Interim Report of the *Advisory Committee* on *Human Radiation Experiments*

October 21, 1994

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
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MEMORANDUM

TO: **Members of the Interagency Working Group**

Secretary Hazel O'Leary, Department of Energy
Secretary William Perry, Department of Defense
Attorney General Janet Reno, Department of Justice
Secretary Donna Shalala. Department of Health and Human Services
Secretary Jesse Brown, Department of Veterans Affairs
Director Alice Rivlin, Office of Management and Budget
Director James Woolsey, Central Intelligence Agency
Administrator Daniel Goldin, National Aeronautics and Space Administration

FROM: **The Advisory Committee on Human Radiation Experiments**

DATE: **October 21, 1994**

RE: **Interim Report**

The Advisory Committee on Human Radiation Experiments is pleased to transmit its Interim Report to the Interagency Working Group.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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EXECUTIVE SUMMARY

The Advisory Committee on Human Radiation Experiments was created by President Clinton to advise the Human Radiation Interagency Working Group (the "Interagency Working Group") on the ethical and scientific criteria applicable to human radiation experiments carried out or sponsored by the U.S. Government. The Committee is composed of 14 members, including a citizen representative and 13 experts in bioethics, radiation oncology and biology, history of science and medicine, epidemiology, nuclear medicine, and law.

Human radiation experiments are defined by the Committee's charter to include

> "(1) experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices. . . . (2) experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation. ["Intentional Releases"]

The Committee's Approach

The Committee seeks to answer several fundamental questions: (1) What ethics criteria should be used to evaluate human radiation experiments? (2) What was the Federal Government's role in human radiation experiments? (3) What are the criteria for determining appropriate Federal responses where wrongs or harms have occurred? (4) What lessons learned from studying past and present research standards and practices should be applied to the future?

As a Federal advisory committee, the Committee asks these questions and seeks to answer them in open public meetings. In addition to meetings in Washington, which contain a period for public comment, and a full Committee meeting in San Francisco, the Committee has scheduled at least three other sessions to hear public comment in regions throughout the country.

The Committee's ability to tell the story of past radiation experiments requires more than the will to search through hundreds of boxes for documents and the intuition to recognize which ones are important. It depends on the Committee's ability to find a common language to address the technically complex, often highly emotional issues related to human radiation experimentation. The voices to which the Committee must listen speak in the languages of medicine, a multiplicity of sciences, the military, sick patients, healthy subjects, policymakers, and philosophers. The Committee cannot understand, much less tell, the story unless it seeks out all who can aid its understanding, and works to bridge the cultural and linguistic gaps among them.

The Committee is also convinced that an important determinant of its success will be its

ability to understand the present just as well as, if not better than, it understands the past. Therefore, it has undertaken the task of sampling the ethical practices and standards governing human radiation research today, evaluating them, and deciding whether change is needed.

Finally, in order to focus its own inquiry, and the ability of the public to assist it, the Committee has identified a number of common themes that will guide its work, and give structure to its final report. These themes include:

- *Consent standards and procedures:* A cornerstone of modern research ethics is the requirement that research proceed only with the informed consent of a competent subject or with adequate safeguards to protect the interests of a subject who cannot give consent. The Committee must understand when policies and practices of informed consent were adopted, when, if ever, the requirement was disregarded and why.

- *Risks and benefits of research:* It is inherent in most research that subjects are put at risk of harm in order to obtain desired benefits. It is the Committee's charge to determine whether the risks to which subjects were exposed, however low, were justified.

- *The selection of research subjects:* The ethics of research turn as much on considerations of justice in the selection of subjects as they do on questions of consent or acceptable risk. The Committee deems it essential that it examine whether particular populations were targeted for participation as research subjects because of their relative lack of economic, social, or political power.

- *Responsibility for experiments:* Who decided which experiments were carried out, and who was responsible for assuring that ethics policies, where they existed, were put into practice?

