the informed consent process.
- Expanded technical assistance to IRBs at institutions receiving DHHS research funds, by means of 12 to 24 site visits per year.
- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects. For example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.
- Ensured that FDA will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.
- Provides administrative support for NBAC.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECRECY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: With regard to 15a, the existing Federal Policy for the Protection of Human Subjects makes no distinction between unclassified research, and requires prospective, legally effective informed consent from human subjects, with only very limited exceptions. IRBs may consider altering or waiving informed consent only when four stringent criteria are met. To alter or waive consent, IRBs are required to find and document 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.

Similarly, the Federal Policy currently leaves to the discretion of IRBs any notification to the prospective subject 1) that classified research is involved, and 2) of the name of the sponsoring government agency.

Changes in IRB authority could be effected by modifications of the Federal Policy. Consideration of modification of the Federal Policy to take account of the Advisory Committees recommendations will be taken up by the Human Subjects Research Subcommittee, Committee on Health, Safety, and Food, National Science and Technology Council. This interagency group meets regularly to ensure uniform implementation of the Federal Policy and to gauge the need for changes.

The IAWG staff is reluctant to propose creating a new oversight body for 15(b). Instead it proposes to use the current IRB system which already must include at least one member not affiliated with the institution. The IRBs could be directed to guarantee participation of non-government persons in reviewing classified research by establishing a dedicated panel for classified research review or by ensuring that all IRB members possess the necessary clearances.

Recommendation 16: a) Review by an independent panel of any planned environmental release where any aspect involves secrecy and b) Environmental oversight of classified programs (now done by EPA) should include keeping review records permanently and reporting to Congress.

Summary Response: (16a) EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. All Federal agencies are obligated by Executive Order 12088 to comply with environmental laws and fully cooperate with EPA, and state, interstate, and local agencies to prevent, control, and abate environmental pollution, regardless of

whether the activities of regulated Federal agencies are classified. There is concern that creating a new regulatory entity, such as an independent review panel, would add to the bureaucratic complexities of ensuring environmental safety.

(16b) While EPA currently does oversee all Federal government operations, whether classified or not, through its enforcement program, which assures compliance with environmental laws by Federal agencies, EPA does not have as yet a systematic information gathering, coordination, or reporting process specifically related to issues of national security and/or activities subject to the Federal government's information secrecy program under Executive Order 12958.

In the past, EPA and state inspectors have obtained, on a case by case basis, appropriate clearances for access to national security information and facilities. To operate an effective enforcement capability over classified projects, EPA is considering systematically identifying cleared personnel and to seek from the operating federal agencies through a series of Memoranda of Understanding the appropriate "need to know" access. This new process would assure that EPA could handle most environmental compliance matters through administrative processes in classified settings. The EPA recommends however that each Federal agency be responsible for its own handling of classified material.

With respect to the National Environmental Policy Act (NEPA), EPA staff that are assigned as liaisons to the Federal Agencies hold the appropriate security clearances and, in the event it becomes necessary to review a classified NEPA document, the individual typically goes to the offices of the lead agency and reviews the classified material there. EPA will establish and maintain a permanent file to document classified NEPA documents and the EPA review components. The EPA policy will address issues including transport, storage, review, and permanent recordkeeping of classified NEPA documents and EPA review comments. EPA will notify all Federal Agencies of its new classified filing and review procedures and will provide Congress with information on request.

Recommendation 17: Ensuring historical records are organized and accessible by
1) hastening movement of records to Archives; 2) making indexes and finding aids

readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

Summary Response: For 1, 2, 3, and 5, the IAWG staff agrees with moving aggressively down the path to openness exemplified by this project and will work to make government records more accessible including using new technology to enhance access. For 4, the IAWG staff is investigating the feasibility of making the records of classified human subjects research permanent, not just the records of destruction.

Current Agency Activities: IAWG members have initiatives underway to ensure that information retrieved for the human radiation experiments project is readily available to the public, and to respond to specific Advisory Committee recommendations on openness.

The Department of Energy:

- The Department has produced three publications which include background information, record series descriptions, topical essays, a list of over 400 experiments, and oral histories. Most of this information, along with over 250,000 scanned historical documents, is located on the Internet, with paper copies of all documents at the Coordination and information Center (CIC) in Nevada.
- In response to Advisory Committee recommendations, DOE is
 - Negotiating the transfer of over 3,000 cubic feet of records to the National Archives; and
 - Actively making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance. To date, finding aids from Headquarters records and a

number of filed sites have been placed in public reading rooms across the DOE complex.

- The Department continues to update its World Wide Web site on the Internet with additional documents of interest and recently added three new experiments to its experiment list.

The Department of Defense:

- The Department is preparing a guide similar to the DOE *Roadmap* that will describe DOD documents found during the human radiation records search, and will identify and list human ionizing radiation experiments conducted or sponsored by the DOD. It will also include information on DOD events that were not human radiation experiments but were specifically included by the DOD in its search efforts, such as atmospheric releases. Scheduled availability is summer 1996.
- The documents will be available on the Internet and hard copies will be deposited at the CIC. DOD has also declassified many documents identified in the search for human radiation experiments and is also planning to transfer them to OpenNet, an Internet source for recently declassified documents.
- DOD has taken the lead in an interagency effort to create a home page on the Internet, modeled after DOE's, providing access to documents located by all agencies as part of this project.
- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

The National Aeronautics and Space Administration:

- NASA will maintain a permanent collection of human radiation experiment records and a database at Johnson Space Center. A process for submission of an response to requests for information has been developed.

- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.
- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.



February 1996

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**COMMENTS OF THE NATIONAL ASSOCIATION OF ATOMIC VETERANS
(NAAV) IN RESPONSE TO REPORT OF THE ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS (ACHRE) AND SUGGESTIONS FOR
STRENGTHENING RECOMMENDATIONS AND REMEDIES
INCORPORATED THEREIN**

Recommendation 2, page 803 to 805

1. Medical followup and expenses should be awarded to all atomic veterans who may have incurred any radiogenic illness, their survivors, and to offspring of atomic veterans who suffer from genetic or mutagenic illnesses. We concur with the Committee's suggestion on page 803, third paragraph and last paragraph on page 805.

Recommendation 4, page 809, 810 and addendum thereto, page 840

2. Notify all veterans exposed to nasopharyngeal radium treatment, and their offspring as well as all veterans exposed to ionizing radiation during the nuclear testing era, 1945 to 1993, and their offspring. We find outrageous the Committee's attempt to play God on pages 809, 810 and therefore do not concur.

Population exposures, page 810 (all under this provision)

3. Approve the Committee's suggestion that the existing laws pertaining to the veterans and others be revisited and extended to similarly situated groups such as those exposed to intentional releases who are not now covered. We suggest that all persons exposed to ionizing radiation in connection with nuclear weapons tests, including Marshall Islanders who are covered under a different framework of remedies, be covered under the same laws, be paid the same amount and be extended the same medical benefits.

Recommendation 5, page 811

4. NAAV concurs with the Committee's recommendation that the Human Radiation Interagency Working Group (Working Group), together with Congress, amend the provisions of the Radiation Exposure Compensation Act of 1990 (RECA) to include other "similarly situated groups such as those exposed to intentional releases...

In addition to the Committee's recommendations, we recommend that all persons covered under that law (RECA), be awarded the same monetary sum (the highest of \$100,000 paid to the uranium workers); that they all be covered for the same illnesses (including lung cancers and other lung ailments to which the uranium workers are eligible); that there be no offsets for Social Security benefits, veterans benefits or other U.S. governmental payments made for the same illness; that there be no restrictions (coffee consumption, cigarette smoking, residence [length of time in the area]), no "working level month" restrictions, and any and all other restrictions contained in P.L. 101-426 and P.L. 101-510 (RECA). We recommend that the so-called "Warner Amendment" repealed in P.L. 101-426 and reinstated in P.L. 101-510 be again repealed completely.

Recommendation 6, page 811

5. NAAV concurs with the Committee's suggestion that the *Report of the National Institutes of Health ad hoc Working Group to Develop Radioepidemiological Tables* (Tables) now relied upon to determine whether relief is appropriate for veterans who participated in atomic testing, be reviewed and updated. Those tables admittedly are the first version (1985) and are based on the knowledge in existence in 1974 (page 79 of the Tables..."Our present knowledge is far from complete and the Tables can be regarded as no more than a guide to causation...each element of the probability-of-causation (PC) calculation...has its own uncertainties.")

In spite of this admission and the outdated information the Tables contains, as recently as August 29, 1994, Secretary of Veterans Affairs (VA), Jesse Brown, sent a fact sheet to the Hon. Lane Evans and co-signers of a letter endorsing our suggestion of inclusion of the radiogenic illnesses in P.L. 98-542 with the "presumptive" cancers in P.L. 100-321 and 102-578 (Enclosure 1). This fact sheet was prepared by the Under Secretary for Benefits and is condensed from the Tables referred to above. The Secretary also sent a similar fact sheet to me quoting from the flawed 1985 *Mortality Study of Nuclear Weapons Test Participants* (Study) by the National Academy of Science (NAS), now being repeated by the same entities--NAS and Defense Nuclear Agency (DNA) (Enclosure 2), and partially funded by the VA.

The Secretary further informed Sen. John D. Rockefeller on July 18, 1994, that as of that date only 414 claims had been granted under the presumptive laws, promulgated in 1988 and 1992, out of over 15,000 filed (Enclosure 3).

In spite of the above, the Committee stated that the "Department of Veterans Affairs agrees with this recommendation." (First paragraph of this colloquy).

It is our recommendation that all claims denied on the basis of decisions based on the Tables and the flawed Study be reviewed in light of the above facts.

Page 812. The Advisory Committee further recommends to the Human Radiation Interagency Working Group that it review whether existing laws governing the

compensation of atomic veterans are now administered in ways that best balance allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including the costs and scientific credibility of dose reconstruction.

The Committee found that the government did not maintain adequate records of all veteran participants...the Committee urged the Working Group in conjunction with Congress to address the concerns promptly. There are five concerns listed; in which we concur. I would like to address the last one (#5), in detail. It asks: [If] the time and money spent on contractors and consultants in administering the program would be better spent on directly aiding veterans and their survivors. Our answer is a resounding "Yes!"

As the letter referred to above from the Secretary of Veterans Affairs to Sen. John D. Rockefeller dated July 18, 1994 states: 414 out of 15,818 claims were granted on a presumptive basis. These did not need dose reconstructions. We have tried to obtain the number of claims granted under P.L. 98-542 which requires dose reconstructions. We have been unable to obtain this information from the VA. (As of the end of September 1991 over 12,000 claims had been received for disability or death alleged to have resulted from exposure to ionizing radiation under both P.L. 100-321 and P.L. 98-542; 258 were granted, 167 of whom were survivors. 25 veterans were rated at 0% (Enclosure 4). The contractor for the Defense Nuclear Agency (DNA), Science Applications International, Inc. (SAIC) charges \$3,000 for each dose reconstruction. The DNA costs for Nuclear Test Personnel Review (NTPR) dose reconstructions for the period 1978 to 1994 is \$13,598,939; the total funding for the Nuclear Test Personnel Review Program for that same time period is \$96,500,000. We do not know what "total funding" encompasses. The total is \$110,098,939 (Enclosure 5). We must get the total of personnel salaries, rents, expenses of all kinds connected with that time period for the operation of the NTPR. The number of dose reconstructions, and the number of claims filed under P.L. 98-542 must be obtained by the Working Group, as well as the total amount of VA benefits paid to claimants under P.L. 98-542 only.

In addition to the above expenses, the Underground Nuclear Test Personnel Review (UNTPR) costs (1962-1993) must be reviewed by the Working Group. I have been attempting under FOIA to obtain these records. These reports and costs are available from the DNA. I have some of them and we have now FOIA'd the names of the military participants but are having a problem with the Privacy Act. There were 65,000 military participants in the underground tests. In the VACEH report you will see there were about a half million other military exposed after 1962.

Recommendation 7, Page 813

7. We concur with the Advisory Committee's recommendation to the Working Group that RECA be amended to provide for all miners who develop lung cancer without requiring a specific level of exposure. We also recommend that all radiation victims be accorded the same consideration.

Recommendation 8, Page 815

8. This recommendation regarding the Marshall Islanders must also apply to all the atomic veterans, specifically those exposed in the Bravo test who suffered high doses of radiation at the same time and during the same tests as the Marshall Islanders.

Recommendation 12, Pages 823-825

9. We concur with this recommendation in its entirety.

Recommendation 14, page 827

10. We concur with this recommendation; however, it must be made clear that "research injuries" include *all* radiation victims, past, present and future.

No specific effort has been made in this Report to address the issue of compensation to the survivors of those who have died of their radiation exposure (and not just those so-called "research subjects.") We are all research subjects--downwinders,, uranium workers, testsite workers, atomic veterans, victims of the deliberate releases and any other individual exposed to ionizing radiation as the result of their being in the vicinity of any radiation device or contaminant. It's the survivors left with the burden of caring for the dying, and the fatherless children; educating them, feeding them, and trying to be father and mother to those children left with no or maybe only one, parent.

I would like to speak to the issue of wives and widows in particular. I speak with at least one widow a day, mostly those left with no means of support and staggering medical costs for the care of their spouse during his last illness; the widows of atomic veterans who do not have the wherewithal to pay for dose reconstructions, and to prosecute a claim. And even if they qualify under the presumptive laws their meager \$800 a month does little to pick up the slack. These women must bear the pain of nursing and then losing a spouse to a horrible, lingering death. They then must pick up the pieces, perhaps sell their homes to pay medical bills and educate their children. The bottom of page 827 and the top of 828 says it all, but I feel you are not addressing the issue of "medical and scientific experimentation" for atomic veterans. True, there's no medical records and the damning documents are buried by the DoD and other agencies. Although the Committee seems to feel that the atomic veterans were not as experimented upon as those injected with plutonium or fed uranium--and I brought this up at your hearings--what do you consider an injection or ingestion of radionuclides? Does the wind swirling about your face filled with plutonium and other alpha emitters unmeasurable on a film badge constitute an injection? These men were inhaling or ingesting these poisons, and although they were not miners and exposed to radon, nor did they have a syringe of plutonium injected into their bodies--what is the difference? It only takes one micron of plutonium to give a full-blown lung cancer. That little tiny speck if inhaled will settle in the alveolar lung sac or the mediastinal lymph nodes and

become a ticking time bomb--perhaps in 15 or 20 years the victim develops lung cancer, lymphoma or other cancers, however, lung cancer for the atomic veteran is impossible to prove. It's okay if you're a miner, but not if you're a veteran.

Are you aware that the individual victim of this experimentation, if he was wearing the uniform of the United States, sworn to defend the Constitutional rights for all Americans, is denied those same Constitutional rights for himself and his family? Yes, we cannot have a trial by a jury of our peers. There are at least six laws denying that right to servicemen/women and their families. My husband and those many other husbands, fathers, brothers, sons forced to absorb these poisons gave their lives for your Constitutional rights. They were sworn to secrecy and only on their deathbeds did they finally reveal those secrets. Our government did a marvelous job of coverup. History books are barren of the lies and deceit necessary to enforce the silence.

In addition to the above recommendations and remedies suggested by the Committee, we suggest the following:

A. That a registry be established for the offspring of the atomic veterans, and that these offspring be awarded financial benefits for their care and treatment if they are afflicted with any genetic/mutagenic physical problems which can be attributed to a parent/grandparent because of his/her participation in any of the radiation-exposed situations outlined in the attached "Proposed Legislative Agenda for the National Association of Atomic Veterans," which we will present to the House and Senate Veterans Affairs Committees (Enclosure 6);

B. That the 11 additional radiation risk activities listed on the enclosure outlined above, be added to the laws pertaining to the atomic veterans; and

C. That the laws concerning atomic veterans referred to above, be amended to encompass those other radiation-risk activities and the dates of exposure to radiation risk activities be extended to 1993. This information is contained in the attached Radiation Risk Activities Report of the Veterans Affairs Committee on Environmental Hazards, August 1993, mandated by P.L. Congress in P.L. 102-578 (Enclosure 7).

We are indebted to President William J. Clinton, The Honorable Hazel O'Leary, Honorable Edward J. Markey, and Eileen Wellsome, those responsible for opening the door so long closed.

*Patricia Broudy
Legislative Director, NAAV*

96 MAR 21
DATE: 12

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COMMENTS/MESSAGES:



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WASHINGTON, DC 20585

Assistant Secretary
Environment, Safety
and Health

IAWG staff, Paul Schuttk

FYI, we are drafting
a response. I believe it
would be best for the
response to be from the
IAWG staff so will send
it around for your review. If
you all think otherwise let me
know.

Steven



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**South Shore Health Center
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February 28, 1996

Tara O'Toole MD
Assistant Secretary for Environment, Safety and Health
United States Department of Energy
1000 Independence Avenue
Washington, DC 20585

Dear Tara:

Thanks very much for meeting with us in the past two days. Please let your staff know that none of our comments were directed personally at them, and in fact, we understand that they are on our side of most of the issues. Nonetheless, the ACHRE report was not close to fair and as a result of the long history problems, some of our frustrations came out during the meeting. This was in and of itself part of the healing process and quite therapeutic. (Better than Valium) I think, that now that our frustrations have been expressed, we can all move forward together. In that spirit, I am sending you a list of suggested solutions to some of the problems that exist.

Problem #1: Response to medical monitoring and medical care.

I agree with your position that medical monitoring, for most of the diseases that may have been induced by the radiation, is more expensive than medical care and of questionable value. Different doctors may have different opinions about this, and different patients may have different opinions on the possible harm that accrues from a skin needle biopsy, or from an echo of the thyroid, or testicle. For that reason, it is even more important that these decisions be made by individual patients and their doctors. Since medical monitoring would cost more than medical care, I think that it is appropriate that medical monitoring be shifted into medical care. Decisions about medical monitoring can be made by physicians and patients together without a rigid set of federal guidelines and rules.

Therefore, the solution to medical monitoring is medical care. I suggest that medical care could be provided by establishing a special class of radiation victims and qualifying them automatically for Medicare. In addition, the Department of Energy or the government could offer to pay the co-pay for this class and thus offer them a little bit more than they otherwise would get.

Arguments for you:

1. This won't cost the government much. Most of these people are already on Medicare.
2. It deals with all of the pros and cons of medical monitoring given that the decisions on this are not clear. It is of course, ridiculous to wait for the medical community to decide what is, and what is not, valuable for monitoring. Thus the decision is appropriately left up to the physician and their patient. This is particularly true with this class of patients that has already been abused. They must be allowed to have as much impact on the decision making process as possible.

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3. Research on the possible health outcomes of the population could also be done. I think that this must be done with a joint research establishment where the victims groups pick at least half of the researchers, and the government, the other half. As much as possible, this should be done through record reviews only. Because this is such a special class that already feels abused, I think that in the case of those experiments and their follow-up for research purposes, additional individual permission must be obtained, prior to even an epidemiologic study on publically available data.

