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" 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 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.

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 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.

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.

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 to include other exposed populations. 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

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.

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.

Summary Response: Extensive analyses to date of radiation exposures in the Marshal 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 does. 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.

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.

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 aspects of this recommendation.

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

Summary Response: The IAWG staff believes that NBAC is the ideal body to implement this recommendation.

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 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 and 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 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.

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: 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.

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 would propose making the records themselves of classified human subject research permanent and the records of destruction of all human subject research permanent.

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 ACHRE 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

    - Transferring over 3,000 cubic feet of records to the National Archives; and

    - Making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance.

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. These documents will be available on the Internet and hard copies will be deposited at the CIC.

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

The National Aeronautics and Space Administration:

- 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.

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 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.