The Committee Begins Its Work

The Committee was created in tandem with a Presidential directive that the executive branch be open to searching inquiry. When it began its work in April 1994, there were few records in hand; the Committee was embarking on a daunting journey into the past and present with neither stars nor compass to chart its course. For example:

- How many human radiation experiments were conducted before 1975? Where could the answer be found? In April it was not clear whether the answer was in the hundreds or the thousands.

- What codes of conduct, if any, existed before 1975 to govern federally sponsored experiments? The prevailing assumption was that until the mid-1960s Federal

agencies, by and large, did not have ethics policies.

- What institutions planned, funded, and conducted experiments, and who had responsibility for ensuring the integrity of experimentation? Where agency organization charts or other road maps existed to guide the way, the fragments at hand were often physically blurred beyond recognition.

Time was short. The Committee therefore had to develop a strategy to quickly gather, organize, and analyze vast amounts of information.

Phase I. The Phase I strategy has three components: (l) the development of a framework for all the information the Committee hoped to collect--the "big picture" into which pieces of the puzzle could be fit; (2) the development of a strategy to mine all available information sources; and (3) the development of an information infrastructure to house and organize all the data. The components of the "big picture" framework include:

- *An experiment database,* to provide a single locale for cataloguing experiments as they are identified;

- *An ethics timeline*, to chart the evolution of Federal and private sector policies and practices pertaining to research ethics;

- *A scientific/medical standards timeline*, to chart the evolution of these standards; and

- *Institutional maps*, to plot the network of public and private institutions that planned, funded, managed, and performed experiments.

Phase II. While Phase I continues, the Committee's brief tenure requires that it turn to the task of evaluating experiments. But on which experiments should it focus? On the one hand, the number of pre-1975 experiments may well be in the thousands, and the number of post-1975 experiments far greater. On the other hand, the Committee may be able to locate only fragments of data about many of these experiments (for example, there is often no information on who subjects were, much less what they were told about the experiment).

The working solution, therefore, is a strategy that seeks to address the basic questions of concern to the Committee and the public by an overlapping set of case studies and samples. First, the Committee is focusing on five groups of biomedical experiments, with each group anchored in one or more specific experiments that have received public attention. Second, the Committee is simultaneously focusing on institutions that conducted the experiments, in order to examine the decisionmaking process and determine responsibility. Third, the Committee's inquiry into intentional releases will focus on determining (l) whether (at this late date) the public can learn who planned the releases, why, and what precautions if any were taken; and (2) whether

intentional releases, which were often shrouded in secrecy, could take place today in the absence of meaningful public notice.

For evaluating the contemporary world of research, the working solution is to conduct three projects: (1) a review of a sample of recently funded research proposals; (2) interviews with subjects of current research; and (3) review of current Federal agency policies for oversight.

Phase III. While Phase I continues, and Phase II has just begun, the Committee is simultaneously turning to Phase III--the tasks of evaluating past and present experiments, recommending policy changes, and developing criteria for a range of remedies that may be appropriate where wrongs or harms have occurred.

Taking Stock: Some Accomplishments and Challenges

Openness: The President's request that the Federal Government open a substantial portion of its Cold War files to the Committee, and the public, was ambitious. There were many reasons for skepticism, including the enormous number of records, the vast number that remained classified, and the potential for bureaucratic delay. These factors remain real. As detailed in this report and agency-specific appendices, the Committee and agency search terms have retrieved important records collections, some of them previously secret, that will provide a new basis for understanding our past and present. In doing so, these collections are producing a road map that should, as present work continues, permit the completion of a substantial search within the Committee's life, and that will remain as a guide for the public in the years to come. It is now clear to the Committee that, with continued public support and interest, the agency commitment to the opening up of a substantial portion of our Cold War archives can continue to be substantial, even unprecedented. It is the Committee's task to help ensure that this search produces results that merit its continuation when the Committee is no longer in existence.

Piecing Together the Secret and Public Worlds of Experiments: The Committee's experiment database presently contains about 400 biomedical experiments conducted before 1975. The Committee possesses at least fragmentary indications of over 1,000 additional experiments. In addition to the 13 intentional releases of ionizing radiation identified in the Charter, the Committee is now aware of hundreds of additional intentional releases.