Administrative Mechanisms: Because preventive activities are generally not covered by Medicare, I suggest that a special code be developed that could be used only with patient who qualified under administrative criteria set up by the President. People who qualify under this code would qualify for certain specific procedures to be reimbursed, such as echo's of the thyroid or testicle. I do not think that other special procedures should be recommended. Normally, Medicare would not cover screening tests. Thus, this special code would allow these to be done.

In my opinion, the recommendations of the committee regarding who should be offered medical care must be turned on their head. That is, the committee concluded that when there is proven harm, people should qualify for medical follow-up. In my opinion, the burden of proof lies with the government; all victims of government radiation experiments should qualify for medical follow up unless the government can prove beyond reasonable doubt that no additional harm came to the person as a result of the experiment. Those individuals who do not qualify for medical care as a benefit should receive an apology and notification when ever that is possible. I personally would define no harm as a dose of radiation that was not above average background of 150 millirem per year. I believe that most of the boys with their toys experiments qualify as part of this class. I do not think that there would be any political problem in establishing this distinction. On the other hand, when radioactive tracers at or above the background were administered or when the experiment had a non-medical purpose even in part or when we are sure that there was harm, as in Vanderbilt, the victims should qualify for medical care and compensation.

Solution #2. Notification.

All individuals should be notified that they were used as guinea pigs and an apology should be given to them.

Political reasons for this:

1. This is the unethical obligation.
2. This criteria for notification is established and implemented by NIOSH. NIOSH is the only agency that has dealt with this problem thus far in the government. It should be easy for the government to argue that the method is the one that should be applied in this case, as well. It is a standard method used by another agency. In fact any contrary policy should be discarded because it conflicts with established precedent.

In addition to notification, a particular support mechanism should be established for psychological counseling. NIOSH notification policy includes a mechanism for this. , Prior to release of study findings NIOSH, meets with local physicians and health departments and establishes a help line for

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the physicians and the patients so that people can get care. As part of the notification, people could be given qualifications statement under Medicare that they could see their own physicians for counseling, if appropriate. I would suggest that state by state or regional professionals be hired by the Department of Energy, (this would not cost too much either) to assist the physicians or psychiatrists in explaining the nature of the risk and the remedies, etc. This would be slightly more than what NIOSH does, but I think that there is an additional ethical obligation to do slightly more, given the fact that these experiments were not voluntary.

Solution #3. Participation of Victims.

I think that the Inter Agency Working Group needs some staff to help them in their work. I can think of no better staff with better experience in locating the records or in evaluating data than the victims themselves. I think that jobs should be posted and applications taken and that the staff on the Inter Agency Working Groups be composed primarily, if not exclusively, of victims (not even their representatives). There is great precedent for this. There are many unions and communities who have educated their members in the methods for epidemiologic studies. The group members have subsequently carried out epidemiologic studies. There is, in fact, a therapeutic benefit to this. This can be part of the therapeutic process. People need to feel that something was gained as a result of the experiments. Thus, the victims and other victims through the victims who are actually working on the project would feel fulfillment in that they themselves were participating in closure of the issue. I do not think that there would be any administrative bar to this. I do not think that there is any ethical problems with this and I think that it is quite reasonable approach.

Disclaimer: the views expressed are my own and do not represent those of the task force, CARS or any other being human or otherwise dead or alive. In fact to paraphrase Feyrabund, I may not agree with them myself in five or ten minutes.

Sincerely yours,

David Egilman MD, MPH

David Egilman, MD, MPH

RECEIVED IN DWB

PROPOSED MODEL FOR PROCESSING HUMAN RADIATION EXPERIMENT CLAIMS
FOR COMPENSATION

Background -- The Advisory Committee Report: In its Final Report, which was presented to the President on October 3, 1995, the Advisory Committee on Human Radiation Experiments recommended that the government provide an apology and financial compensation to the subjects (or their next of kin) of experiments in which efforts were made by the government to keep information secret for the purpose of avoiding embarrassment or potential legal liability, and where the secrecy had the effect of denying individuals the opportunity to pursue potential grievances. In addition, the Advisory Committee recommended an apology and compensation to the subjects or their surviving immediate family members for experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted. The Advisory Committee identified several categories of experiments as candidates for compensation under each recommendation.

The President's Response: Upon accepting the Advisory Committee's Final Report, the President extended the Nation's apology to the experiment subjects and their families and directed his Cabinet to use and build on the Advisory Committee's recommendations to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience. Thus, the charge to the Human Radiation Interagency Group was to identify a process by which the government may consider claims for compensation for subjects of human radiation experiments identified by the Advisory Committee on Human Radiation Experiments.

A Process for Implementation: The Human Radiation Interagency Working Group has worked to develop a process through which the government can consider compensation claims and has determined that the Federal Tort Claims Act (FTCA) -- and in particular, the administrative claims process of the FTCA, 28 U.S.C. §2672 -- is the most efficient and immediately available system of relief for persons who allege physical injury as a result of their participation in human radiation experiments. The FTCA has been the Nation's vehicle for compensation of personal injury claims against the government for the past half century. Indeed, even before the Advisory Committee had issued its Final Report, several alleged subjects of human radiation experiments or members of their families had proceeded under the FTCA in pursuit of their claims for compensation, and the United States has taken the initiative to resolve those claims in a just and compassionate manner.

I. SUMMARY OF ADMINISTRATIVE CLAIMS PROCESS AS IT APPLIES TO HUMAN RADIATION EXPERIMENT CLAIMS

A. The Federal Tort Claims Act Claims Process Overview

The administrative claim process under the Federal Tort Claims Act is straightforward and facilitates the prompt consideration of claims for personal injuries. The burden on a claimant is minimal, involving the completion of a standard form that identifies the essential information that must be provided to initiate the claim. Also, the process is well understood by the federal agencies to which claims will be presented; and experienced personnel are already in place to process the claims, inform claimants of any additional information that is required to support the claims, and ensure that meritorious claims receive prompt and just adjudication. Finally, a claimant who is dissatisfied with the agency's decision on his claim retains the option of pursuing his case in federal court. Indeed, even if a claimant elects to pursue his claim through a lawsuit, the opportunity for resolution of the claim without full litigation exists because the government's willingness to engage in settlement negotiations or alternative dispute resolution.

B. Teamwork Approach to Human Radiation Experiment Claims Processing

The effectiveness of the Federal Tort Claims Act process as a vehicle for resolution of human radiation experiment claims has been enhanced by involvement of legal counsel from the key agencies, who are intimately familiar with the history of human radiation experiments and who participated in the work of the Human Radiation Interagency Working Group. Teams comprised of agency attorneys and Department of Justice attorneys have given priority to resolving the human radiation experiment claims in a prompt and just manner. In addition, because some experiments were conducted by independent contractors who have been indemnified by a federal agency, the government teams have been able to augment the Federal Tort Claims process by calling upon the indemnified contractors also to participate in settlement discussions, enhancing the prospect for claims resolution.

In furtherance of the Administration's commitment to providing relief for persons harmed in the human radiation experiments, the government has already taken the initiative to offer monetary settlements to claimants who elected early to pursue their claims under the Federal Tort Claims Act. In short, the government already has in place a well established system for relief, which affords multiple opportunities for just resolution of claims arising from human radiation experiments.

C. The Claims Process, Procedural Steps

Any person seeking financial compensation from the United States for physical injuries caused by the negligent or wrongful act or omission of an employee of a federal agency acting within the scope of his office or employment must present his claim in writing to the federal agency for which the employee worked.

In the case of human radiation experiments, which may have been conducted decades ago, the employee that the claimant alleges to have acted negligently or wrongfully may have worked for a federal agency that no longer exists or that has changed its name. For instance, the employee may have worked for a predecessor agency of the Department of Energy, such as the Atomic Energy Commission, or of the Department of Defense, or the Department of Health and Human Services. In those circumstances, the successor agency is the proper agency to which the claim should be presented. Personnel from every agency participating in the Interagency Working Group have been instructed to give priority to any human radiation experiment administrative claims to ensure that claims are presented to the proper agency and are coordinated with the Department of Justice to ensure fair and consistent consideration of the claims.

It is important to note that the United States may only provide compensation under the Federal Tort Claims Act for the conduct of an employee of a federal agency, a term which does not include any contractor with the United States. Thus, a claim must be based on the alleged negligent or wrongful conduct of a federal employee in order for the claim to be considered. Claimants will be informed if their claim does not involve wrongful conduct of a government employee. However, in certain cases involving the conduct of private institutions or individuals that were indemnified by a federal agency such as the Department of Energy, the government may jointly pursue settlement on behalf of both the United States and the indemnified contractor.

If a judgment is rendered against the United States, or a claim is settled by the government for an amount over \$2,500, the successful claimant is paid from the Judgment Fund, a continuing appropriation dedicated to payment of judgments and settlement of claims against the United States. If a private institution or individual indemnified by a federal agency settles a claim, or a judgment is taken against the institution or individual, the settlement or judgment amount is reimbursed by the indemnifying agency from the agency's appropriated funds.

A standard form (Standard Form 95) is available from all federal agencies for a claimant to file a claim. That form (a copy of which is attached) is a simple, two-sided document that contains instructions to a claimant or a claimant's personal

representative concerning the basic information that is required to initiate the claims process. Claimants are free to use additional pages, if necessary, to state in detail the facts and circumstances concerning the claimed injury. In essence, a claimant is required to provide the agency with a sum-certain amount of damages sought for the claimed injury and sufficient information to provide the agency a basis to investigate the claim.

In general, agencies will follow a simplified claims process that can result in offers of compensation if the subject participated in a human radiation experiment in which a government agency was involved in actions falling with the criteria outlined by the Advisory Committee on Human Radiation Experiments. As needed, the agencies will seek expert advice on scientific and medical issues to resolve the claims.

Since harm to an experiment subject will likely be a significant issue in connection with many human radiation experiment claims, medical information will be needed to offer relief in these cases. Thus, a claimant can expedite consideration of a claim by providing medical records or other available medical information at the outset. If the agency requires additional information to process the claim, it may contact the claimant or his representative and request the needed information.

The federal agency to which the claim has been presented is allowed up to six months within which to investigate and make a final disposition of a claim before a lawsuit may be filed. The agency is allowed this initial six-month period to consider the claim and decide whether to adjust, compromise, settle, or deny the claim. Because radiation experiment claims involve questions of policy, agencies are required to consult with the Department of Justice before they may be settled.

Claims presented in connection with the human radiation experiments already investigated by the Advisory Committee can be addressed in less than six months. Indeed, settlement negotiations are already underway in connection with a number of those claims. If any claims are filed in connection with alleged human radiation experiments that were not among those studied by the Advisory Committee on Human Radiation Experiments, investigation and consideration of those claims could require more than six months before a final determination can be made. The additional time might be required to conduct searches of government or private archives in order to establish the government's role in connection with the alleged experiment and the nature and extent of a subject's participation in the experiment and any evidence of resulting injury. In light of the broad expanse of the Advisory Committee's investigation, few additional experiments are likely to result in claims.

In all cases, the claimant is not required to file suit at the expiration of the initial six-month period if the federal agency has not made a final determination of the claim. Once a claim has been filed, the claimant may await the agency's decision. On the other hand, the claimant may, at his option, deem the claim finally denied six months after the claim was filed with the appropriate agency and may then file an action in federal court.

Denial of a claim must be in writing and sent by certified or registered mail. If the agency does finally deny a claim, the claimant must file suit within six months of the denial or the claim is forever barred. An award of compensation in response to a claim constitutes satisfaction of the government's liability, and the matter is terminated without any litigation.

D. Standards for Consideration of Human Radiation Experiment Claims

The Administration has embraced the recommendations of the Advisory Committee on Human Radiation Experiments and has made a commitment to consider the claims of experiment subjects or their families under a system that -- in the President's words -- meets the standards of justice and conscience. Accordingly, every human radiation experiment claim presented (including the claims of persons who had previously sued the United States even before the Advisory Committee's Final Report) will be reviewed by the federal agency to which the claim is presented and by representatives of the Department of Justice for a determination of whether the claim meets the standards articulated by the Advisory Committee in its recommendations and can be compensated under existing law.

In general, the criteria to be applied by the agencies will be that reasonable compensation will be offered, to the extent legally permissible, to an experiment subject (or surviving family member) if the subject participated in a human radiation experiment in which a government agency was involved in actions falling within the following criteria outlined by the Advisory Committee:

1. Experiments in which excessive secrecy deprived individuals the opportunity to pursue potential grievances; or
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which the interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

Conclusion

The affected federal agencies and Department of Justice will pursue fair and reasonable compensation for persons whose claims meet the standards of the Advisory Committee and the requirements of justice. The Administration has voiced its commitment to providing reasonable compensation to injured parties to the extent permitted by law. In reviewing any claim, the agencies will give great weight to the Advisory Committee recommendations and do as much as possible under the law to provide relief for human radiation experiment subjects. Every effort will be made to offer compensation through settlement negotiations or use of alternative dispute resolution in appropriate cases so that needless litigation can be avoided. If persons were harmed by their participation in federally conducted or sponsored human radiation experiments but compensation may not be provided under current law, we will so inform the claimants and notify representatives of the Administration so that support for legislative relief may be pursued in appropriate cases.

DRAFT*Pat Glynn*

**APPLICATION OF FEDERAL TORT CLAIMS ACT PROCEDURES
TO HUMAN RADIATION EXPERIMENT CLAIMS FOR COMPENSATION**

In its Final Report, which was presented to the President on October 3, 1995, the Advisory Committee on Human Radiation Experiments recommended that the government provide an apology and financial compensation to the subjects (or their next of kin) of experiments in which efforts were made by the government to keep information secret for the purpose of avoiding embarrassment or potential legal liability, and where the secrecy had the effect of denying individuals the opportunity to pursue potential grievances. The Advisory Committee identified 18 subjects of plutonium injection experiments conducted in the mid-1940s as candidates for compensation under this recommendation. In addition, the Advisory Committee recommended an apology and compensation to the subjects or their surviving immediate family members for experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted. In addition to the plutonium injection cases, to the extent that a subject allegedly was injured as a result of the experiment, the Advisory Committee identified several additional categories of experiments as candidates for compensation under this recommendation.

receiving Upon accepting the Advisory Committee's Final Report, the President extended the Nation's apology to the experiment subjects and their families and directed his Cabinet to use and build on the Advisory Committee's recommendations to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience. Thus, the charge to the Human Radiation Interagency Group was to identify a process by which the government may consider claims for compensation for subjects of human radiation experiments identified by the Advisory Committee on Human Radiation Experiments.

The Human Radiation Interagency Working Group has worked to develop a process through which the government can consider compensation claims and has determined that the Federal Tort Claims Act (FTCA) -- and in particular, the administrative claims process of the FTCA, 28 U.S.C. §2672 -- is the most efficient and immediately available system of relief for persons who allege physical injury as a result of their participation in human radiation experiments. The FTCA has been the Nation's vehicle for compensation of personal injury claims against the government for the past half century. Indeed, even before the Advisory Committee had issued its Final Report, several alleged subjects of human radiation experiments or members of their families had proceeded under the FTCA in pursuit of their claims for compensation.

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SUMMARY OF ADMINISTRATIVE CLAIMS PROCESS AS IT APPLIES TO HUMAN RADIATION EXPERIMENT CLAIMS

problem road block

The administrative claim process under the Federal Tort Claims Act is straightforward and facilitates the prompt consideration of claims for personal injuries. The burden on a claimant is minimal, involving the completion of a standard form that identifies the essential information that must be provided to initiate the claim. Also, the process is well understood by the federal agencies to which claims will be presented, and experienced personnel are already in place to process the claims, inform claimants of any additional information that is required to support the claims, and ensure that meritorious claims receive prompt and just adjudication. Finally, a claimant who is dissatisfied with the agency's decision on his claim retains the option of pursuing his case in federal court. Indeed, even if a claimant elects to pursue his claim through a lawsuit, the opportunity for resolution of the claim without full litigation exists because the government's willingness to engage in settlement negotiations or alternative dispute resolution.

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Consistently with the Administration's commitment to providing relief for persons harmed in the human radiation experiments, the government has already taken the initiative to offer monetary settlements in the plutonium injection cases to claimants who elected to proceed with lawsuits. In short, the Federal Tort Claims Act is a well established system for relief, which affords multiple opportunities for just resolution of claims arising from human radiation experiments.

Employees or former employees The Claims Process

Any person seeking financial compensation from the United States for physical injuries caused by the negligent or wrongful act or omission of an employee of a federal agency acting within the scope of his office or employment must present his claim in writing to the federal agency for which the employee worked.

In the case of human radiation experiments, which may have been conducted decades ago, the employee that the claimant alleges to have acted negligently or wrongfully may have worked for a federal agency that no longer exists or that has changed its name. For instance, the employee may have worked for a predecessor agency of the Department of Energy, such as the Atomic Energy Commission, or of the Department of Defense, or the Department of Health and Human Services. In those circumstances, the successor agency is the proper agency to which the claim should be presented. Personnel from every agency participating in the Interagency Working Group have been instructed to give priority to any human radiation experiment administrative claims to ensure that claims are presented to the proper agency and are

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coordinated with the Department of Justice to ensure fair and consistent consideration of the claims.

It is important to note that the United States may only provide compensation for the conduct of an employee of a federal agency, a term which does not include any contractor with the United States. Thus, a claim must be based on the alleged negligent or wrongful conduct of a federal employee in order for the claim to be considered. Claimants will be informed if their claim does not involve wrongful conduct of a government employee.

A standard form (Standard Form 95) is available from all federal agencies for a claimant to file a claim. That form (a copy of which is attached) is a simple, two-sided document that contains instructions to a claimant or a claimant's personal representative concerning the basic information that is required to initiate the claims process. Claimants are free to use additional pages, if necessary, to state in detail the facts and circumstances concerning the claimed injury. In essence, a claimant is required to provide the agency with a sum-certain amount of damages sought for the claimed injury and sufficient information to provide the agency a basis to investigate the claim.

Since harm to an experiment subject will likely be the most significant issue in connection with any human radiation experiment claim, medical information will be needed to offer relief in these cases. Thus, a claimant can expedite consideration of a claim by providing medical records or other available medical information at the outset. If the agency requires additional information to process the claim, it may contact the claimant or his representative and request the needed information.

★ The federal agency to which the claim has been presented is allowed up to six months within which to investigate and make a final disposition of a claim before a lawsuit may be filed. The agency is allowed this initial six month period to consider the claim and decide whether to adjust, compromise, settle, or deny the claim. In general, agencies will follow a simplified claims process that can result in offers of compensation if the subject participated in a human radiation experiment in which a government agency was involved in actions falling within the criteria outlined by the Advisory Committee on Human Radiation Experiments. As needed, the agencies will seek expert advice on scientific and medical issues to resolve the claims. The agency may contact the claimant during its investigation to request additional information or in an effort to settle the claim.

Claims presented in connection with the human radiation experiments already investigated by the Advisory Committee can be addressed in less than six months. Generally, for experiments

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involving government misconduct, the key questions will involve the injury assessment, which will require review of medical data submitted by the claimant or gathered by the agency. Investigation and consideration of other claims might require more than six months before a final determination can be made. For instance, a claim that might be filed in connection with an alleged human radiation experiment that was not one of those studied by the Advisory Committee on Human Radiation Experiments could require extensive searches of government or private archives in order to establish the government's role in connection with the alleged experiment and the nature and extent of a subject's participation in the experiment and any evidence of resulting injury. In those cases, the claimant is not required to file suit at the expiration of the initial six-month period if the federal agency has not made a final determination of the claim; but the claimant may, at his option, deem the claim finally denied six months after the claim was filed with the appropriate agency and may then file an action in federal court.