The Committee is learning that secrecy is not always the primary bar to comprehending the past. A vast amount of data already is public, but it is often widely scattered. For example, piecing together the story of human experimentation in connection with atomic bomb tests requires the Committee to combine discrete collections of public data with newly declassified data while continuing to search for further secret and public pieces of the puzzle.

Piecing Together the Hidden History of Federal Ethics Policy and Practice: Documents delivered by the agencies, and others located by the Committee, have revealed that there was discussion at the highest reaches of government--often in secret--about the need for

human experimentation and for policies to govern it. Committee and agency staff have placed the highest priority on tracking down the twists and turns in these discussions and in the policies and practices that flowed from them.

Discovery of the Past in the Present: When the Committee began its work six months ago, it might reasonably have been assumed that research conducted in the mid-century world was so different from current research that its relevance would be limited. However, the story that is unfolding raises questions of continuing relevance to today. For example:

- At mid-century, ethics policies were discussed and recorded on paper. A key question then, as today, is the relationship between policy and practice.

- Even as policies were put on paper, it was not always clear what they covered. Did they cover sick patients as well as healthy volunteers? In cases involving soldiers and workers, for example, what was understood by responsible decisionmakers to be the difference between experimentation with healthy volunteers and occupational safety monitoring? Then, as today, the boundaries of experimentation may not have been fixed.

- Even with the benefits of openness, basic information on some experiments (notably the intentional releases) remains secret. Could these releases be conducted today without basic public disclosure?

Outreach: The Committee has heard from many members of the public who have written, called, visited its offices, or testified at its open meetings. In many cases these communications have brought important insight and information to the Committee's attention. The Committee's public reading room provides access not only to basic Committee material (e.g., transcripts of meetings) but a collection of important documents that were previously classified or not readily available in an organized form. The Committee's experiment and document collection databases should soon be available to the public on Internet.

Challenges: The primary challenge to the Committee now, as at the onset, is the overwhelming nature of its tasks. Agency and Committee document and information searches are progressing and should result in substantial new information about known experiments, policies, and practices, and perhaps discovery of heretofore unknown experiments, policies, and practices. However, (l) search efforts are necessarily time consuming and uncertain; (2) data on many experiments will likely continue to remain fragmentary; (3) it appears that many important collections have been long since lost or destroyed; (4) a great number of relevant collections contain classified data; the declassification process may be a substantial bottleneck.

Work To Be Done

In the next six months, the Committee will continue with the tasks of data gathering and organizing. The focus of the work, however, will be developing criteria for judging historical and contemporary experiments, policies, and procedures, as well as criteria for remedies that may be appropriate where harms or wrongs have occurred. Based on what the Committee has learned, it will make specific recommendations regarding policies for the future.

INTRODUCTION

CHARGE AND MANDATE

The Advisory Committee on Human Radiation Experiments was created by President Clinton to advise the Human Radiation Interagency Working Group [1] (the "Interagency Working Group") on the ethical and scientific criteria applicable to human radiation experiments carried out or sponsored by the U.S. Government. (See Appendices A and B for Executive Order and Charter.) The Committee is composed of 14 members, including a citizen representative and 13 nationally recognized experts in bioethics, radiation oncology and biology, history of science and medicine, epidemiology, nuclear medicine, and law. (A list of Committee members is attached as Appendix C.)

Human radiation experiments are defined by the Committee's Charter to include

> "(1) experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices . . . .
> (2) experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation." [2]

The Committee is mandated to review experiments conducted between 1944 and May 1974, the date the Department of Health, Education, and Welfare issued regulations for the protection of human subjects. Experiments done after May 30, 1974, may be sampled to determine if further inquiry into experiments is warranted.

The Committee is also mandated to determine the ethical and scientific standards and criteria by which to evaluate the pre-May 1974 experiments, and the extent to which the experiments were consistent with such standards. The Committee "shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical followup was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific criteria, including standards of informed consent, that prevailed at the time

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

[2] Charter, section 3, Appendix B.

of the experiments and that exist today."[3] Upon completing its review, the Committee may recommend that subjects (or families) be notified of potential health risks and the need for medical followup, and it "may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments."[4]

HOW THE COMMITTEE FUNCTIONS

The Committee, as a Federal advisory committee, is an exercise in open government. Basic decisionmaking is conducted in open public meetings. The Committee has scheduled 13 (generally two-day) full Committee meetings over the course of its one-year term. In addition to a full Committee meeting in San Francisco, the Committee has scheduled at least three other public comment sessions in different regions of the country, as discussed below. Each meeting is announced in the *Federal Register*. (Dates and locations of meetings can be found in Appendix D.)

At each meeting, staff and Committee members provide progress reports on the range of ongoing and anticipated tasks and projects. These have included the investigation and retrieval of documents related to agency searches, experiments and the world in which they were set, institutions of interest, past and present ethics policies, and contemporary research practices. Each meeting includes a public comment period. Committee meetings also include self-education presentations on the relevant aspects of radiation, ethics, law, history of experimentation, and Federal regulation. All meetings are transcribed, and the transcripts and meeting minutes are available to the public.

The Committee has been extremely fortunate to assemble a multidisciplinary staff of substantial talent. The staff currently includes 34 full- and part-time members, supplemented by several expert consultants. The staff includes individuals with backgrounds in internal medicine, nuclear medicine, bioethics, physics, epidemiology, molecular biology, history (e.g., radiation science, human experimentation, the Cold War), law, health policy, communications, archival creation and management, and information systems development. The staff works at the direction of the Committee, and subcommittees have been formed to oversee staff work between meetings. The staff also consults with experts in dose reconstruction and other relevant technical areas.

As discussed in Part III of this report, outreach is an essential component of the Committee's activities. Staff routinely meets with individuals and groups who are interested in learning about the Committee and from whom the Committee can learn. A public reading room at the Committee's offices contains basic Committee materials (such as Committee meeting

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[3] Charter, section 4.a, Appendix B.

[4] Charter, sections 4.c and 4.d, Appendix B.

briefing books and transcripts) and key collections of historical documents assembled by the Committee. The Committee expects that indices to document collections and its experiment database will shortly be available on Internet.

THE COMMITTEE'S APPROACH

The Committee seeks to answer several fundamental questions: (1) What ethics criteria should be used to evaluate human radiation experiments? (2) What was the Federal Government's role in human radiation experiments? (3) What are the criteria for determining appropriate Federal responses where wrongs or harms have occurred? (4) What lessons learned from studying past and present research standards and practices should be applied to the future?

The Committee has been gathering vast amounts of information and working to render it orderly and accessible. Its members are currently engaged in the complex task of analyzing the scientific and ethical standards and procedures by which experiments on human subjects should be judged, both retrospectively and in the present. Once this task is completed, the Committee will draft a final report answering the above questions in the form of recommendations to the Interagency Working Group.

Created in tandem with a Presidential directive that the executive branch be open to searching inquiry, the Committee began its work with few records, a huge task, and a short time frame. The work began with an examination of a largely untold part of the history of the Cold War. The examination entails digging into warehouses full of public and private records and probing the memories of numerous individuals.

The Committee's work involves integrating ideas and information relating to big science and microdoses of radioactive isotopes, global policy and knotty ethical dilemmas, and the pain and fear of ordinary individuals. But this represents only half the job. The Committee is convinced that an important determinant of its success will be its ability to understand the present as well as, if not better than, it understands the past. Therefore, it has taken on the task of sampling and evaluating the ethical practices and standards governing human radiation research today, in order to determine whether change is needed.