Denial of a claim must be in writing and sent by certified or registered mail. If the agency does finally deny a claim, the claimant must file suit within six months of the denial or the claim is forever barred. An award of compensation in response to a claim constitutes satisfaction of the government's liability, and the matter is terminated without any litigation.

Consideration of Human Radiation Experiment Claims

The Administration has embraced the recommendations of the Advisory Committee on Human Radiation Experiments and has made a commitment to consider the claims of experiment subjects or their families under a system that -- in the President's words -- meets the standards of justice and conscience. Accordingly, every human radiation experiment claim presented (including the claims of persons who had previously sued the United States even before the Advisory Committee's Final Report) will be reviewed by the federal agency to which the claim is presented and by representatives of the Department of Justice for a determination of whether the claim meets the standards articulated by the Advisory Committee in its recommendations and can be compensated under existing law.

The affected federal agencies and Department of Justice will pursue fair and reasonable compensation for persons whose claims meet the standards of the Advisory Committee and the requirements of justice. The Administration has voiced its commitment to providing reasonable compensation to injured parties to extent permitted by law. In reviewing any claim, the agencies will give great weight to the Advisory Committee recommendations and do as much as possible under the law to provide relief for human radiation experiment subjects. Every effort will be made to offer compensation through settlement negotiations or use of

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alternative dispute resolution in appropriate cases so that
needless litigation can be avoided. if persons were harmed by
their participation in federally conducted or sponsored human
radiation experiments but compensation may not be provided under
current law, we will so inform the claimants and notify
representatives of the Administration so that support for
legislative relief may be pursued in appropriate cases.

**CLAIM FOR DAMAGE,
INJURY, OR DEATH**

INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions.

FORM APPROVED
OMB NO.
1105-0008

1. Submit To Appropriate Federal Agency:

2. Name, Address of claimant and claimant's personal representative, if any.
(See instructions on reverse.) (Number, street, city, State and Zip Code)

3. TYPE OF EMPLOYMENT

☐ MILITARY ☐ CIVILIAN

4. DATE OF BIRTH

5. MARITAL STATUS

6. DATE AND DAY OF ACCIDENT

7. TIME (A.M. OR P.M.)

8. Basis of Claim: (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof) (Use additional pages if necessary.)

9.

PROPERTY DAMAGE

NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, street, city, State, and Zip Code)

BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF DAMAGE AND THE LOCATION WHERE PROPERTY MAY BE INSPECTED. (See instructions on reverse side.)

10.

PERSONAL INJURY/WRONGFUL DEATH

STATE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE NAME OF INJURED PERSON OR DECEDENT.

11.

WITNESSES

NAME

ADDRESS (Number, street, city, State, and Zip Code)

12. (See instructions on reverse)

AMOUNT OF CLAIM (in dollars)

12a. PROPERTY DAMAGE

12b. PERSONAL INJURY

12c. WRONGFUL DEATH

12d. TOTAL. (Failure to specify may cause forfeiture of your rights.)

I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE ACCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM

13a. SIGNATURE OF CLAIMANT (See instructions on reverse side.)

13b. Phone number of signatory

14. DATE OF CLAIM

**CIVIL PENALTY FOR PRESENTING
FRAUDULENT CLAIM**

The claimant shall forfeit and pay to the United States the sum of \$2,000, plus double the amount of damages sustained by the United States. (See 31 U.S.C. 3729.)

**CRIMINAL PENALTY FOR PRESENTING FRAUDULENT
CLAIM OR MAKING FALSE STATEMENTS**

Fine or not more than \$10,000 or imprisonment for not more than 5 years or both. (See 18 U.S.C. 287, 1001.)

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Previous editions not usable.

NSN 7540-00-834 4046

STANDARD FORM 95 (Rev. 7-85)
PRESCRIBED BY DEPT. OF JUSTICE
28 CFR 14.2

This Notice is provided in accordance with the Privacy Act, 5 U.S.C. 552a(e)(3), and concerns the information requested in the letter to which this Notice is attached.
A. Authority: The requested information is withheld pursuant to one or more of the following: 5 U.S.C. 301, 28 U.S.C. 501 et seq., 28 U.S.C. 2671 et seq., 28 C.F.R. Part 14.

- B. Principal Purpose:** The information requested is to be used in evaluating claims.
C. Routine Use: See the Notices of Systems of Records for the agency to whom you are submitting this form for this information.
D. Effect of Failure to Respond: Disclosure is voluntary. However, failure to supply the requested information or to execute the form may render your claim "invalid".

INSTRUCTIONS

Complete all items - Insert the word NONE where applicable
 A CLAIM SHALL BE DEEMED TO HAVE BEEN PRESENTED WHEN A FEDERAL AGENCY RECEIVES FROM A CLAIMANT, HIS DULY AUTHORIZED AGENT, OR LEGAL REPRESENTATIVE AN EXECUTED STANDARD FORM 95 OR OTHER WRITTEN NOTIFICATION OF AN INCIDENT, ACCOMPANIED BY A CLAIM FOR MONEY DAMAGES IN A SUM CERTAIN FOR INJURY TO OR LOSS OF

Any instructions or information necessary in the preparation of your claim will be furnished, upon request, by the office indicated in item #1 on the reverse side. Complete regulations pertaining to claims asserted under the Federal Tort Claims Act can be found in Title 28, Code of Federal Regulations, Part 14. Many agencies have published supplemental regulations also. If more than one agency is involved, please state each agency.

No claim may be filed by a duly authorized agent or other legal representative, provided evidence satisfactory to the Government is submitted with said claim establishing express authority to act for the claimant. A claim presented by an agent or legal representative must be presented in the name of the claimant. If the claim is signed by the agent or legal representative, it must show the title or legal capacity of the person signing and be accompanied by evidence of his/her authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian or other representative.

If claimant intends to file claim for both personal injury and property damage, claim for both must be shown in item 12 of this form.

The amount claimed should be substantiated by competent evidence as follows:
 (a) In support of the claim for personal injury or death, the claimant should submit a written report by the attending physician, showing the nature and extent of injury, the nature and extent of treatment, the degree of permanent disability, if any, the prognosis, and the period of hospitalization, or incapacitation, attaching itemized bills for medical, hospital, or burial expenses actually incurred.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden.

to Director, Tort Branch
 Civil Division
 U.S. Department of Justice
 Washington, DC 20530

and in the
 Office of Management and Budget
 Paperwork Reduction Project (105-0008)
 Washington, DC 20503

INSURANCE COVERAGE

In order that subrogation claims may be adjudicated, it is essential that the claimant provide the following information regarding the insurance coverage of his vehicle or property.
 15. Do you carry accident insurance? ☐ Yes, if yes, give name and address of insurance company (Number, street, city, State, and Zip Code) and policy number. ☐ No

16. Have you filed claim on your insurance carrier in this instance, and if so, is it full coverage or deductible?

17. If deductible, state amount

18. If claim has been filed with your carrier, what action has your insurer taken or proposes to take with reference to your claim? (If necessary that you ascertain these facts)

19. Do you carry public liability and property damage insurance? ☐ Yes, if yes, give name and address of insurance carrier (Number, street, city, State, and Zip Code) ☐ No

PROPOSED GOVERNMENT RESPONSES TO RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Background

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The Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the committee was charged to provide expert advice to the Cabinet-level Interagency Working Group on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

Final Report of the Advisory Committee

The committee's report, currently in near-final form, begins by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" are then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environmental releases of radioactivity are also reviewed.

The committee also considered issues related to some radiation exposures associated with government activity that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

Advisory Committee Recommendations

The Committee's recommendations fall into the following three major areas:

- **Biomedical Experiments and Population Exposures, 1944-1974**

- **Current Human Subject Protection**
- **Secrecy and Openness**

Government Response to Recommendations

A group of representatives from all agencies represented in the Interagency Working Group, including the Departments of Energy, Defense, Health and Human Services, Veterans Affairs, and Justice, the National Aeronautics and Space Administration, and the Central Intelligence Agency, with participation by the Office of Management and Budget and the White House Office of Science and Technology Policy, has been meeting over the past month to consider government-wide options to address the recommendations of the Advisory Committee. This group divided into three subcommittees paralleling the three major areas of the Advisory Committee's recommendations. Each subcommittee developed options, which were presented to the entire group for discussion. The options covered the entire range of potential government responses, from those that agencies can take individually and in cooperation, to those that call for Presidential action.

The following three packages - one from each subcommittee - represent the consensus view of the group of agency representatives.

Remedies Subcommittee

PROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES FROM 1944 - 1974

SUMMARY

The responses described in the following pages address the findings and recommendations of the Advisory Committee on Human Radiation Experiments dealing with experiments and population exposures in the period 1944-1974, recommendations one (1) through seven (7). These recommendations are still undergoing revision by the committee and the proposed responses must therefore be considered as subject to change.

While the committee has not identified cases where subjects were physically harmed, it has identified a small number of cases occurring during WW II (less than 25 in total) where the government deliberately kept the true nature of the experiments from the subjects. In those cases, the committee recommends compensation to surviving family members.

The committee also considered issues related to some radiation exposures associated with government activity that were not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners and residents of the Marshall Islands exposed to the fallout from a 1954 nuclear weapons test. The committee's major recommendation for these groups is that existing laws governing compensation should be reexamined to assure fairness and equity.

The proposed responses described in more detail below would endorse the basic thrust of the committee's recommendations, including:

- An apology and a commitment to work with Congress to secure compensation commensurate with the violation of dignity in the case of the plutonium injection subjects and others identified by the committee who were treated similarly;
- Review of the standards governing compensation of uranium miners and the administration of laws governing compensation of atomic veterans;
- Review of whether new data call for expanding the scope of medical

programs for Marshall Islanders.

**PROPOSED GOVERNMENT RESPONSES TO ADVISORY COMMITTEE
RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND
POPULATION EXPOSURES FROM 1944 - 1974**

RECOMMENDATION 1

The Advisory Committee recommends to the Interagency Working Group that the government deliver a personal, individualized apology and provide financial compensation to the subjects of human radiation experiments in which efforts were made by the government to keep information secret from these individuals and from the public for the purpose of avoiding embarrassment and/or potential legal liability, and where this secrecy had the effect of denying individuals the opportunity to pursue alleged grievances.

RECOMMENDED GOVERNMENT RESPONSE

Work with Congress to pass legislation to apologize and compensate the affected families for any dignitary harm that may have been suffered by the subjects of the experiments, either because the subjects' consent was not adequately obtained, or the government improperly denied the subjects and their families an opportunity to pursue legal redress.

Compensation would be commensurate with amounts paid to other groups that Congress has previously compensated for similar harms. (Japanese internees were paid \$20,000 in 1988).

Claimants would be required to release claims of dignitary harm against the government, its contractors and their employees in exchange for the compensation. However, the proposed legislation would explicitly preserve any existing or future claim of physical harm resulting from the experiments. [The government could also defer claims of physical harm in accordance with any decision made respecting recommendation 2.]

RECOMMENDATION 2

The Advisory Committee recommends to the Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which

intervention considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their surviving immediate family members.

[The agencies are waiting for the Advisory Committee's revised/clarified recommendation, further discussion is required.]

RECOMMENDATION 3

As of the time this report was prepared, the Advisory Committee had withdrawn these recommendations for revision. The Compensation Subcommittee will not provide response options until the nature of these recommendations is more certain.

RECOMMENDATION 4

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in geographic areas currently covered by the law may have resulted.

RECOMMENDED GOVERNMENT RESPONSE

The government agrees with the Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will consider whether existing law should be amended to cover those affected.

RECOMMENDATION 5(1)

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to ensure that the epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing are reviewed and updated so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure are clearly and unequivocally covered by the statutes.

Recommendation 5(2)

The Advisory Committee further recommends to the Interagency Working Group that it review whether existing laws governing compensation of atomic veterans are now administered in ways that produce the best balance in allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including costs of dose reconstruction.

RECOMMENDED GOVERNMENT RESPONSE

The Secretary of Veterans Administration will appoint a Working Group that will include representatives from the Department of Veteran Affairs, the Department of Health and Human Services and the Department of Defense to provide a written report to the Interagency Working Group by January 31, 1995. The report will

- Recommend that most feasible way to accomplish updating the epidemiological tables to develop a budget request for the President's FY 1997 budget;
- Describe the administration of laws governing compensation of Atomic Veterans; and
- Recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

RECOMMENDATION 6

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners to provide compensation to all miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be

reviewed to determine whether compensation should be extended to include uranium millers, and documentation standards or all claimants should be liberalized.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that the provisions of the Radiation Exposure Compensation Act (RECA) relating to uranium miners should be reviewed to ensure that they are fair, comparable to compensation standards for other radiation-exposed populations and consistent with current scientific data. The Administration will establish a committee of governmental and non-governmental experts to review these issues as well as the Department of Justice's implementing regulations under RECA. The committee will be asked to complete its review within 6 months. Based on the committee's findings, the Administration will work with Congress to enact appropriate statutory changes and amend the existing regulations under RECA.

[hold uranium millers discussion to see if recommendation remains in report]

RECOMMENDATION 7

The Advisory Committee supports the Department of Energy's program of Medical monitoring and treatment for the exposed inhabitants of the Marshall Islands atolls of Rongelap and Utirik, and recommends that this program be continued as long as any member of the exposed population remains alive. Furthermore, the Advisory Committee recommends that the program be reviewed to determine if it is appropriate to add to the program the population of Ailuk, and the population of other atolls whose inhabitants may have been received exposure comparable to or greater than those of Ailuk. The Advisory Committee also recommends that consideration be given to the involvement of the Marshall Islanders in the design of any further medical research to be conducted upon them.

RECOMMENDED GOVERNMENT RESPONSE

Extensive analyses of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other atolls were substantially less than exposures on Rongelap and Utirik. However, the Department of Energy will undertake a review of available information, including any new data that has been developed, to determine whether a reconsideration of radiation exposures on Ailuk and other atolls is warranted.

Summary of Responses to ACHRE Recommendations 8-13

The responses that have been developed on the following pages to address Recommendations 8 through 13 of the Advisory Committee on Human Radiation Experiments (ACHRE) cover a broad range of approaches, some of which involve activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that can be implemented immediately while others will require some preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission, an independent body to be established by the President "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research".

Generally, the responses to the recommendations cover the following categories of activities:

- Remand specific ACHRE recommendations to the proposed National Bioethics Advisory Commission (NBAC) which will provide expert advice on issues of bioethics.
- Develop educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in nonfederally funded research with the ethical considerations in conducting research involving human subjects.
- Implement training programs within federal agencies to educate senior level officials on regulations and policies governing human subjects research, e.g., the activities proposed by the Department of Defense.
- Send official notifications to institutions conducting federally funded research (a) reminding them of their ongoing responsibilities with respect to IRB review and (b) informing them of their new responsibilities regarding additional requirements to be incorporated into the informed consent procedures and forms.
- Pool resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the Government's system for the protection of human subjects.
- Consider proposing legislation to remedy some of the gaps in the current system for protecting human subjects.

Recommendation 8

The Advisory Committee recommends to the Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

The Government has in recent years mounted several activities that address this subject. For example:

- DHHS: The National Institutes of Health (NIH) requires all institutions receiving National Research Service Award institutional training grants to provide pre- and postdoctoral trainees on these grants with instruction in the responsible conduct of research. This curriculum includes, among other things, policies on the appropriate use of human subjects and animals in research.
- DHHS: The NIH completed development of a Core Curriculum in Clinical Research to train young clinical investigators in its Clinical Center. This course, which is mandatory, includes several modules on protection of human subjects and a specific module on bioethics.
- NASA: Established an external Bioethics Task Force to review NASA procedures for all experimentation involving human subjects and to recommend appropriate policy changes. Report to be issued in fall 1995.
- DOE: Holds educational regulatory and bioethics update meetings for the entire DOE system (to which other federal agencies are also invited).
- DOD: Convenes an annual Tri-Service Clinical Investigations Postgraduate Short Course, generally attended by 200-300 physicians, scientists, nurses, pharmacists and other research support personnel, that emphasizes contemporary human subjects protection issues.
- DOE: Has computerized and established worldwide web access to the Department's human subjects newsletter, resource manual and database.
- DOD: Requires investigators' familiarity with the Belmont Report, the Common Rule, DOD Directives and all applicable regulations and instructions through the assurance process with each facility.
- VA: Has established a special office to conduct random site visits to VA medical centers to review local implementation of national VA policy for the protection of human subjects.

Response

- (a) A major effort will be launched to "upgrade" or expand these activities. These will consist of:
- DHHS: The NIH Clinical Center Clinical Bioethics Program will be expanded and additional resources will be provided, including an SES position, FTEs and space. Following implementation and assessment in the NIH Clinical Center, the Core Curriculum in Clinical Research may be offered to trainees in extramural institutions and/or further disseminated by publication of the syllabus or making it available on the Internet.
 - DOE: Will be requiring educational/ethics updates from all DOE institutions that are involved with human subjects research. Will be establishing an educational plan for all IRBs beginning in FY 1996.
 - DOD: Will adopt the investigator assurances of familiarity with the Belmont Report, the Common Rule and related requirements as a standard for all activities involving human subjects research. Will incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals.
 - NASA: Works with international partners to enhance the ethical training and understanding of all investigators involved in space-related human research and to ensure an transnational sensitivity to ethical issues in human subjects research.
- (b) Invite associations of medical schools and universities as well as scientific societies to join with the Government in launching a broad initiative to heighten the consciousness of the research community with respect to ethics of human subjects research. These might include the expansion of existing university-based research ethics programs and convening workshops in conjunction with the annual meetings of these different organizations.
- (c) OPRR can convene, in conjunction with its counterparts in the other federal agencies, 2-3 regional workshops of IRB chairpersons to allow for the exchange of ideas/approaches, to stimulate the discussions of common problems and to address emerging issues in the arena of human subjects protection.

- (d) The President can announce that he will be signing an Executive Order establishing the National Bioethics Advisory Commission (NBAC) and introduce the chairperson of the Commission.