Among the obstacles the Committee must overcome in meeting its mandate is the lack of a common language to address the technically complex, often highly emotional issues related to human radiation experimentation. The voices to which the Committee must listen speak in the languages of medicine, a multiplicity of sciences, the military, sick patients, healthy subjects, policymakers, philosophers, and individuals in a variety of other roles. The Committee is seeking out and paying careful attention to everyone it can find who can contribute to its understanding, and it is working hard to bridge the linguistic and cultural gaps that can hinder its

progress.[5] Together with the documentary evidence that the staff has unearthed and is continuing to gather, the Committee is drawing on these disparate voices to articulate the vital themes that will give structure and substance to its final report. To date the Committee has identified nine such themes, italicized in the paragraphs that follow, but other themes may come to light as the work shifts to analysis and normative judgment.

It was obvious to the Committee from the language in its charter that a primary theme would be *consent standards and procedures*. A cornerstone of modern research ethics is the requirement that research proceed only with the informed consent of a competent subject or with adequate safeguards to protect the interests of a subject who cannot give consent. It now appears that, as it relates to government-conducted or government-sponsored research, this requirement and its application have evolved over time. It is important to understand when these policies and practices were adopted; when, if ever, the requirement was disregarded; and why.

Similarly, it was clear that the Committee would have to make *assessments of the potential harms and benefits* of the experiments it is charged with studying. It is in the nature of most research that subjects may be exposed to risks in order to obtain desired information. It is therefore important to understand (to the extent possible) the level of risk to which subjects were exposed, as well as researchers' perceptions of the risk. It is also important to assess whether the potential benefits to the subject or to society were sufficient to justify the risk to which subjects were exposed. The Committee is aware that, within and outside the scientific community, there is study and debate regarding the effects of low doses of radiation. The Committee must be sensitive to all viewpoints. At the same time, the Committee and the public must understand the relation between this discussion and the Committee's charge. For example, the doses in historical experiments evaluated by the Committee may not differ from those in use today in routine and accepted diagnostic procedures. It is not the Committee's charge to go beyond presently accepted radiation standards. By the same token, it is not the Committee's view that contemporaneously accepted practices are risk free, and can have no health effects; accepted practices often may well involve risks. It is the Committee's charge to assess whether the risk, however low, was justified. For example, were subjects informed of the risk and the purpose(s) for its being undertaken? Was their consent obtained? Where consent was obtained, were some populations (e.g., indigent persons) chosen as subjects to the exclusion of others?

Another theme the Committee noted early in its work concerns the *selection of research subjects*. The ethics of research turn as much on considerations of justice in the selection of subjects as they do on questions of consent or acceptable risk. The Committee deems it essential that it examine whether particular populations were targeted for participation as research subjects because of their relative lack of economic, social, or political power. For instance, fetuses, infants, children, prisoners, soldiers, minorities, the poor, the terminally ill, persons with

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[5] At the end of this report is a sampling of the bureaucratic terms and acronyms that punctuate the Committee's reading material, and to some extent this interim report.

cognitive disabilities, and the institutionalized may have been chosen as subjects because of their relative powerlessness.

The Committee also recognizes the importance of *understanding the organizational and structural context* in which experiments were carried out. This theme includes the way in which (and by which) agency experiments were funded, the evolution of the institutions involved in the experimentation, and the way in which decisions were made. This area also addresses questions such as who decided which experiments and research programs were carried out and which were not, and by what authority these decisions were made.

Along with the institutional factors, the Committee recognizes the human elements that must be taken into account if it is to fulfill its mandate. For example, what were *the attitudes of researchers* about the experiments they were conducting? How did researchers reason about whether to use animal or human subjects for their experiments? What were researchers' personal views about what constituted an acceptable consent from a subject? What did the word "informed" mean to the researchers in the context of consent?

Although the Committee was appointed in response to potential abuses, it was evident to members from the outset that the *medical and other scientific benefits of radiation* was a theme that deserved attention. A great many diagnostic, therapeutic, and basic science applications have been developed as a result of government-sponsored research involving radiation. The story of human radiation experiments would be incomplete if it did not include an account of the benefits derived from this research.