Recommendation 9

The Advisory Committee recommends to the Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

- 1. Mechanisms for ensuring that IRBs appropriately allocate their time so as to enable adequate review of studies that pose more than minimal risk to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal risk studies.**

Response

- (a) Agencies will remind institutions and their IRBs that the current regulations provide for an expedited review process for certain categories of minimal risk research and for minor changes in ongoing research and emphasize their continued and enhanced use of this mechanism.
 - (b) Consider extending a pilot program to reduce the administrative burdens on award applicants (known at NIH as the "Just-In-Time" experiment) to include a feature that would permit IRBs to delay their review of proposed research until preliminary determinations of the proposals' competitiveness have been made by the agency.
 - (c) Ask the Human Subjects Research Subcommittee of the Health, Safety and Food Research Committee of the National Science and Technology Council to consider the implications of implementing this subrecommendation.
- 2. Mechanisms for ensuring that the information provided to potential subjects (a) clearly distinguishes research from treatment, (b) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (c) clearly explains the potential for discomfort and pain that may accompany participation in the research.**
- 3. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.**

4. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.**

Response

- (a) Implement the above three subrecommendations by instructing IRBs and investigators to address these issues in protocols and consent procedures/forms.
- (b) Announce that on October 2-3, 1995, the Department of Energy, in conjunction with the Subcommittee on Human Subjects Research, Committee on Health, Safety, Food Research & Development, National Science and Technology Council, will convene staff from all federal agencies conducting or supporting human subjects research. Federal officials will be briefed on ACHRE findings and recommendations and caucus for 2 days on at this conference. (The Subcommittee on Human Subjects Research meets bimonthly to coordinate implementation of the Federal Policy for Protection of Human Subjects and will be assessing actions to be taken by federal officials subsequent to the October 2-3 conference.)

5. **Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.**

Response

Issue an official reminder to IRBs that they already have the responsibility to review the science in research proposals to determine the appropriateness of the use of human subjects in such research, and to stress that patients participating in therapeutic research should have access to the same level of medical care that would have been available to them were they not participating in research. IRBs have the authority to call upon external resources for expertise in areas not represented by their members.

Recommendation 10

The Advisory Committee recommends to the Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Response

The National Bioethics Advisory Commission would be the ideal body to implement this recommendation. Inasmuch as the NBAC is intended "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research", this recommendation fits very appropriately with the NBAC's charter. Under provisions of the Federal Advisory Committee Act, all NBAC meetings would be open and provide for public access. (See Recommendation 8, Option d.)

Recommendation 11

The Advisory Committee recommends to the Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subjects research.

- 1. Review of policies and procedures: Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of the member of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.**

Response

DOD Directives and Military Department regulations require the voluntary and fully informed consent of any person participating as a subject in research projects sponsored or conducted by the Department, as required by 32 CFR 219 (The Common Rule).

- 2. Appreciation of regulations: Education in applicable human subjects regulations should be a routine component of the training of officers and of investigators.**

Mechanisms are needed to ensure that all officers and investigators have an adequate appreciation of all regulations (including DOD regulations and directives and Service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

Response

DOD will incorporate education in human subjects regulations into executive level training for commanders and senior leadership. DOD will also incorporate methods for providing detailed training for investigators, institutional review board members, research administrators and research support personnel.

3. **Maximizing voluntariness:** The Service Secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an *ad hoc* basis in some military research. First, that no unit officers nor noncommissioned officer (NCOs) be present at any subject recruitment session in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.

Response

- (a) DOD is revising its Directive or Military Department regulations such that officers and senior noncommissioned officers in the chain of command will not be present during research recruitment briefings. This requirement shall apply to research and development studies where briefings are given to potential subjects.
 - (b) DOD is also revising its Directive or Military Department regulations to require that an ombudsman be present at group recruitment briefings to monitor that the voluntary nature of participation is stressed and that adequate information is provided about the proposed research.
4. **Maintenance of a registry:** The Secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-

25, to maintain a registry of all volunteers in human studies and experiments conducted under Research and Development programs. Such registries serve to facilitate confirmation of participation in research by subjects and their long-term follow-up.

Response

DOD is revising its Directive on human subjects research to include a provision that each of the Military Departments establish and maintain a registry of volunteers in biomedical studies conducted under research and development programs.

Recommendation 12

The Advisory Committee recommends that the Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects -- oversight, sanctions and scope.

Response

The following three subrecommendations should be collectively referred to the National Bioethics Advisory Commission. However, *additional* strategies are also outlined below.

1. Oversight mechanisms to examine outcomes and performance.

Response

- (a) Develop an interagency grants program to stimulate the research community to propose a variety of approaches to evaluating the performance and outcomes of the Government's system for protecting the rights/interest of human subjects, e.g., the recent program announcement of the National Institute of Mental Health seeking proposals for studying the informed consent process in research subjects with mental disorders.
- (b) Strengthen the federal agency offices with responsibility for oversight of human subjects protection.
- (c) Initiate a program for evaluating the cost effectiveness of different approaches for ensuring quality control of institutional systems for protection of human subjects.
- (d) Implement the NIH study to evaluate the implementation of the federally mandated Human Subjects Protection Program, specifically the extent to which the Program provides adequate protection for the rights and well-being of human subjects.

2. Appropriateness of sanctions for violations of human subjects protection.

Response

- (a) Provide the same sanctions for violation of human subjects regulations as exist for violation of animal welfare regulations.
- (b) In the case of DOD, failure to comply with its Directives and Military Department regulations can result in administrative and judicial punishment under the Uniform Code of Military Justice.

3. Extension of human subjects protection to nonfederally funded research.

Response

- (a) Enact legislation that would extend requirements for protection of human subjects to research not funded or conducted by the Federal Government (such as most research involving assisted reproductive technologies).
- (b) Work with the American Medical Association, state medical societies and state licensing boards to launch an educational program to familiarize physicians and others engaged in nonfederally funded research with the ethical considerations in conducting human subjects research.

Recommendation 13

The Advisory Committee recommends that the federal government review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue

Response

This issue has been studied off and on over the last 20 years but, because of its complexity, has never reached resolution. With the establishment of the proposed National Bioethics Advisory Commission and the release of the ACHRE report calling for compensation of subjects involved in Cold War era radiation experiments, the time may be right for a definitive examination of the issue and development of recommendations/guidelines for compensation of

injured human subjects.

Secrecy and Openness Subcommittee

FROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON SECRECY AND OPENNESS

SUMMARY

The responses described in the following pages address the findings and recommendations of the Advisory Committee on Human Radiation Experiments in the area of secrecy and openness, recommendations 14 through 17. These fall into two general categories. First, additional safeguards are recommended for classified human subjects research and environmental oversight of classified programs. These recommendations are not limited to radiation - related research or programs. Second, the committee calls for continued progress in making government records publicly accessible .

The proposed government actions, summarized below, range from those that can be announced immediately and would apply across the government to those which will require additional development and consultation:

- Presidential directive that no waivers of full informed consent will be permitted in classified research and that the government sponsoring agency will be disclosed to potential subjects in all classified research;
- Request that EPA review whether additional steps are necessary to ensure robust environmental oversight of classified programs;
- Direct the Interagency Working Group, working with the National Archives and Records Administration, to develop an aggressive plan to increase public accessibility of government's records, including the use of new technological advances and to review policies governing access to records of contractors;
- Redesignate records related to human subjects research to prevent destruction in the future;
- High-priority review by the National Archives of CIA record-keeping system, addressing means to improve public access;
- Direct CIA to give top priority in declassification review to human subjects research records.

Secrecy and Openness Subcommittee

PROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON SECRECY AND OPENNESS

RECOMMENDATION 14a: The Advisory Committee recommends to the Interagency Working Group the adoption of a Federal policy requiring the informed consent of all human subjects of classified research, and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring Federal agency and that the project involves classified information.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs all departments and agencies that, effective immediately, there will be no federal funding of classified research where an Institutional Review Board has waived informed consent or where a determination has been made that the research is exempt from IRB review. President also directs that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects: (i) the identity of the sponsoring Federal agency, and (ii) a statement that the project involves classified information.

The National Bioethics Advisory Committee is requested to evaluate whether the federal rules governing human subjects protection should be revised to codify the President's directive.

RECOMMENDATION 14b: The Advisory Committee recommends to the Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives with security clearances, charged with determining: 1) that the proposed experiment has scientific merit; 2) that risks to subjects are acceptable and risk/benefit balance is appropriate; 3) that prospective subjects have been fully informed and participation is voluntary. Records should be kept permanently.

RECOMMENDED GOVERNMENT RESPONSE:

Institutional Review Boards ("IRB") are already required to include at least

one member not affiliated with the institution. The President directs all agencies to ensure the participation of non-government persons in review of classified research, either by establishing a dedicated panel for classified research or by ensuring that IRB members all have the necessary security clearances.

RECOMMENDATION 15a: The Advisory Committee recommends that an independent review panel be assigned the task of reviewing any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret, or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

RECOMMENDED GOVERNMENT RESPONSE:

The President indicates that EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. Creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety but the President will seek EPA's views on whether additional steps are necessary to ensure robust environmental oversight of classified facilities and programs.

RECOMMENDATION 15b: The Advisory Committee recommends to the Interagency Working Group that an appropriate government agency, currently the Environmental Protection Agency, maintain a program directed at the oversight of classified programs, with suitably cleared personnel. This program should maintain critical records, such as environmental impact statements and environmental permits permanently. The agencies subject to regulation should ensure the timely consideration of environmental impacts and oversight and the timely provision of all necessary clearances. EPA should provide regular unclassified reports to Congress describing the extent of its activities as well as any significant problems.

(The Interagency Working Group sought clarification from the Committee on the intent of this recommendation. According to the executive director, the Committee is not asking here for expansion of EPA's substantive authority under NEPA and other existing environmental laws.)

RECOMMENDED GOVERNMENT RESPONSE:

The President directs that permanent files on classified environmental impact statements and environmental review of classified activities shall be maintained by EPA.

RECOMMENDATIONS 16(1), 16(2), 16(3): The Advisory Committee recommends that the Interagency Working Group take steps to ensure the continued application of the lessons learned from the efforts to organize and make accessible to the public, and the government itself, the nations's historical records.

- (1) The most important historical collections should be entrusted to the National Archives. The agencies and the National Archives should review the extent to which this is now being done and develop policies to hasten the transfer of agency records to the National Archives.
- (2) Agencies should make readily available all existing inventories, indices, folder listings and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review and declassified versions of these finding aids should be also be made available.
- (3) The Interagency Working Group should ensure the development of policies to improve public access to records held by agencies or deposited in Federal Record Centers.

RECOMMENDED GOVERNMENT RESPONSE:

The President commends the agencies for the progress made through this project in delivering information to people. He commits the administration to continuing aggressively down the path to openness exemplified by this and other initiatives. He directs the Interagency Working Group, working with the National Archives and Records Administration, to advise him on measures to make the government's records more readily accessible to citizens, which should include consideration of the potential uses of new technology to enhance access. The Interagency Working Group should be asked to report back by a date certain within a few months.

RECOMMENDATION 16(4): The Advisory Committee recommends that agencies maintain complete records, available to the public, of document destruction.

RECOMMENDED GOVERNMENT RESPONSE:

The President should, via Executive Order, institute new policy regarding human subjects research records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained permanently by National records Centers. Disposition instruction of current records should be updated to reflect new policy with specific emphasis on enforcement of records maintenance standards at all levels.

The President also directs that all records of classified projects involving human subject testing are to be labeled "permanent retention" in all agencies. This indicates that they are of historical value, must be reviewed for declassification 25 years after their creation and should go to the National Archives at 30 years.

RECOMMENDATION 16(5): The Advisory Committee recommends that the Interagency Working Group review and develop policies concerning public access to records generated or held by private contractors and institutions receiving Federal funding.

RECOMMENDED GOVERNMENT RESPONSE

The President directs the Interagency Working Group to develop guidelines for performing the policy review called for by this recommendation. The President also directs the Departments of Justice and State to review existing laws and regulations related to the implementation of this recommendation.

RECOMMENDATION 17a: The Advisory Committee recommends that the CIA's recordkeeping system be reviewed to ensure that records are accessible upon legitimate request from the public or governmental sources.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs the National Archives and Records Administration to give priority to its review of CIA's records system that is scheduled for October 1995. NARA is specifically directed to address means to improve public access to the agency's records.

RECOMMENDATION 17b: The Advisory Committee recommends that all CIA records bearing on programs of secret human research, such as MKULTRA and the related CIA human behavior projects from the late 1940s through the early 1970s, become a top priority for declassification review, with the expectation that most, if not all, of these documents can be declassified and made available to the public.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs CIA, as part of its compliance with the Executive Order 12958, to give top priority to declassification review of records related to human subject research.



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January 31, 1996

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No. of Pages (Including cover sheet):

9

TO: Phil Caplan

FAX #: 456-2215

Steve Neuwirth

456-1647

FROM: J. PATRICK GLYNN, Director TEL #: 202-616-4200

SPECIAL INSTRUCTION: Attached is a re-write of the memo I circulated
earlier regarding the Radiation Experiment Claims Process.

Ram
410 / 757-7041

PROPOSED MODEL FOR PROCESSING HUMAN RADIATION EXPERIMENT CLAIMS FOR COMPENSATION

Background -- The Advisory Committee Report: In its Final Report, which was presented to the President on October 3, 1995, the Advisory Committee on Human Radiation Experiments recommended that the government provide an apology and financial compensation to the subjects (or their next of kin) of experiments in which efforts were made by the government to keep information secret for the purpose of avoiding embarrassment or potential legal liability, and where the secrecy had the effect of denying individuals the opportunity to pursue potential grievances. In addition, the Advisory Committee recommended an apology and compensation to the subjects or their surviving immediate family members for experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted. The Advisory Committee identified several categories of experiments as candidates for compensation under each recommendation.

The President's Response: Upon accepting the Advisory Committee's Final Report, the President extended the Nation's apology to the experiment subjects and their families and directed his Cabinet to use and build on the Advisory Committee's recommendations to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience. Thus, the charge to the Human Radiation Interagency Group was to identify a process by which the government may consider claims for compensation for subjects of human radiation experiments identified by the Advisory Committee on Human Radiation Experiments.

A Process for Implementation: The Human Radiation Interagency Working Group has worked to develop a process through which the government can consider compensation claims and has determined that the Federal Tort Claims Act (FTCA) -- and in particular, the administrative claims process of the FTCA, 28 U.S.C. §2672 -- is the most efficient and immediately available system of relief for persons who allege physical injury as a result of their participation in human radiation experiments. The FTCA has been the Nation's vehicle for compensation of personal injury claims against the government for the past half century. Indeed, even before the Advisory Committee had issued its Final Report, several alleged subjects of human radiation experiments or members of their families had proceeded under the FTCA in pursuit of their claims for compensation, and the United States has taken the initiative to resolve those claims in a just and compassionate manner.

I. SUMMARY OF ADMINISTRATIVE CLAIMS PROCESS AS IT APPLIES TO HUMAN RADIATION EXPERIMENT CLAIMS

A. The Federal Tort Claims Act Claims Process Overview

The administrative claim process under the Federal Tort Claims Act is straightforward and facilitates the prompt consideration of claims for personal injuries. The burden on a claimant is minimal, involving the completion of a standard form that identifies the essential information that must be provided to initiate the claim. Also, the process is well understood by the federal agencies to which claims will be presented; and experienced personnel are already in place to process the claims, inform claimants of any additional information that is required to support the claims, and ensure that meritorious claims receive prompt and just adjudication. Finally, a claimant who is dissatisfied with the agency's decision on his claim retains the option of pursuing his case in federal court. Indeed, even if a claimant elects to pursue his claim through a lawsuit, the opportunity for resolution of the claim without full litigation exists because the government's willingness to engage in settlement negotiations or alternative dispute resolution.

B. Teamwork Approach to Human Radiation Experiment Claims Processing

The effectiveness of the Federal Tort Claims Act process as a vehicle for resolution of human radiation experiment claims has been enhanced by involvement of legal counsel from the key agencies, who are intimately familiar with the history of human radiation experiments and who participated in the work of the Human Radiation Intcragency Working Group. Teams comprised of agency attorneys and Department of Justice attorneys have given priority to resolving the human radiation experiment claims in a prompt and just manner. In addition, because some experiments were conducted by independent contractors who have been indemnified by a federal agency, the government teams have been able to augment the Federal Tort Claims process by calling upon the indemnified contractors also to participate in settlement discussions, enhancing the prospect for claims resolution.

In furtherance of the Administration's commitment to providing relief for persons harmed in the human radiation experiments, the government has already taken the initiative to offer monetary settlements to claimants who elected early to pursue their claims under the Federal Tort Claims Act. In short, the government already has in place a well established system for relief, which affords multiple opportunities for just resolution of claims arising from human radiation experiments.

C. The Claims Process, Procedural Steps

Any person seeking financial compensation from the United States for physical injuries caused by the negligent or wrongful act or omission of an employee of a federal agency acting within the scope of his office or employment must present his claim in writing to the federal agency for which the employee worked.

In the case of human radiation experiments, which may have been conducted decades ago, the employee that the claimant alleges to have acted negligently or wrongfully may have worked for a federal agency that no longer exists or that has changed its name. For instance, the employee may have worked for a predecessor agency of the Department of Energy, such as the Atomic Energy Commission, or of the Department of Defense, or the Department of Health and Human Services. In those circumstances, the successor agency is the proper agency to which the claim should be presented. Personnel from every agency participating in the Interagency Working Group have been instructed to give priority to any human radiation experiment administrative claims to ensure that claims are presented to the proper agency and are coordinated with the Department of Justice to ensure fair and consistent consideration of the claims.

It is important to note that the United States may only provide compensation under the Federal Tort Claims Act for the conduct of an employee of a federal agency, a term which does not include any contractor with the United States. Thus, a claim must be based on the alleged negligent or wrongful conduct of a federal employee in order for the claim to be considered. Claimants will be informed if their claim does not involve wrongful conduct of a government employee. However, in certain cases involving the conduct of private institutions or individuals that were indemnified by a federal agency such as the Department of Energy, the government may jointly pursue settlement on behalf of both the United States and the indemnified contractor.

If a judgment is rendered against the United States, or a claim is settled by the government for an amount over \$2,500, the successful claimant is paid from the Judgment Fund, a continuing appropriation dedicated to payment of judgments and settlement of claims against the United States. If a private institution or individual indemnified by a federal agency settles a claim, or a judgment is taken against the institution or individual, the settlement or judgment amount is reimbursed by the indemnifying agency from the agency's appropriated funds.

A standard form (Standard Form 95) is available from all federal agencies for a claimant to file a claim. That form (a copy of which is attached) is a simple, two-sided document that contains instructions to a claimant or a claimant's personal

representative concerning the basic information that is required to initiate the claims process. Claimants are free to use additional pages, if necessary, to state in detail the facts and circumstances concerning the claimed injury. In essence, a claimant is required to provide the agency with a sum-certain amount of damages sought for the claimed injury and sufficient information to provide the agency a basis to investigate the claim.

In general, agencies will follow a simplified claims process that can result in offers of compensation if the subject participated in a human radiation experiment in which a government agency was involved in actions falling with the criteria outlined by the Advisory Committee on Human Radiation Experiments. As needed, the agencies will seek expert advice on scientific and medical issues to resolve the claims.

Since harm to an experiment subject will likely be a significant issue in connection with many human radiation experiment claims, medical information will be needed to offer relief in these cases. Thus, a claimant can expedite consideration of a claim by providing medical records or other available medical information at the outset. If the agency requires additional information to process the claim, it may contact the claimant or his representative and request the needed information.

The federal agency to which the claim has been presented is allowed up to six months within which to investigate and make a final disposition of a claim before a lawsuit may be filed. The agency is allowed this initial six-month period to consider the claim and decide whether to adjust, compromise, settle, or deny the claim.

Claims presented in connection with the human radiation experiments already investigated by the Advisory Committee can be addressed in less than six months. Indeed, settlement negotiations are already underway in connection with a number of those claims. If any claims are filed in connection with alleged human radiation experiments that were not among those studied by the Advisory Committee on Human Radiation Experiments, investigation and consideration of those claims could require more than six months before a final determination can be made. The additional time might be required to conduct searches of government or private archives in order to establish the government's role in connection with the alleged experiment and the nature and extent of a subject's participation in the experiment and any evidence of resulting injury. In light of the broad expanse of the Advisory Committee's investigation, few additional experiments are likely to result in claims.

In all cases, the claimant is not required to file suit at the expiration of the initial six-month period if the federal agency has not made a final determination of the claim. Once a claim has been filed, the claimant may await the agency's decision. On the other hand, the claimant may, at his option, deem the claim finally denied six months after the claim was filed with the appropriate agency and may then file an action in federal court.

Denial of a claim must be in writing and sent by certified or registered mail. If the agency does finally deny a claim, the claimant must file suit within six months of the denial or the claim is forever barred. An award of compensation in response to a claim constitutes satisfaction of the government's liability, and the matter is terminated without any litigation.

D. Standards for Consideration of Human Radiation Experiment Claims

The Administration has embraced the recommendations of the Advisory Committee on Human Radiation Experiments and has made a commitment to consider the claims of experiment subjects or their families under a system that -- in the President's words -- meets the standards of justice and conscience. Accordingly, every human radiation experiment claim presented (including the claims of persons who had previously sued the United States even before the Advisory Committee's Final Report) will be reviewed by the federal agency to which the claim is presented and by representatives of the Department of Justice for a determination of whether the claim meets the standards articulated by the Advisory Committee in its recommendations and can be compensated under existing law.

In general, the criteria to be applied by the agencies will be that reasonable compensation will be offered, to the extent legally permissible, to an experiment subject (or surviving family member) if the subject participated in a human radiation experiment in which a government agency was involved in actions falling within the following criteria outlined by the Advisory Committee:

1. Experiments in which excessive secrecy deprived individuals the opportunity to pursue potential grievances;
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which the interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

Conclusion

The affected federal agencies and Department of Justice will pursue fair and reasonable compensation for persons whose claims meet the standards of the Advisory Committee and the requirements of justice. The Administration has voiced its commitment to providing reasonable compensation to injured parties to the extent permitted by law. In reviewing any claim, the agencies will give great weight to the Advisory Committee recommendations and do as much as possible under the law to provide relief for human radiation experiment subjects. Every effort will be made to offer compensation through settlement negotiations or use of alternative dispute resolution in appropriate cases so that needless litigation can be avoided. If persons were harmed by their participation in federally conducted or sponsored human radiation experiments but compensation may not be provided under current law, we will so inform the claimants and notify representatives of the Administration so that support for legislative relief may be pursued in appropriate cases.

**CLAIM FOR DAMAGE,
INJURY, OR DEATH**

INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions.

FORM APPROVED
OMB NO.
1105-0008

1. Submit To Appropriate Federal Agency:

2. Name, Address of claimant and claimant's personal representative, if any.
(See instructions on reverse.) (Number, street, city, State and Zip Code)

3. TYPE OF EMPLOYMENT

☐ MILITARY ☐ CIVILIAN

4. DATE OF BIRTH

5. MARITAL STATUS

6. DATE AND DAY OF ACCIDENT

7. TIME (A.M. OR P.M.)

8. Basis of Claim (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof) (Use additional pages if necessary.)

9. **PROPERTY DAMAGE**

NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, street, city, State, and Zip Code)

BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF DAMAGE AND THE LOCATION WHERE PROPERTY MAY BE INSPECTED. (See instructions on reverse side.)

10. **PERSONAL INJURY/WRONGFUL DEATH**

STATE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE NAME OF INJURED PERSON OR DECEDENT.

11. **WITNESSES**

NAME

ADDRESS (Number, street, city, State, and Zip Code)

12. (See instructions on reverse)

AMOUNT OF CLAIM (in dollars)

12a. PROPERTY DAMAGE

12b. PERSONAL INJURY

12c. WRONGFUL DEATH

12d. TOTAL (Failure to specify may cause forfeiture of your rights.)

I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE ACCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM

13a. SIGNATURE OF CLAIMANT (See instructions on reverse side.)

13b. Phone number of signatory

14. DATE OF CLAIM

**CIVIL PENALTY FOR PRESENTING
FRAUDULENT CLAIM**

The claimant shall forfeit and pay to the United States the sum of \$2,000. plus double the amount of damages sustained by the United States.
(See 31 U.S.C. 3729.)

**CRIMINAL PENALTY FOR PRESENTING FRAUDULENT
CLAIM OR MAKING FALSE STATEMENTS**

Fine of not more than \$10,000 or imprisonment for not more than 5 years or both. (See 18 U.S.C. 287, 1001.)

PRIVACY ACT NOTICE

This Notice is provided in accordance with the Privacy Act, 5 U.S.C. 552a(c)(3), and concerns the information requested in the letter to which this Notice is attached.

A. **Authority:** The requested information is solicited pursuant to one or more of the following: 5 U.S.C. 301, 28 U.S.C. 501 et seq., 28 U.S.C. 2671 et seq., 28 C.F.R. Part 14.

- B. **Principal Purpose:** The information requested is to be used in evaluating claims.
 C. **Routine Use:** See the Notices of Systems of Records for the agency to whom you are submitting this form for this information.
 D. **Effect of Failure to Respond:** Disclosure is voluntary. However, failure to supply the requested information or to execute the form may render your claim "invalid".

INSTRUCTIONS

Complete all items - Insert the word **NONE** where applicable

A CLAIM SHALL BE DEEMED TO HAVE BEEN PRESENTED WHEN A FEDERAL AGENCY RECEIVES FROM A CLAIMANT, HIS DULY AUTHORIZED AGENT, OR LEGAL REPRESENTATIVE AN EXECUTED STANDARD FORM 95 OR OTHER WRITTEN NOTIFICATION OF AN INCIDENT, ACCOMPANIED BY A CLAIM FOR MONEY DAMAGES IN A SUM CERTAIN FOR INJURY TO OR LOSS OF

Any instructions or information necessary in the preparation of your claim will be furnished, upon request, by the office indicated in item #1 on the reverse side. Complete regulations pertaining to claims asserted under the Federal Tort Claims Act can be found in Title 28, Code of Federal Regulations, Part 14. Many agencies have published supplemental regulations also. If more than one agency is involved, please state each agency.

The claim may be filed by a duly authorized agent or other legal representative, provided evidence satisfactory to the Government is submitted with said claim establishing express authority to act for the claimant. A claim presented by an agent or legal representative must be presented in the name of the claimant. If the claim is signed by the agent or legal representative, it must show the title or legal capacity of the person signing and be accompanied by evidence of his/her authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian or other representative.

If claimant intends to file claim for both personal injury and property damage, claim or both must be shown in item 12 of this form.

The amount claimed should be substantiated by competent evidence as follows:

- (a) In support of the claim for personal injury or death, the claimant should submit a written report by the attending physician, showing the nature and extent of injury, the nature and extent of treatment, the degree of permanent disability, if any, the prognosis, and the period of hospitalization, or incapacitation, attaching itemized bills for medical, hospital, or burial expenses actually incurred.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden,

Director, Torts Branch
 Civil Division
 U.S. Department of Justice
 Washington, DC 20530

and to the
 Office of Management and Budget
 Paperwork Reduction Project (1105-0008)
 Washington, DC 20503

INSURANCE COVERAGE

order that subrogation claims may be adjudicated, it is essential that the claimant provide the following information regarding the insurance coverage of his vehicle or property.

5. Do you carry accident insurance? ☐ Yes, if yes, give name and address of insurance company (Number, street, city, State, and Zip Code) and policy number. ☐ No

16. Have you filed claim on your insurance carrier in this instance, and if so, is it full coverage or deductible?

17. If deductible, state amount

18. If claim has been filed with your carrier, what action has your insurer taken or proposes to take with reference to your claim? (It is necessary that you ascertain these facts)

- Do you carry public liability and property damage insurance? ☐ Yes, if yes, give name and address of insurance carrier (Number, street, city, State, and Zip Code) ☐ No

Fax Cover Sheet

96 MAY 8 P10:58

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Please Deliver to:

Phil Caplan

Fax #: 94562215
Company: WH

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 28

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Message:

Preparatory Materials for IAWG Conference Call
on Thursday, May 8, 1996 at 10:00 am. Materials
include an updated version of the draft White
Paper, then a one page memo outlining the
purposes of this IAWG call follows. Thanks
If you have problems, call 586-6151. Call-in
number is 202-287-1007.

This fax was sent using Castelle's FaxPress network fax server.

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The Committee's report began by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" were then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity were also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at selected hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

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The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments were proposed as candidates by the Committee.

Summary Response: The agencies involved, in coordination with the Department of Justice, are engaged in ongoing discussions with numerous claimant representatives concerning compensation issues.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment was proposed as a candidate with the indication that there may be many others.

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

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Recommendation 4: No need for subject notification and medical follow-up with criteria for subsequent notification if new experiments come to light. These criteria included both the level of risk from radiation exposure and the potential benefit from medical follow-up in exposed individuals.

Summary Response: (revised) The IAWG staff has generally agreed with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee are appropriate for evaluating future cases. This recommendation has generated a great deal of controversy among stakeholders, which was expressed at the Stakeholders Workshop on February 26, and 27, 1996 held by the IAWG. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally seemed to want some form of notification along with medical care provided by physicians of their own choice, rather than medical follow-up by the government. They viewed the latter as a continuation of suspect government activities.

In addition, at hearings on human radiation experiments held by the Senate Committee on Governmental Affairs on March 12, 1996, Senator Glenn suggested that subjects may want to be notified whether or not they were harmed.

In response, the IAWG staff has further discussed and reviewed its response to this recommendation. Many staff members have pointed out that the entire human radiation experiments effort as carried out by the Federal agencies has involved a public notification process, though generally not at the level of individual participants. Lists of experiments have been made public as has a large volume of documents. The whole process has received extensive publicity.

In one example, the National Aeronautics and Space Administration (NASA) sent a detailed letter notifying all current and former NASA employees, contractors and grantees about the human research radiation review.

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Headquarters, the nine NASA Field Installations, and the Jet Propulsion Laboratory participated in this notification. These avenues of notification included those universities and institutions at which human radiation research was performed through NASA grants. Additional notification was accomplished through various NASA alumnae associations and professional organizations. At the same time, NASA did not and does not retain any administrative or individual medical records of human radiation research subjects.

In addition, through the Interagency Helpline, individuals who thought they may have been involved in experiments have had their case reviewed by the appropriate agency. In response to these inquiries, for example, DOE has notified a number of individuals that they appear to have been participants in a human radiation experiment in which DOE had some involvement.

Several agencies have been reviewing this issue of notification in specific areas.

Treatment with Nasopharyngeal (NP) Radium during Military Service

The Departments of Defense (DOD) and Veterans Affairs (VA) have been considering a relatively large group which has attracted public attention: the servicemen who received NP irradiation during and immediately following World War II. Nasopharyngeal irradiation was considered accepted medical treatment at the time, and records identifying that individual treatment took place are difficult to locate. DOD has been able to locate names of a few servicemen receiving this treatment and in these cases has sent a letter informing the servicemen of this fact and providing a fact sheet about the therapy.

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

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providers for consideration when they were examined or evaluated. VA officials have published information on NP radium treatments in medical journals and sent information to veterans' service organizations for their newsletters.

The VA and CDC are planning a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP radiation do not have special eligibility for VA care. A current bill (HR #2080), if enacted, would provide priority eligibility to veterans treated with NP radium in service. A VA legislative proposal also currently under consideration would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program.

Alaskan Natives

A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force is currently determining appropriate follow-on concerning the minors involved in the Iodine-131 study. In general, the Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM in its recent report concerning the Iodine-131 experiments involving Native Alaskans. Efforts are ongoing to locate documents about experiments involving Native Alaskans and to identify the six Native Alaskans and six soldiers whose names were omitted from the study report.

DOE Efforts

In addition to the subjects of the plutonium injection experiments, whose next-of-kin, where located, were notified, DOE is trying to identify whether there are

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any other subjects for whom it has information that would make notification possible. Although the agency does not currently believe that this information is available, a letter has been sent to all DOE facilities at which human radiation experiments were identified, asking them to provide detailed information about the kind of individual information available, if any, relating to the subjects, the feasibility of notification and whether any kind of notification process has already taken place. DOE has carefully considered the issues raised by notification and the agency's continuing concerns about the value and feasibility of this process were included in the testimony of Dr. Tara O'Toole before the Senate Committee on Governmental Affairs on March 12, 1996.

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 (RECA) to cover other exposed populations, including citizens exposed around the Hanford site.

Summary Response: (revised) The IAWG staff agrees with the Advisory Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will work with Congress to amend existing laws to cover those affected. The GAO has been provided with a list of all studies currently in process.

Recommendation 6: (revised) Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

Summary Response: The VA has established a Task Force led by the Undersecretary for Benefits to evaluate the likelihood of injury due to exposure to ionizing radiation. Representatives are included from the Departments of

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Defense (DOD) and Health and Human Services (HHS). The Task Force is also evaluating the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to their radiation exposures while in military service. The report is expected to be completed in the late spring or early summer of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic tables; describe the administration of laws governing compensation of Atomic Veterans; and if appropriate recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise was established to review the provisions in RECA that relate to compensation for uranium miners. The committee also reviewed the Department of Justice's (DOJ) implementing regulations under RECA to ensure that they are not unduly restrictive. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee report is in the process of completion.

The committee has agreed on a series of recommendations that propose significant and substantial modification to the statutory compensation criteria for lung cancer and nonmalignant respiratory diseases, and to the regulations that govern proof of these diseases. In a few instances, it has recommended that statutory criteria be modified but has not proposed specific alternative criteria. This was the case where, in the time allotted, the Committee was unable to locate sufficient reliable data to analyze or because the appropriate solution ultimately depends on a purely policy judgement.

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Recommendation 8: Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involving the Marshall Islanders in the design of any further medical research conducted on them; and establishing an independent panel to review the adequacy of the current monitoring and treatment program.

Summary Response: (revised) Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid doses. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If new data is developed to indicate that residents of atolls south and east of Bikini other than Rongelap and Utirik are at increased health risk, Congress would need to consider expanding the current medical surveillance program.

The planned Joint Commission for Accreditation of Healthcare Organizations (JCAHO) review of the DOE Marshall Islands Program, administered by the Brookhaven National Laboratory, has recently been suspended. At the request of the Government of the Republic of the Marshall Islands (RMI), the mechanism for such a review is being reevaluated based on further input from RMI. Discussions with the RMI Ambassador to the United States have taken place and RMI has requested a broader review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

Representatives of RMI participated in the February Stakeholders Workshop and DOE is generally working with RMI representatives to determine how to enhance the program to better meet their current needs. DOE is also in the

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process of locating additional documentation requested by RMI and facilitating their access to material already located.

CURRENT HUMAN SUBJECT PROTECTION (revised)

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented in the near term while others will require preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975 on October 3, 1995. (Presidential appointments to NBAC are pending.)

In general, agency activities in response to these recommendations fall into the following categories:

- Remanding specific Advisory Committee recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-Federally funded research with the ethical considerations in conducting research involving human subjects;
- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research;

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- Reminding institutions conducting Federally funded research of their ongoing responsibilities with respect to Institutional Review Board (IRB) review;
- Pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the government's system for the protection of human subject, and to establish processes for oversight or review of compliance;
- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects.
- Implementing educational workshops and an active dialogue with international partners with whom Federal agencies cooperate in human research to develop common ethical principles and to ensure the rights of human subjects are protected, e.g. specific activities proposed by NASA.

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Summary Response: NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate government entities in the areas of bioethical issues arising from research on human biology and behavior and the clinical applications of that research. NBAC will also identify broad principles to govern the ethical conduct of research. The IAWG staff has identified activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these

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activities that will be carried out by HHS, DOE, DOD, and NASA. Some of these are discussed below.

In addition, the National Institutes of Health (NIH) is leading an interagency initiative to fund the development of new knowledge related to the informed consent process. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process. A Request for Applications (RFA) is in preparation, and Fiscal Year 1997 monies are intended to support this RFA.

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explain benefits, and clearly describe the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk.

Summary Response: The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and will provide oversight and review to ensure compliance. The IAWG staff will work with NBAC and the National Science and Technology Council in carrying out these recommendations.

The Office of Protection from Research Risks (OPRR) leads a national educational effort to showcase the Advisory Committee's message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual

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public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the Advisory Committee recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, and Houston. The November 1996 PRIM&R annual conference in San Diego is expected to address IRB implementation of the recommendations. The recent placement of the Advisory Committee report on the World Wide Web makes it possible for IRBs to examine its full text.

In October, 1995, the Food and Drug Administration (FDA) issued a major, 154-page revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take account of the latest thinking and to provide guidance to IRBs.

OPRR and FDA make extensive use of public meetings, forums, hearings, FAX call, and electronic media to address evolving issues on human subject protections. OPRR and FDA actively identify and mail to IRBs and other interested parties copies of Federal Register notices and "Dear Colleague" letters regarding human subject protections.

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum.

Summary Response: It is expected that NBAC will develop and maintain a forum for implementing this continuing review and interpretation of ethical rules.

Recommendation 12: Improving the rights and interests of military personnel with respect to human subject research by reviewing policies and procedures,

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educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revising directives or Military Department regulations to meet these proposals and incorporating appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research. In the summer of 1996, DOD will publish a revised human subject protection regulation that will include policy changes recommended by the Advisory Committee. For example, new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence.

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: In addition to Federal agencies undertaking specific activities in response to this recommendation, some of which are described below, it is expected that NBAC will fully address this recommendation in carrying out its responsibilities.

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally-funded research should be compensated.

Summary Response: The IAWG staff recommends to NBAC that it begin an early assessment of compensation for research injury. Despite being addressed twice before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of the long-standing social policy issue remains elusive.

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NBAC Update: The principal response of the Executive Branch to the Advisory Committee findings and recommendations was the creation of NBAC. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its chartering was catalyzed by the Advisory Committee report, NBAC in fact represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these Committee recommendations based on their merits, as judged by NBAC.

The President is expected to appoint the NBAC membership soon, with meetings to begin in mid-1996. Reports provided to NBAC by agencies that carry out current human research will permit NBAC to begin a critical assessment of the implementation of the 1991 Federal Policy for the Protection of Human Subject ("Common Rule"). Such independent analysis is critically needed, five years after the promulgation of the regulations.

At the March 12th hearing, both the Chairman and the Ranking Minority Member of the Senate Committee on Governmental Affairs expressed concerns about human subjects protections in non-Federally-funded research -- a specific Advisory Committee concern as well. The Advisory Committee had called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG staff will work closely with the Senate Committee as it pursues this issue. NBAC can also be expected to address this issue.