Because radiation experimentation evolved in tandem with the development of nuclear weapons, it seemed inevitable to the Committee that *national security considerations* would become part of the radiation experimentation story. Therefore, the relationship of experimentation, secrecy, and national security forms an important theme for the Committee to consider. One key question is the extent to which national security may have been invoked to justify the bypassing of ethics policies or the intentional exposure of populations to releases of radioactive materials.

Underlying all of these themes is a central question for the Committee: *what was the role of the U.S. Government* where harms or wrongs were done to citizens who took part in radiation research? Information about the knowledge or ignorance of Federal agencies and officials relating to harms or wrongs to research subjects, and the extent to which relevant policies were followed or violated, will inform the Committee's conclusions and recommendations.

Finally, the over-arching context for the Committee's retrospective judgments is that during the historical period specified by its charter (1944-1974), the United States was not only in the throes of the Cold War, but it was also living through the early stages of a profound scientific and social revolution. It was the *dawn of the Atomic Age*. The power of the atom was seen as a source of great promise--it would cure cancer and provide limitless cheap energy. But

it was also the source of the most destructive force ever created by humanity and unleashed on the earth. A complete understanding of human radiation experiments must situate the research in this complex cultural context.

TASKS AND STRATEGIES: AN OVERVIEW OF THE FIRST SIX MONTHS AND THE INTERIM REPORT

In order to begin its task of evaluation, the Committee had to obtain basic information about the experiments it had identified and the worlds in which they were set. Relevant information might be located in any of hundreds of libraries or warehouses throughout the country, and in the memories of thousands of citizens. Time was short.

The Committee had to develop a strategy to address the simultaneous undertaking of three basic tasks--information gathering, information organization, and information analysis--each of which was fraught with uncertainty. The strategy had to be sufficiently disciplined to meet the Committee's time frame, yet sufficiently ambitious to understand and address the details of experiments with ionizing radiation, ethics policies governing them, and organizational charts of long-lost governmental organizations and agencies. At the same time, the strategy had to be sufficiently flexible to accommodate the possibility of dead ends, incomplete information, and most importantly, new discoveries leading to new avenues of research.

Phase I: Gathering Information - "Big Picture" Mapping, Targeted Document Searches, and the Creation of Data Management Infrastructure

The first phase of the strategy involved three components, the first of which was the development of a framework for all the information-the "big picture" into which the pieces of the puzzle could be fit. As discussed below, the components of this framework included:

- An experimental database, to provide a single locale for cataloguing experiments as they are identified and storing basic information as it is retrieved;
- An ethics timeline, to chart the evolution of Federal and private sector policies and practices pertaining to research ethics;
- A scientific and medical standards timeline, to chart the evolution of these standards; and
- Institutional maps, to plot the network of public and private institutions that planned, funded, managed, and performed the experiments and used the resulting data.

The second component of this phase was an effort to identify the world of potential

sources of information, and the most efficient methods to mine these sources. As discussed in Parts II - III below, for example, this strategy involved:

- Refocusing agency document searches on headquarter level collections, in order to gain an overview of the forest in which individual experiments were set and identify data trails that might be followed;

- Surveying private archives and library sources;

- Initiating oral history, interview, and outreach projects to tap individual memories; and

- Planning several research projects to assess and evaluate human experimentation that is ongoing today.

The third component of this first phase of the strategy was the development of the technical infrastructure needed to house and make accessible the increasingly large body of information being received by the Committee. As discussed in Part IV, this component includes the creation of electronic databases available to both the Committee and the public.

Phase II: Information Organization - Gathering the Threads, Focusing on Experiments

While Phase I is still in progress, the Committee's brief tenure requires that it simultaneously focus on particular experiments (or groups of them) in order to begin the evaluative process. But on which experiments should energies be focused? The elements of the strategic problem include the following: (l) the number of pre-1975 experiments and intentional releases may well be in the thousands, and the number of post-1975 experiments even larger; (2) data gathering will remain incomplete even as evaluation begins; and (3) the Committee may be able to collect only fragments of data about many (and probably most) experiments.