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies

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represented on the IAWG) were required to review this research in the light of the Advisory Committee recommendations and report to NBAC. DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (along with many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995 Executive Order. The following are some specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Developed a newly revised handbook on protecting human subjects which is in pre-publication review. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research.
- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited approximately once every three years.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These will be reviewed by a team charged with improving and monitoring the quality of these documents.
- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.
- Issued a brochure to educate the DOE community on human subjects protection, updated its human subjects research database, held its annual human subjects workshop and created a World Wide Web Home Page on human subject programs.

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The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human subjects of research and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:
 - Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations in the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
 - Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

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The National Aeronautics and Space Administration:

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jawarski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's final report. NASA Headquarters has also established a process for oversight and assurance.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and Center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the international space station was agreed upon and will undergo periodic review.

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- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed, and final approval rests with the Agency Director.
- Disseminated an Agency Bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects; for example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.

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- Ensured that FDA will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECRECY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: (revised) The IAWG staff proposes that the President and/or Agency Head direct all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. Also, in all Federally funded classified research, two

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additional elements of information be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency and 2) a statement that the project involves classified information.

NBAC should then evaluate whether the Federal rules governing human subjects protection should be revised to codify these directives.

The IAWG staff is reluctant to propose creating a new oversight body for 15(b) but proposes to use the current IRB system which already must include at least one member not affiliated with the institution. The IRBs could be directed to ensure that participation of non-government persons in reviewing the classified research by establishing a dedicated panel or ensuring that all IRB members have the necessary clearances.

Recommendation 16: a) Review by an independent panel of any planned environmental release where any aspect involves secrecy and b) Environmental oversight of classified programs (now done by EPA) should include keeping review records permanently and reporting to Congress.

Summary Response: (revised) EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. There is concern that creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety.

EPA's ability to oversee classified operations to assure compliance with environmental laws could be improved through implementation of "a program directed at the oversight of classified programs, with suitably cleared personnel," as stated in Recommendation 16b. The narrative accompanying Recommendation 16b correctly states that all Federal agencies are obligated by Executive Order 12088 to comply with environmental laws and fully cooperate with EPA, and State, Interstate, and local agencies to prevent, control, and abate

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environmental pollution, regardless of whether the activities of regulated Federal agencies are classified.

1. While EPA currently does oversee all Federal government operations, whether classified or not, through its enforcement program, which assures compliance with environmental laws by Federal agencies, EPA does not have as yet a systematic information gathering, coordination, or reporting process specifically related to issues of national security and/or activities subject to the Federal government's information secrecy program under Executive Order 12356.
2. In May 1995, EPA and the Air Force signed a Memorandum of Agreement assuring environmental compliance at a secret operating location known as the "Operating Location Near Groom Lake". Discussions are now taking place between EPA and the Air Force to establish through a second, broader Memorandum of Understanding an EPA operational enforcement capability over all classified Air Force projects. EPA's goal is to take lessons learned from reaching such a Memorandum of Understanding to then discuss comparable issues with other affected agencies.
3. In the past, EPA and state inspectors have obtained, on a case by case basis, appropriate clearances for access to national security information and facilities. To operate an effective enforcement capability over classified projects, EPA is considering systematically identifying cleared personnel and to seek from the operating Federal agencies through a series of Memoranda of Understanding the appropriate "need to know" access. This new process would assure that EPA could handle most environmental compliance matters through administrative processes in classified settings.

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The National Environmental Policy Act (NEPA) directs Federal agencies to prepare an environmental impact statement for "major Federal actions significantly affecting the quality of the human environment." Section 309 of the Clean Air Act directs EPA to review Federal proposals for legislation, regulations and major federal actions significantly affecting the quality of the human environment and comment in writing.

The Council on Environmental Quality regulations state that "...[e]nvironmental assessments and environmental impact statements (EIS) which address classified proposals may be safeguarded and restricted from public dissemination in accordance with agencies' own regulations applicable to classified information." (Section 1507.3(c))

Under the aforementioned provisions, EPA has reviewed classified documents that have been prepared to comply with NEPA. This happens occasionally, not frequently. EPA staff that are assigned as liaisons to the DOD and DOE hold the appropriate security clearances and, in the event it becomes necessary to review a classified NEPA document, the individual typically goes to the offices of the lead agency and reviews the classified material there. EPA has seen no need to establish a system to document this procedure, and does not have any evidence that federal actions are not being appropriately reviewed in the NEPA review process.

Typically the documents that are reviewed are support documents to the EIS, which is public, and the documents have not presented data that suggest environmental impacts other or in addition to those presented in the public sections of the EIS. Should the reviewer determine that a problem exists, that problem would be surfaced to EPA senior management holding the necessary security clearance, and the issue would be further discussed with the lead agency.

EPA does not now keep a record of which EISs have classified sections. However, should it prove desirable, EPA could add this information to its

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existing tracking system. It should be noted, however, that EPA only knows about classified sections if the lead agency notifies it that they exist. With regard to reports to Congress, EPA has no reason to believe at this time that there is either a significant workload for review or significant adverse environmental effects likely to occur.

EPA's recommendation for NEPA document review is that each Federal agency should be responsible for overseeing its own handling of classified material. EPA should continue to review at a lead agency's request classified documents associated with the NEPA process. To that end, staff assigned to work with the DOD and DOE should have the relevant security clearances. It should continue to be the lead agency's responsibility, however, to trigger such a review. EPA does not have the authority to compel, or the access to discover, the existence of classified documents. Should it be deemed advisable, EPA could modify its tracking systems to include the existence of classified documents associated with a particular EIS or, if necessary, totally classified documents that are not officially filed with EPA or made public..

Recommendation 17: Ensuring historical records are organized and accessible by 1) hastening movement of records to Archives; 2) making indexes and finding aids readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

Summary Response: (revised) For 1, 2, 3, and 5, the IAWG staff agrees with moving aggressively down the path to openness exemplified by this project and will work to make government records more accessible including using new technology to enhance access. For 4, the IAWG staff would propose making the records themselves of classified human subject research permanent and the records of destruction of all human subject research permanent.

24

Current Agency Activities: IAWG members have initiatives underway to ensure that information retrieved for the human radiation experiments project is readily available to the public, and to respond to specific Advisory Committee recommendations on openness.

The Department of Energy:

- The Department has produced three publications which include background information, record series descriptions, topical essays, a list of over 400 experiments, and oral histories. Most of this information, along with over 250,000 scanned historical documents, is located on the Internet, with paper copies of all documents at the Coordination and information Center (CIC) in Nevada.
- In response to Advisory Committee recommendations, DOE is
 - Negotiating the transfer of over 3,000 cubic feet of records to the National Archives; and
 - Actively making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance. To date, finding aids from Headquarters records and a number of field sites have been placed in public reading rooms across the DOE complex.
- The Department continues to update its World Wide Web site on the Internet with additional documents of interest and recently added three new experiments to its experiment list.

The Department of Defense:

- The Department is preparing a guide similar to the DOE *Roadmap* that will describe DOD documents found during the human radiation records

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search, and will identify and list human ionizing radiation experiments conducted or sponsored by the DOD. It will also include information on DOD events that were not human radiation experiments but were specifically included by the DOD in its search efforts, such as atmospheric releases. Scheduled availability is summer 1996.

- The documents will be available on the Internet and hard copies will be deposited at the CIC. DOD has also declassified many documents identified in the search for human radiation experiments and is also planning to transfer them to OpenNet, an Internet source for recently declassified documents.
- DOD has taken the lead in an interagency effort to create a home page, on the model of DOE's, with access to documents located by all agencies as part of this project.
- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

The National Aeronautics and Space Administration:

- NASA will maintain a permanent collection of human radiation experiment records and database at Johnson Space Center and a process for submission of a response to requests for information has been developed.
- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

26

The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.
- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.

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Attached is a revised version of the draft whitepaper, incorporating the material recently provided by the agencies. This is a draft of a draft! Please let me have any suggestions for revisions, additions, or changes that you may have.

The teleconference is Thursday at 10:00 and the number is 202 287 1007. The GAO will NOT be participating in this teleconference. After some discussion it was agreed that it would be preferable to have a teleconference for only the IAWG staff before we include the GAO, since we have not talked with one another for a number of weeks. In addition, several congressional staffers - Chris Kline from Senator John Glenn's Office and John Root from Senator Ted Steven's Office - have also asked to be included on this call with the GAO. We will try to set up this call for sometime next week.

The following is a proposed agenda for the teleconference.

- 1. Individual agency updates and discussion/comments on the redrafted White Paper.**
- 2. Update/Discussion on issues of notification and compensation**
- 3. Update by Phil Caplan on White House initiatives in relation to HRE.**
- 4. Discussion of phone call to be held next week with GAO and congressional staff.**
- 5. Discussion of next steps to be taken by IAWG staff.**

Fax Cover Sheet

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Please Deliver to:

Phil Caplan

Fax #: 94562215
Company: WH

From:

AZIM, LORI

Fax #:
Phone:

Pages: 16

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Message:

White paper on IAWG Staff Draft Response to ACHRE Recommendations. Please give your substantial comments to Elly Melamed at (T)202/586-6857 or (F)202/586-2268. If you want to send your comments via e-mail, my address is: lori.azim@hq.doe.gov
DUE DATE IS TUES, FEB. 20 AT NOON
Thanks! Questions, call me at 202/586-5319.

*FAX
from
PM Caplan*

This fax was sent using Castelle's FaxPress network fax server.

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The committee's report begins by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" ^{were} ~~are~~ then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity ^{were} ~~are~~ also reviewed.

The committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

this document is strictly for discussion purposes only. It was prepared by staff of various agencies and has not been finally approved by those agencies. All responses are preliminary.

The effected agencies, in
coordination with the Department
of Justice, are engaged
in ongoing discussions with
numerous claimant representatives
~~concerning~~ concerning compensation issues.

The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments ~~are~~ ^{were} proposed as candidates by the Committee.

Summary Response: As recommended by the Advisory Committee, in coordination with the Department of Justice (DOJ), and to the extent permitted by law, subjects (or their surviving immediate family members) will be offered reasonable financial compensation for human radiation experiments in which a government agency was involved in actions falling within the Advisory Committee criteria:

1. Experiments in which excessive secrecy deprived individuals of the opportunity to pursue potential grievances;
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

A streamlined administrative process, based on Federal Tort Claims Act procedures or other applicable law, will be used to offer compensation as part of a settlement of relevant claims. Maximum effort will be made to avoid lengthy litigation, including use of alternative dispute resolution, such as mediation or arbitration, where appropriate. The amount of compensation will be based on the extent of

physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies will seek expert advice on scientific and medical issues. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek legislative relief in appropriate case.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment ~~is~~ proposed as a candidate with the indication that there may be many others. *yes*

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

Recommendation 4: No need for subject notification and medical follow-up with criteria for subsequent notification if new experiments come to light.

Summary Response: The IAWG staff agrees with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee is appropriate for evaluating future cases. ~~Although no specific action is planned or proposed,~~ the IAWG recognizes that this recommendation has generated a great deal of controversy among stakeholders and is soliciting stakeholder input. *start*

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 to include other exposed populations. *including* Hanford ~~is~~ *specifically mentioned.*

Summary Response: The IAWG agrees with the Advisory Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the

will work with Congress to amend

government should ~~consider whether existing laws should be amended~~ to cover those affected.

Recommendation 6: Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

Summary Response: The Department of Veterans Affairs (VA) is establishing a Task Force led by the Undersecretary for Benefits to evaluate the likelihood of injury due to exposure to ionizing radiation. Representatives will be included from the Department of Defense (DOD) and the Department of Health and Human Services (HHS). The Task Force will also evaluate the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to their radiation exposures while in military service. The report is expected to be completed in the late spring of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic tables; describe the administration of laws governing compensation of Atomic Veterans; and recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise has been established to review the provisions in RECA that relate to compensation for uranium miners. The committee will also review DOJ's implementing regulations under RECA to ensure that they are not unduly restrictive, and review existing data to determine whether further study of uranium millers and open-pit miners is warranted. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee has held several meetings and anticipates submitting a final report in late April 1996.

slab 47 **Recommendation 8:** Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involve the Marshall Islanders in the design of any further medical research conducted on them; and ~~that~~ an independent panel ~~be established~~ to review the adequacy of the current monitoring and treatment program. *ing* ✓

✓ **Summary Response:** Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other norther Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utrik based upon external dose measurements and on estimates of thyroid ~~doses~~. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by the Centers for Disease Control (CDC). If new data is developed to indicate that residents of atolls other than Utrik and Rongelap are at increased health risk, DOE will consider including them in an appropriate medical surveillance program.

The Joint Commission for Healthcare Organizations (JCAHO) is doing an independent review of the DOE Marshall Island Medical Program which has been administered by the Brookhaven National Laboratory. JCAHO will review medical records of selected Marshallese exposed patients to determine if medical care has been provided in a manner consistent with the best medical practice at the time of care, with appropriate followup and medical treatment. The review is currently underway.

CURRENT HUMAN SUBJECT PROTECTION

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented immediately while others will require preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975. (Presidential appointments to NBAC are

pending.)

In general, agency activities in response to these recommendations fall into the following categories:

- Remanding specific ACHRE recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in no-Federally funded research with the ethical considerations in conducting research involving human subjects;
- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research, e.g. specific activities proposed by DOD.
- Sending official notifications to institutions conducting Federally funded research (a) reminding them of their ongoing responsibilities with respect to Institutional Review Board (IRB) review and (b) informing them of their new responsibilities regarding additional requirements to be incorporated into the informed consent procedures and forms;
- Pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the government's system for the protection of human subjects;
- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects.

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Also,
Summary Response: The IAWG staff has identified listed activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these activities that will be carried out by HHS, DOE, DOD, and the National Aeronautics and Space Administration (NASA). (Most importantly, NBAC can take the lead on this issue.)
NBAC will

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explains benefits, and clearly describes the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk. ✓

Summary Response: The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and the IAWG staff will work with NBAC and the National Science and Technology Council in carrying out some *these* aspects of this recommendation. ✓

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum.

NBAC will hold public hearings and maintain a forum
Summary Response: The IAWG staff believes that NBAC is the ideal body to implement this recommendation. *for review and interpretation of these issues.*

Recommendation 12: Improving the rights and interests of military personnel with respect to human subject research by reviewing policies and procedures, educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revising directives or Military Department regulations to meet these proposals and incorporating appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research.

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: In addition to proposing additional activities that could be taken in each of these areas, the IAWG staff also proposes that these issues be collectively referred to NBAC. ?

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally funded research should be compensated.

Summary Response: The IAWG staff agrees that now is the appropriate time to resolve this issue and proposes that it be handled by NBAC. ?

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies represented on the IAWG) are required to revise this research in the light of the Advisory Committee recommendations and report to NBAC. Agencies are currently completing this review. The following are specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Developed a newly revised handbook on protecting human subjects which is in pre-publication review. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research.
- Has begun a program of regular site visits, for education and review, to its facilities performing human subjects research. Each site will be visited approximately once every three years.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These will be reviewed by a team charged with improving and monitoring the quality of these documents.

- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.
- Issued a brochure to educate the DOE community on human subjects protection, updated its human subjects research database, held its annual human subjects workshop and created a World Wide Web Home Page on human subject programs.

The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human subjects of research and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:
 - Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations: in the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
 - Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration:

- Established a Bioethics Task Force composed of outside experts and headed by Dr. Baruch Brody, Director of the Center for Ethics, Baylor College of Medicine, to review all NASA human use policies and provide recommendations.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and recommendations of the ACHRE were incorporated into agency and Center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. It was agreed to establish an International Space Station Multinational Review Board to review human subject protection, safety, and ethical issues.
- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed, and final approval rests with the Agency Director.
- Disseminated an Agency Bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval

is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects; for example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.
- Ensured that the Food and Drug Administration will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECRECY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an

independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: The IAWG staff proposes that the President and/or Agency Head direct all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. Also, in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects:

1) the identity of the sponsoring Federal agency and 2) a statement that the project involves classified information.

NBAC should then evaluate whether the Federal rules governing human subjects protection should be revised to codify these directives.

The IAWG staff is reluctant to ^{propose} create a new oversight body for 15(b) but proposes to use the current IRB system which already must include at least one member not affiliated with the institution. The IRBs could be directed to ensure that participation of non-government persons in reviewing the classified research by establishing a dedicated panel or ensuring that all IRB members have the necessary clearances.

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Summary Response: EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. Creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety but the views of EPA will be sought on whether additional steps are necessary to ensure robust environmental oversight of classified facilities and programs.

It is the understanding of the IAWG staff that the Advisory Committee is not asking for an expansion of EPA's authority under current laws. The IAWG staff proposes that permanent files on classified environmental impact statements and

environmental review of classified activities be maintained by EPA.

Recommendation 17: Ensuring historical records are organized and accessible by 1) hastening movement of records to Archives; 2) making indexes and finding aids readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

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- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

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- NASA is planning to maintain a permanent collection of human radiation experiment records and database at Johnson Space Center.
- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

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- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and the Department of Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. All of the paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority

given to declassification of CIA historical records such as MKUltra.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.

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copy of entire
policy package

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9/5



PROPOSED GOVERNMENT RESPONSES TO RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Background

The Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the committee was charged to provide expert advice to the Cabinet-level Interagency Working Group on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

Final Report of the Advisory Committee

The committee's report, currently in near-final form, begins by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" are then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation clinical settings. Intentional environmental releases of radioactivity are also reviewed.

The committee also considered issues related to some radiation exposures associated with government activity that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at leading hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

Advisory Committee Recommendations

The Committee's recommendations fall into the following three major areas:

- **Biomedical Experiments and Population Exposures, 1944-1974**

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- **Current Human Subject Protection**
- **Secrecy and Openness**

Government Response to Recommendations

A group of representatives from all agencies represented in the Interagency Working Group, including the Departments of Energy, Defense, Health and Human Services, Veterans Affairs, and Justice, the National Aeronautics and Space Administration, and the Central Intelligence Agency, with participation by the Office of Management and Budget and the White House Office of Science and Technology Policy, has been meeting over the past month to consider government-wide options to address the recommendations of the Advisory Committee. This group divided into three subcommittees paralleling the three major areas of the Advisory Committee's recommendations. Each subcommittee developed options, which were presented to the entire group for discussion. The options covered the entire range of potential government responses, from those that agencies can take individually and in cooperation, to those that call for Presidential action.

The following three packages - one from each subcommittee - represent the consensus view of the group of agency representatives.

Remedies Subcommittee

PROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES FROM 1944 - 1974

SUMMARY

The responses described in the following pages address the findings and recommendations of the Advisory Committee on Human Radiation Experiments dealing with experiments and population exposures in the period 1944-1974, recommendations one (1) through seven (7). These recommendations are still undergoing revision by the committee and the proposed responses must therefore be considered as subject to change.

While the committee has not identified cases where subjects were physically harmed, it has identified a small number of cases occurring during WW II (less than 25 in total) where the government deliberately kept the true nature of the experiments from the subjects. In those cases, the committee recommends compensation to surviving family members.

The committee also considered issues related to some radiation exposures associated with government activity that were not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners and residents of the Marshall Islands exposed to the fallout from a 1954 nuclear weapons test. The committee's major recommendation for these groups is that existing laws governing compensation should be reexamined to assure fairness and equity.

The proposed responses described in more detail below would endorse the basic thrust of the committee's recommendations, including:

- An apology and a commitment to work with Congress to secure compensation commensurate with the violation of dignity in the case of the plutonium injection subjects and others identified by the committee who were treated similarly;
- Review of the standards governing compensation of uranium miners and the administration of laws governing compensation of atomic veterans;
- Review of whether new data call for expanding the scope of medical

programs for Marshall Islanders.

Remedies Subcommittee**PROPOSED GOVERNMENT RESPONSES TO ADVISORY COMMITTEE
RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND
POPULATION EXPOSURES FROM 1944 - 1974****RECOMMENDATION 1**

The Advisory Committee recommends to the Interagency Working Group that the government deliver a personal, individualized apology and provide financial compensation to the subjects of human radiation experiments in which efforts were made by the government to keep information secret from these individuals and from the public for the purpose of avoiding embarrassment and/or potential legal liability, and where this secrecy had the effect of denying individuals the opportunity to pursue alleged grievances.

RECOMMENDED GOVERNMENT RESPONSE

Work with Congress to pass legislation to apologize and compensate the affected families for any dignitary harm that may have been suffered by the subjects of the experiments, either because the subjects' consent was not adequately obtained, or the government improperly denied the subjects and their families an opportunity to pursue legal redress.

Compensation would be commensurate with amounts paid to other groups that Congress has previously compensated for similar harms. (Japanese internees were paid \$20,000 in 1988).

Claimants would be required to release claims of dignitary harm against the government, its contractors and their employees in exchange for the compensation. However, the proposed legislation would explicitly preserve any existing or future claim of physical harm resulting from the experiments. [The government could also defer claims of physical harm in accordance with any decision made respecting recommendation 2.]

RECOMMENDATION 2

The Advisory Committee recommends to the Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which

intervention considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their surviving immediate family members.

[The agencies are waiting for the Advisory Committee's revised/clarified recommendation, further discussion is required.]

RECOMMENDATION 3

As of the time this report was prepared, the Advisory Committee had withdrawn these recommendations for revision. The Compensation Subcommittee will not provide response options until the nature of these recommendations is more certain.

RECOMMENDATION 4

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in geographic areas currently covered by the law may have resulted.

RECOMMENDED GOVERNMENT RESPONSE

The government agrees with the Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will consider whether existing law should be amended to cover those affected.

RECOMMENDATION 5(1)

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to ensure that the epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing are reviewed and updated so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure are clearly and unequivocally covered by the statutes.

Recommendation 5(2)

The Advisory Committee further recommends to the Interagency Working Group that it review whether existing laws governing compensation of atomic veterans are now administered in ways that produce the best balance in allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including costs of dose reconstruction.

RECOMMENDED GOVERNMENT RESPONSE

The Secretary of Veterans Administration will appoint a Working Group that will include representatives from the Department of Veteran Affairs, the Department of Health and Human Services and the Department of Defense to provide a written report to the Interagency Working Group by January 31, 1995. The report will

- Recommend that most feasible way to accomplish updating the epidemiological tables to develop a budget request for the President's FY 1997 budget;
- Describe the administration of laws governing compensation of Atomic Veterans; and
- Recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

RECOMMENDATION 6

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners to provide compensation to all miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be

reviewed to determine whether compensation should be extended to include uranium millers, and documentation standards or all claimants should be liberalized.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that the provisions of the Radiation Exposure Compensation Act (RECA) relating to uranium miners should be reviewed to ensure that they are fair, comparable to compensation standards for other radiation-exposed populations and consistent with current scientific data. The Administration will establish a committee of governmental and non-governmental experts to review these issues as well as the Department of Justice's implementing regulations under RECA. The committee will be asked to complete its review within 6 months. Based on the committee's findings, the Administration will work with Congress to enact appropriate statutory changes and amend the existing regulations under RECA.

[hold uranium millers discussion to see if recommendation remains in report]

RECOMMENDATION 7

The Advisory Committee supports the Department of Energy's program of Medical monitoring and treatment for the exposed inhabitants of the Marshall Islands atolls of Rongelap and Utirik, and recommends that this program be continued as long as any member of the exposed population remains alive. Furthermore, the Advisory Committee recommends that the program be reviewed to determine if it is appropriate to add to the program the population of Ailuk, and the population of other atolls whose inhabitants may have been received exposure comparable to or greater than those of Ailuk. The Advisory Committee also recommends that consideration be given to the involvement of the Marshall Islanders in the design of any further medical research to be conducted upon them.

RECOMMENDED GOVERNMENT RESPONSE

Extensive analyses of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other atolls were substantially less than exposures on Rongelap and Utirik. However, the Department of Energy will undertake a review of available information, including any new data that has been developed, to determine whether a reconsideration of radiation exposures on Ailuk and other atolls is warranted.

Summary of Responses to ACHRE Recommendations 8-13

The responses that have been developed on the following pages to address Recommendations 8 through 13 of the Advisory Committee on Human Radiation Experiments (ACHRE) cover a broad range of approaches, some of which involve activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that can be implemented immediately while others will require some preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission, an independent body to be established by the President "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research".

Generally, the responses to the recommendations cover the following categories of activities:

- Remand specific ACHRE recommendations to the proposed National Bioethics Advisory Commission (NBAC) which will provide expert advice on issues of bioethics.
- Develop educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in nonfederally funded research with the ethical considerations in conducting research involving human subjects.
- Implement training programs within federal agencies to educate senior level officials on regulations and policies governing human subjects research, e.g, the activities proposed by the Department of Defense.
- Send official notifications to institutions conducting federally funded research (a) reminding them of their ongoing responsibilities with respect to IRB review and (b) informing them of their new responsibilities regarding additional requirements to be incorporated into the informed consent procedures and forms.
- Pool resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the Government's system for the protection of human subjects.
- Consider proposing legislation to remedy some of the gaps in the current system for protecting human subjects.

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August 25, 1995

Recommendation 8

The Advisory Committee recommends to the Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

The Government has in recent years mounted several activities that address this subject. For example:

- **DHHS:** The National Institutes of Health (NIH) requires all institutions receiving National Research Service Award institutional training grants to provide pre- and postdoctoral trainees on these grants with instruction in the responsible conduct of research. This curriculum includes, among other things, policies on the appropriate use of human subjects and animals in research.
- **DHHS:** The NIH completed development of a Core Curriculum in Clinical Research to train young clinical investigators in its Clinical Center. This course, which is mandatory, includes several modules on protection of human subjects and a specific module on bioethics.
- **NASA:** Established an external Bioethics Task Force to review NASA procedures for all experimentation involving human subjects and to recommend appropriate policy changes. Report to be issued in fall 1995.
- **DOE:** Holds educational regulatory and bioethics update meetings for the entire DOE system (to which other federal agencies are also invited).
- **DOD:** Convenes an annual Tri-Service Clinical Investigations Postgraduate Short Course, generally attended by 200-300 physicians, scientists, nurses, pharmacists and other research support personnel, that emphasizes contemporary human subjects protection issues.
- **DOE:** Has computerized and established worldwide web access to the Department's human subjects newsletter, resource manual and database.
- **DOD:** Requires investigators' familiarity with the Belmont Report, the Common Rule, DOD Directives and all applicable regulations and instructions through the assurance process with each facility.
- **VA:** Has established a special office to conduct random site visits to VA medical centers to review local implementation of national VA policy for the protection of human subjects.

Response

- (a) A major effort will be launched to "upgrade" or expand these activities. These will consist of:
- DHHS: The NIH Clinical Center Clinical Bioethics Program will be expanded and additional resources will be provided, including an SES position, FTEs and space. Following implementation and assessment in the NIH Clinical Center, the Core Curriculum in Clinical Research may be offered to trainees in extramural institutions and/or further disseminated by publication of the syllabus or making it available on the Internet.
 - DOE: Will be requiring educational/ethics updates from all DOE institutions that are involved with human subjects research. Will be establishing an educational plan for all IRBs beginning in FY 1996.
 - DOD: Will adopt the investigator assurances of familiarity with the Belmont Report, the Common Rule and related requirements as a standard for all activities involving human subjects research. Will incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals.
 - NASA: Works with international partners to enhance the ethical training and understanding of all investigators involved in space-related human research and to ensure an transnational sensitivity to ethical issues in human subjects research.
- (b) Invite associations of medical schools and universities as well as scientific societies to join with the Government in launching a broad initiative to heighten the consciousness of the research community with respect to ethics of human subjects research. These might include the expansion of existing university-based research ethics programs and convening workshops in conjunction with the annual meetings of these different organizations.
- (c) OPRR can convene, in conjunction with its counterparts in the other federal agencies, 2-3 regional workshops of IRB chairpersons to allow for the exchange of ideas/approaches, to stimulate the discussions of common problems and to address emerging issues in the arena of human subjects protection.

- (d) The President can announce that he will be signing an Executive Order establishing the National Bioethics Advisory Commission (NBAC) and introduce the chairperson of the Commission.

Recommendation 9

The Advisory Committee recommends to the Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

1. **Mechanisms for ensuring that IRBs appropriately allocate their time so as to enable adequate review of studies that pose more than minimal risk to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal risk studies.**

Response

- (a) Agencies will remind institutions and their IRBs that the current regulations provide for an expedited review process for certain categories of minimal risk research and for minor changes in ongoing research and emphasize their continued and enhanced use of this mechanism.
 - (b) Consider extending a pilot program to reduce the administrative burdens on award applicants (known at NIH as the "Just-In-Time" experiment) to include a feature that would permit IRBs to delay their review of proposed research until preliminary determinations of the proposals' competitiveness have been made by the agency.
 - (c) Ask the Human Subjects Research Subcommittee of the Health, Safety and Food Research Committee of the National Science and Technology Council to consider the implications of implementing this subrecommendation.
2. **Mechanisms for ensuring that the information provided to potential subjects (a) clearly distinguishes research from treatment, (b) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (c) clearly explains the potential for discomfort and pain that may accompany participation in the research.**
3. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.**

4. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.**

Response

- (a) Implement the above three subrecommendations by instructing IRBs and investigators to address these issues in protocols and consent procedures/forms.
- (b) Announce that on October 2-3, 1995, the Department of Energy, in conjunction with the Subcommittee on Human Subjects Research, Committee on Health, Safety, Food Research & Development, National Science and Technology Council, will convene staff from all federal agencies conducting or supporting human subjects research. Federal officials will be briefed on ACHRE findings and recommendations and caucus for 2 days on at this conference. (The Subcommittee on Human Subjects Research meets bimonthly to coordinate implementation of the Federal Policy for Protection of Human Subjects and will be assessing actions to be taken by federal officials subsequent to the October 2-3 conference.)
5. **Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.**

Response

Issue an official reminder to IRBs that they already have the responsibility to review the science in research proposals to determine the appropriateness of the use of human subjects in such research, and to stress that patients participating in therapeutic research should have access to the same level of medical care that would have been available to them were they not participating in research. IRBs have the authority to call upon external resources for expertise in areas not represented by their members.

Recommendation 10

The Advisory Committee recommends to the Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Response

The National Bioethics Advisory Commission would be the ideal body to implement this recommendation. Inasmuch as the NBAC is intended "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research", this recommendation fits very appropriately with the NBAC's charter. Under provisions of the Federal Advisory Committee Act, all NBAC meetings would be open and provide for public access. (See Recommendation 8, Option d.)

Recommendation 11

The Advisory Committee recommends to the Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subjects research.

1. **Review of policies and procedures:** Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of the member of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.

Response

DOD Directives and Military Department regulations require the voluntary and fully informed consent of any person participating as a subject in research projects sponsored or conducted by the Department, as required by 32 CFR 219 (The Common Rule).

2. **Appreciation of regulations:** Education in applicable human subjects regulations should be a routine component of the training of officers and of investigators.

Mechanisms are needed to ensure that all officers and investigators have an adequate appreciation of all regulations (including DOD regulations and directives and Service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

Response

DOD will incorporate education in human subjects regulations into executive level training for commanders and senior leadership. DOD will also incorporate methods for providing detailed training for investigators, institutional review board members, research administrators and research support personnel.

- 3. Maximizing voluntariness: The Service Secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an *ad hoc* basis in some military research. First, that no unit officers nor noncommissioned officer (NCOs) be present at any subject recruitment session in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.**

Response

- (a) DOD is revising its Directive or Military Department regulations such that officers and senior noncommissioned officers in the chain of command will not be present during research recruitment briefings. This requirement shall apply to research and development studies where briefings are given to potential subjects.
- (b) DOD is also revising its Directive or Military Department regulations to require that an ombudsman be present at group recruitment briefings to monitor that the voluntary nature of participation is stressed and that adequate information is provided about the proposed research.
- 4. Maintenance of a registry: The Secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-**

25, to maintain a registry of all volunteers in human studies and experiments conducted under Research and Development programs. Such registries serve to facilitate confirmation of participation in research by subjects and their long-term follow-up.

Response

DOD is revising its Directive on human subjects research to include a provision that each of the Military Departments establish and maintain a registry of volunteers in biomedical studies conducted under research and development programs.

Recommendation 12

The Advisory Committee recommends that the Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects -- oversight, sanctions and scope.

Response

The following three subrecommendations should be collectively referred to the National Bioethics Advisory Commission. However, *additional* strategies are also outlined below.

1. Oversight mechanisms to examine outcomes and performance.

Response

- (a) Develop an interagency grants program to stimulate the research community to propose a variety of approaches to evaluating the performance and outcomes of the Government's system for protecting the rights/interest of human subjects, e.g., the recent program announcement of the National Institute of Mental Health seeking proposals for studying the informed consent process in research subjects with mental disorders.
- (b) Strengthen the federal agency offices with responsibility for oversight of human subjects protection.
- (c) Initiate a program for evaluating the cost effectiveness of different approaches for ensuring quality control of institutional systems for protection of human subjects.
- (d) Implement the NIH study to evaluate the implementation of the federally mandated Human Subjects Protection Program, specifically the extent to which the Program provides adequate protection for the rights and well-being of human subjects.

2. Appropriateness of sanctions for violations of human subjects protection.**Response**

- (a) Provide the same sanctions for violation of human subjects regulations as exist for violation of animal welfare regulations.
- (b) In the case of DOD, failure to comply with its Directives and Military Department regulations can result in administrative and judicial punishment under the Uniform Code of Military Justice.

3. Extension of human subjects protection to nonfederally funded research.**Response**

- (a) Enact legislation that would extend requirements for protection of human subjects to research not funded or conducted by the Federal Government (such as most research involving assisted reproductive technologies).
- (b) Work with the American Medical Association, state medical societies and state licensing boards to launch an educational program to familiarize physicians and others engaged in nonfederally funded research with the ethical considerations in conducting human subjects research.

Recommendation 13

The Advisory Committee recommends that the federal government review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue

Response

This issue has been studied off and on over the last 20 years but, because of its complexity, has never reached resolution. With the establishment of the proposed National Bioethics Advisory

Commission and the release of the ACHRE report calling for compensation of subjects involved in Cold War era radiation experiments, the time may be right for a definitive examination of the issue and development of recommendations/guidelines for compensation of

injured human subjects.

PROPOSED GOVERNMENT RESPONSES TO RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Background

The Advisory Committee on Human Radiation Experiments, chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the committee was charged to provide expert advice to the Cabinet-level Interagency Working Group on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

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The committee also considered issues related to some radiation exposures associated with government activity that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

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The proposed responses described in more detail below would endorse the basic thrust of the committee's recommendations, including:

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- Review of whether new data call for expanding the scope of medical

programs for Marshall Islanders.

Remedies Subcommittee

PROPOSED GOVERNMENT RESPONSES TO ADVISORY COMMITTEE RECOMMENDATIONS ON REMEDIES FOR BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES FROM 1944-1974 (as of 9/25/95)

RECOMMENDATION 1

The Advisory Committee recommends to the Interagency Working Group that the government deliver a personal, individualized apology and provide financial compensation to the subjects of human radiation experiments in which efforts were made by the government to keep information secret from these individuals and from the public for the purpose of avoiding embarrassment and/or potential legal liability, and where this secrecy had the effect of denying individuals the opportunity to pursue alleged grievances.

RECOMMENDED GOVERNMENT RESPONSE

The President directs the Department of Energy to work with Department of Justice and the affected Department of Energy contractors to pursue reasonable compensation for, and apology to, the families of individuals identified by the Advisory Committee, either through settlement of outstanding claims or other forms of dispute resolution, such as the use of a neutral mediator or arbitrator.

RECOMMENDATION 2

The Advisory Committee recommends to the Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which intervention considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their surviving immediate family members.

RECOMMENDED GOVERNMENT RESPONSE

The Administration agrees with the Advisory Committee that an apology and compensation is warranted for human radiation experiments for which there was governmental involvement in actions falling within the criteria identified by the Advisory Committee. Agencies will therefore be encouraged to pursue administrative resolution of such cases and, if necessary, seek expert advice on scientific and medical issues. The Administration is also willing to work with Congress to seek legislative relief in appropriate cases.

RECOMMENDATION 3

The Advisory Committee recommends to the Interagency Working Group that for subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject.

RECOMMENDED GOVERNMENT RESPONSE

[The preliminary Administration response is to thank the Committee for the recommendation, but to explain that the recommendation is unworkable given incomplete records, and a lack of criteria as to what constitutes an injustice.]

SECOND RECOMMENDATION 3

The Advisory Committee has found no subject of biomedical experiments for whom there is a need to provide active notification and medical follow-up for the purpose of protecting their health. In the event that other experiments of concern come to light in the future, we recommend to the Interagency Working Group that subsequent decisions for notification be based on evaluation of both the level of risk from radiation exposure and the potential benefit from medical follow-up in exposed individuals.

Additionally, the Advisory Committee has found no evidence to indicate that the subjects of human radiation experiments we reviewed would have had greater likelihood of incurring heritable (genetic) effects than the general population, and thus does not recommend notification or medical follow-up for descendants of subjects of human radiation experiments.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee is appropriate for evaluating future cases.

RECOMMENDATION 4

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows

that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in geographic areas currently covered by the law may have resulted.

RECOMMENDED GOVERNMENT RESPONSE

The government agrees with the Committee's concern about treating exposed population fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will consider whether existing law should be amended to cover those affected.

RECOMMENDATION 5(1)

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to ensure that the epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing are reviewed and updated so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure are clearly and unequivocally covered by the statutes.

RECOMMENDATION 5(2)

The Advisory Committee further recommends to the Interagency Working Group that it review whether existing laws governing compensation of atomic veterans are now administered in ways that produce the best balance in allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including costs of dose reconstruction.

RECOMMENDED GOVERNMENT RESPONSE

The Secretary of Veterans Administration will appoint a Working Group that will include representatives from the Department of Veteran Affairs, the Department of Health and Human Services and the Department of Defense to provide a written report to the Interagency Working Group by January 31, 1995. The report will

- Recommend that most feasible way to accomplish updating the epidemiological tables to develop a budget request for the President's FY 1997 budget;
- Describe the administration of laws governing compensation of Atomic Veterans; and
- Recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

RECOMMENDATION 6

The Advisory Committee recommends to the Interagency Working Group that it work with Congress to amend the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners to provide compensation to all miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether compensation should be extended to include uranium millers, and documentation standards or all claimants should be liberalized.

RECOMMENDED GOVERNMENT RESPONSE

Agree with the Advisory Committee that the provisions of the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners should be reviewed to ensure that they are fair, comparable to compensation standards for other radiation-exposed populations and consistent with current scientific data. The Administration will establish a committee of experts to review the eligibility criteria of RECA in light of these concerns. The committee will also review the Department of Justice's implementing regulations under RECA to ensure that they are not unduly restrictive, and review existing data to determine whether further study of uranium millers and open-pit miners is warranted. The committee will be asked to complete its review within 6 months. Based on the committee's findings, the Administration will work with Congress to enact appropriate statutory changes, and amend the existing Department of Justice regulations as appropriate.

RECOMMENDATION 7

The Advisory Committee supports the Department of Energy's program of Medical monitoring and treatment for the exposed inhabitants of the Marshall Islands atolls of Rongelap and Utirik, and recommends that this program be continued as long as any member of the exposed population remains alive. Furthermore, the Advisory Committee recommends that the program be reviewed to determine if it is appropriate to add to the program the population of Ailuk, and the population of other atolls whose inhabitants may have been received exposure comparable to or greater than those of Ailuk. The Advisory Committee also recommends that consideration be given to the involvement of the Marshall Islanders in the design of any further medical research to be conducted upon them.

RECOMMENDED GOVERNMENT RESPONSE

Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Islands atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid dose. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by the U.S. Department of Energy

and managed by the Centers for Disease Control. If new data is developed to indicate that residents of atolls other than Utirik and Rongelap are at increased health risk, the Department will consider including them in an appropriate medical surveillance program.

The Department will embark in November, 1995, on an independent review of the Brookhaven National Laboratory Marshall Islands medical program. This independent review will be conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and is designed to address the adequacy of the current medical monitoring and medical care programs.

Summary of Responses to ACHRE Recommendations 8-13

The responses that have been developed on the following pages to address Recommendations 8 through 13 of the Advisory Committee on Human Radiation Experiments (ACHRE) cover a broad range of approaches, some of which involve activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that can be implemented immediately while others will require some preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission, an independent body to be established by the President "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research".

Generally, the responses to the recommendations cover the following categories of activities:

- Remand specific ACHRE recommendations to the proposed National Bioethics Advisory Commission (NBAC) which will provide expert advice on issues of bioethics.
- Develop educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in nonfederally funded research with the ethical considerations in conducting research involving human subjects.
- Implement training programs within federal agencies to educate senior level officials on regulations and policies governing human subjects research, e.g., the activities proposed by the Department of Defense.
- Send official notifications to institutions conducting federally funded research (a) reminding them of their ongoing responsibilities with respect to IRB review and (b) informing them of their new responsibilities regarding additional requirements to be incorporated into the informed consent procedures and forms.
- Pool resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the Government's system for the protection of human subjects.
- Consider proposing legislation to remedy some of the gaps in the current system for protecting human subjects.

Recommendation 8

The Advisory Committee recommends to the Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

The Government has in recent years mounted several activities that address this subject. For example:

- DHHS: The National Institutes of Health (NIH) requires all institutions receiving National Research Service Award institutional training grants to provide pre- and postdoctoral trainees on these grants with instruction in the responsible conduct of research. This curriculum includes, among other things, policies on the appropriate use of human subjects and animals in research.
- DHHS: The NIH completed development of a Core Curriculum in Clinical Research to train young clinical investigators in its Clinical Center. This course, which is mandatory, includes several modules on protection of human subjects and a specific module on bioethics.
- NASA: Established an external Bioethics Task Force to review NASA procedures for all experimentation involving human subjects and to recommend appropriate policy changes. Report to be issued in fall 1995.
- DOE: Holds educational regulatory and bioethics update meetings for the entire DOE system (to which other federal agencies are also invited).
- DOD: Convenes an annual Tri-Service Clinical Investigations Postgraduate Short Course, generally attended by 200-300 physicians, scientists, nurses, pharmacists and other research support personnel, that emphasizes contemporary human subjects protection issues.
- DOE: Has computerized and established worldwide web access to the Department's human subjects newsletter, resource manual and database.
- DOD: Requires investigators' familiarity with the Belmont Report, the Common Rule, DOD Directives and all applicable regulations and instructions through the assurance process with each facility.
- VA: Has established a special office to conduct random site visits to VA medical centers to review local implementation of national VA policy for the protection of human subjects.

Response

- (a) A major effort will be launched to "upgrade" or expand these activities. These will consist of:
- DHHS: The NIH Clinical Center Clinical Bioethics Program will be expanded and additional resources will be provided, including an SES position, FTEs and space. Following implementation and assessment in the NIH Clinical Center, the Core Curriculum in Clinical Research may be offered to trainees in extramural institutions and/or further disseminated by publication of the syllabus or making it available on the Internet.
 - DOE: Will be requiring educational/ethics updates from all DOE institutions that are involved with human subjects research. Will be establishing an educational plan for all IRBs beginning in FY 1996.
 - DOD: Will adopt the investigator assurances of familiarity with the Belmont Report, the Common Rule and related requirements as a standard for all activities involving human subjects research. Will incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals.
 - NASA: Works with international partners to enhance the ethical training and understanding of all investigators involved in space-related human research and to ensure an transnational sensitivity to ethical issues in human subjects research.
- (b) Invite associations of medical schools and universities as well as scientific societies to join with the Government in launching a broad initiative to heighten the consciousness of the research community with respect to ethics of human subjects research. These might include the expansion of existing university-based research ethics programs and convening workshops in conjunction with the annual meetings of these different organizations.
- (c) OPRR can convene, in conjunction with its counterparts in the other federal agencies, 2-3 regional workshops of IRB chairpersons to allow for the exchange of ideas/approaches, to stimulate the discussions of common problems and to address emerging issues in the arena of human subjects protection.

- (d) The President can announce that he will be signing an Executive Order establishing the National Bioethics Advisory Commission (NBAC) and introduce the chairperson of the Commission.

Recommendation 9

The Advisory Committee recommends to the Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

- 1. Mechanisms for ensuring that IRBs appropriately allocate their time so as to enable adequate review of studies that pose more than minimal risk to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal risk studies.**

Response

- (a) Agencies will remind institutions and their IRBs that the current regulations provide for an expedited review process for certain categories of minimal risk research and for minor changes in ongoing research and emphasize their continued and enhanced use of this mechanism.
 - (b) Consider extending a pilot program to reduce the administrative burdens on award applicants (known at NIH as the "Just-In-Time" experiment) to include a feature that would permit IRBs to delay their review of proposed research until preliminary determinations of the proposals' competitiveness have been made by the agency.
 - (c) Ask the Human Subjects Research Subcommittee of the Health, Safety and Food Research Committee of the National Science and Technology Council to consider the implications of implementing this subrecommendation.
- 2. Mechanisms for ensuring that the information provided to potential subjects (a) clearly distinguishes research from treatment, (b) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (c) clearly explains the potential for discomfort and pain that may accompany participation in the research.**
- 3. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.**

4. **Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.**

Response

- (a) Implement the above three subrecommendations by instructing IRBs and investigators to address these issues in protocols and consent procedures/forms.
- (b) Announce that on October 2-3, 1995, the Department of Energy, in conjunction with the Subcommittee on Human Subjects Research, Committee on Health, Safety, Food Research & Development, National Science and Technology Council, will convene staff from all federal agencies conducting or supporting human subjects research. Federal officials will be briefed on ACHRE findings and recommendations and caucus for 2 days on at this conference. (The Subcommittee on Human Subjects Research meets bimonthly to coordinate implementation of the Federal Policy for Protection of Human Subjects and will be assessing actions to be taken by federal officials subsequent to the October 2-3 conference.)
5. **Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this medical benefit as would be available to them without participating in research.**

Response

Issue an official reminder to IRBs that they already have the responsibility to review the science in research proposals to determine the appropriateness of the use of human subjects in such research, and to stress that patients participating in therapeutic research should have access to the same level of medical care that would have been available to them were they not participating in research. IRBs have the authority to call upon external resources for expertise in areas not represented by their members.

Recommendation 10

The Advisory Committee recommends to the Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Response

The National Bioethics Advisory Commission would be the ideal body to implement this recommendation. Inasmuch as the NBAC is intended "to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research", this recommendation fits very appropriately with the NBAC's charter. Under provisions of the Federal Advisory Committee Act, all NBAC meetings would be open and provide for public access. (See Recommendation 8, Option d.)

Recommendation 11

The Advisory Committee recommends to the Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subjects research.

- 1. Review of policies and procedures: Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of the member of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.**

Response

DOD Directives and Military Department regulations require the voluntary and fully informed consent of any person participating as a subject in research projects sponsored or conducted by the Department, as required by 32 CFR 219 (The Common Rule).

- 2. Appreciation of regulations: Education in applicable human subjects regulations should be a routine component of the training of officers and of investigators.**

Mechanisms are needed to ensure that all officers and investigators have an adequate appreciation of all regulations (including DOD regulations and directives and Service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

Response

DOD will incorporate education in human subjects regulations into executive level training for commanders and senior leadership. DOD will also incorporate methods for providing detailed training for investigators, institutional review board members, research administrators and research support personnel.

3. **Maximizing voluntariness:** The Service Secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an *ad hoc* basis in some military research. First, that no unit officers nor noncommissioned officer (NCOs) be present at any subject recruitment session in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.

Response

- (a) DOD is revising its Directive or Military Department regulations such that officers and senior noncommissioned officers in the chain of command will not be present during research recruitment briefings. This requirement shall apply to research and development studies where briefings are given to potential subjects.
 - (b) DOD is also revising its Directive or Military Department regulations to require that an ombudsman be present at group recruitment briefings to monitor that the voluntary nature of participation is stressed and that adequate information is provided about the proposed research.
4. **Maintenance of a registry:** The Secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-

25, to maintain a registry of all volunteers in human studies and experiments conducted under Research and Development programs. Such registries serve to facilitate confirmation of participation in research by subjects and their long-term follow-up.

Response

DOD is revising its Directive on human subjects research to include a provision that each of the Military Departments establish and maintain a registry of volunteers in biomedical studies conducted under research and development programs.

Recommendation 12

The Advisory Committee recommends that the Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects -- oversight, sanctions and scope.

Response

The following three subrecommendations should be collectively referred to the National Bioethics Advisory Commission. However, *additional* strategies are also outlined below.

1. Oversight mechanisms to examine outcomes and performance.

Response

- (a) Develop an interagency grants program to stimulate the research community to propose a variety of approaches to evaluating the performance and outcomes of the Government's system for protecting the rights/interest of human subjects, e.g., the recent program announcement of the National Institute of Mental Health seeking proposals for studying the informed consent process in research subjects with mental disorders.
- (b) Strengthen the federal agency offices with responsibility for oversight of human subjects protection.
- (c) Initiate a program for evaluating the cost effectiveness of different approaches for ensuring quality control of institutional systems for protection of human subjects.
- (d) Implement the NIH study to evaluate the implementation of the federally mandated Human Subjects Protection Program, specifically the extent to which the Program provides adequate protection for the rights and well-being of human subjects.

2. Appropriateness of sanctions for violations of human subjects protection.

Response

- (a) Provide the same sanctions for violation of human subjects regulations as exist for violation of animal welfare regulations.
- (b) In the case of DOD, failure to comply with its Directives and Military Department regulations can result in administrative and judicial punishment under the Uniform Code of Military Justice.

3. Extension of human subjects protection to nonfederally funded research.

Response

- (a) Enact legislation that would extend requirements for protection of human subjects to research not funded or conducted by the Federal Government (such as most research involving assisted reproductive technologies).
- (b) Work with the American Medical Association, state medical societies and state licensing boards to launch an educational program to familiarize physicians and others engaged in nonfederally funded research with the ethical considerations in conducting human subjects research.

Recommendation 13

The Advisory Committee recommends that the federal government review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue

Response

This issue has been studied off and on over the last 20 years but, because of its complexity, has never reached resolution. With the establishment of the proposed National Bioethics Advisory Commission and the release of the ACHRE report calling for compensation of subjects involved in Cold War era radiation experiments, the time may be right for a definitive examination of the issue and development of recommendations/guidelines for compensation of

injured human subjects.

Secrecy and Openness Subcommittee

PROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON SECRECY AND OPENNESS

SUMMARY

The responses described in the following pages address the findings and recommendations of the Advisory Committee on Human Radiation Experiments in the area of secrecy and openness, recommendations 14 through 17. These fall into two general categories. First, additional safeguards are recommended for classified human subjects research and environmental oversight of classified programs. These recommendations are not limited to radiation - related research or programs. Second, the committee calls for continued progress in making government records publicly accessible .

The proposed government actions, summarized below, range from those that can be announced immediately and would apply across the government to those which will require additional development and consultation:

- Presidential directive that no waivers of full informed consent will be permitted in classified research and that the government sponsoring agency will be disclosed to potential subjects in all classified research;
- Request that EPA review whether additional steps are necessary to ensure robust environmental oversight of classified programs;
- Direct the Interagency Working Group, working with the National Archives and Records Administration, to develop an aggressive plan to increase public accessibility of government's records, including the use of new technological advances and to review policies governing access to records of contractors;
- Redesignate records related to human subjects research to prevent destruction in the future;
- High-priority review by the National Archives of CIA record-keeping system, addressing means to improve public access;
- Direct CIA to give top priority in declassification review to human subjects research records.

Secrecy and Openness Subcommittee

PROPOSED GOVERNMENT RESPONSE TO ADVISORY COMMITTEE RECOMMENDATIONS ON SECRECY AND OPENNESS

RECOMMENDATION 14a: The Advisory Committee recommends to the Interagency Working Group the adoption of a Federal policy requiring the informed consent of all human subjects of classified research, and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring Federal agency and that the project involves classified information.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs all departments and agencies that, effective immediately, there will be no federal funding of classified research where an Institutional Review Board has waived informed consent or where a determination has been made that the research is exempt from IRB review. President also directs that in all Federally funded classified research, two additional elements of information will henceforth be provided when consent is sought from potential human subjects: (i) the identity of the sponsoring Federal agency, and (ii) a statement that the project involves classified information.

The National Bioethics Advisory Committee is requested to evaluate whether the federal rules governing human subjects protection should be revised to codify the President's directive.

RECOMMENDATION 14b: The Advisory Committee recommends to the Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives with security clearances, charged with determining: 1) that the proposed experiment has scientific merit; 2) that risks to subjects are acceptable and risk/benefit balance is appropriate; 3 that prospective subjects have been fully informed and participation is voluntary. Records should be kept permanently.

RECOMMENDED GOVERNMENT RESPONSE:

Institutional Review Boards ("IRB") are already required to include at least

one member not affiliated with the institution. The President directs all agencies to ensure the participation of non-government persons in review of classified research, either by establishing a dedicated panel for classified research or by ensuring that IRB members all have the necessary security clearances.

RECOMMENDATION 15a: The Advisory Committee recommends that an independent review panel be assigned the task of reviewing any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret, or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

RECOMMENDED GOVERNMENT RESPONSE:

The President indicates that EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. Creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety but the President will seek EPA's views on whether additional steps are necessary to ensure robust environmental oversight of classified facilities and programs.

RECOMMENDATION 15b: The Advisory Committee recommends to the Interagency Working Group that an appropriate government agency, currently the Environmental Protection Agency, maintain a program directed at the oversight of classified programs, with suitably cleared personnel. This program should maintain critical records, such as environmental impact statements and environmental permits permanently. The agencies subject to regulation should ensure the timely consideration of environmental impacts and oversight and the timely provision of all necessary clearances. EPA should provide regular unclassified reports to Congress describing the extent of its activities as well as any significant problems.

(The Interagency Working Group sought clarification from the Committee on the intent of this recommendation. According to the executive director, the Committee is not asking here for expansion of EPA's substantive authority under NEPA and other existing environmental laws.)

RECOMMENDED GOVERNMENT RESPONSE:

The President directs that permanent files on classified environmental impact statements and environmental review of classified activities shall be maintained by EPA.

RECOMMENDATIONS 16(1), 16(2), 16(3): The Advisory Committee recommends that the Interagency Working Group take steps to ensure the continued application of the lessons learned from the efforts to organize and make accessible to the public, and the government itself, the nations's historical records.

- (1) The most important historical collections should be entrusted to the National Archives. The agencies and the National Archives should review the extent to which this is now being done and develop policies to hasten the transfer of agency records to the National Archives.
- (2) Agencies should make readily available all existing inventories, indices, folder listings and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review and declassified versions of these finding aids should be also be made available.
- (3) The Interagency Working Group should ensure the development of policies to improve public access to records held by agencies or deposited in Federal Record Centers.

RECOMMENDED GOVERNMENT RESPONSE:

The President commends the agencies for the progress made through this project in delivering information to people. He commits the administration to continuing aggressively down the path to openness exemplified by this and other initiatives. He directs the Interagency Working Group, working with the National Archives and Records Administration, to advise him on measures to make the government's records more readily accessible to citizens, which should include consideration of the potential uses of new technology to enhance access. The Interagency Working Group should be asked to report back by a date certain within a few months.

RECOMMENDATION 16(4): The Advisory Committee recommends that agencies maintain complete records, available to the public, of document destruction.

RECOMMENDED GOVERNMENT RESPONSE:

The President should, via Executive Order, institute new policy regarding human subjects research records of destruction. Such Order should mandate that all records of destruction regarding classified research be maintained permanently by National records Centers. Disposition instruction of current records should be updated to reflect new policy with specific emphasis on enforcement of records maintenance standards at all levels.

The President also directs that all records of classified projects involving human subject testing are to be labeled "permanent retention" in all agencies. This indicates that they are of historical value, must be reviewed for declassification 25 years after their creation and should go to the National Archives at 30 years.

RECOMMENDATION 16(5): The Advisory Committee recommends that the Interagency Working Group review and develop policies concerning public access to records generated or held by private contractors and institutions receiving Federal funding.

RECOMMENDED GOVERNMENT RESPONSE

The President directs the Interagency Working Group to develop guidelines for performing the policy review called for by this recommendation. The President also directs the Departments of Justice and State to review existing laws and regulations related to the implementation of this recommendation.

RECOMMENDATION 17a: The Advisory Committee recommends that the CIA's recordkeeping system be reviewed to ensure that records are accessible upon legitimate request from the public or governmental sources.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs the National Archives and Records Administration to give priority to its review of CIA's records system that is scheduled for October 1995. NARA is specifically directed to address means to improve public access to the agency's records.

RECOMMENDATION 17b: The Advisory Committee recommends that all CIA records bearing on programs of secret human research, such as MKULTRA and the related CIA human behavior projects from the late 1940s through the early 1970s, become a top priority for declassification review, with the expectation that most, if not all, of these documents can be declassified and made available to the public.

RECOMMENDED GOVERNMENT RESPONSE:

The President directs CIA, as part of its compliance with the Executive Order 12958, to give top priority to declassification review of records related to human subject research.