The need, therefore, was for a strategy that (l) made use of available data; (2) was likely to address particular experiments and releases of clear public concern; (3) would not neglect experiments and releases simply because applicable data were not readily available; (4) addressed experiments and releases that involved basic issues of concern to the public and the Committee; and (5) was sufficiently flexible so as not to be derailed by information roadblocks.

The working solution for the pre-1975 world of experiments, as discussed in Part I, is a two-part strategy that combines (1) a focus on groups of experiments, with each group anchored by one or more well-publicized, widely discussed experiments; and (2) a focus on the institutions that conducted experiments, with each institution offering the opportunity to examine responsibility for decisionmaking about undertaking, funding, and performing experiments. The hope and expectation is that this strategy will permit an understanding of both important

individual experiments (or groups of them) and the systems and contexts in which they were set.

The working solution for the intentional releases is to determine (1) whether, at this late date, the public can learn who planned the releases, why, and what precautions, if any were taken; and (2) whether intentional releases, which were often shrouded in secrecy, could take place today in the absence of meaningful public notice. The working solution for the contemporary world of research involves three activities:

1. a review of a sample of recently funded research proposals (including radiation and non-radiation treatments), with the ethical evaluation focusing upon the processes of subject selection, harm/benefit, and informed consent and disclosure of information;

2. interviews with subjects of current research, attempting to assess their attitudes and beliefs related to research participation; and

3. collection of current agency policies related to the oversight of research on human subjects.

The details of the components and activities of Phase II are discussed in the body of this interim report.

Phase III: Information Analysis - Evaluation and Recommendations

While Phase I continues, and Phase II has just begun, the Committee must simultaneously turn to the Phase III tasks of evaluating past and present experiments, recommending policy changes, and developing criteria for a range of remedies that may be appropriate where wrongs or harms have occurred. The development of a strategy for this effort is the immediate priority of the Committee as the first six months of its tenure come to an end. Specifically, the Committee currently is focusing on the development of ethical standards for judging past and present experiments and releases, as well as the above mentioned criteria. In Part V of this interim report, the Committee takes stock of where it has been; in Part VI the Committee summarizes the work to be done in the next six months.

PART I. AREAS OF INQUIRY: THE FRAMEWORK AND PIECES OF THE PUZZLE

When the Committee began operations in late April 1994, it had limited information about the experiments it was to study and about the ethical and scientific standards of the past in which they were set. The Committee had not only to collect information scattered in files and warehouses throughout the country but, at the same time, to create and test the framework needed to ensure that there is a "big picture" into which pieces of the puzzle could be fit. In this section we discuss the components of the framework, and some of the pieces of the puzzle that have already been assembled. In Part II, we discuss the methods for locating the pieces, including the Committee's work with the Interagency Working Group search teams. While the framework and search method are discussed separately, in practice they are inseparable, and continually inform one another.

A. THE PROBLEM: WIDELY DISPERSED AND FRAGMENTARY INFORMATION

How many human radiation experiments were conducted prior to 1975? By whom? What were they about? In April, even the most approximate answers to such questions were guesswork. There was no known place or combination of locations to investigate that ensured the quick compilation of even a reasonably complete list of experiments.

The Committee could begin with documents that were assembled during the 1980s and that underlay the "Markey report."[6] But review of the materials available for the Markey report confirmed that, even for that relatively well-known group of experiments, basic information was lacking. The Department of Health and Human Services (HHS) reported that its data on mid-century research grants was limited to capsule descriptions that often did not permit distinction of work performed on humans from that performed on other forms of life. Components of Department of Defense (DOD) and other agencies did provide lists of human experiments; in many cases, however, even when reports on the research were available they often lacked data on basic questions of concern (for example, who the subjects were and what they were told about the risks of the experiment).

What codes of conduct, if any, existed to govern federally sponsored experiments? Who developed them? How were they put into effect? There was no readily identifiable body of ethics policies that governed human experimentation in the pre-1974 period. Indeed, the prevailing assumption was that until the mid-1960s Federal agencies, by and large, did not even

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[6] "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens," Report Prepared by the Subcommittee on Energy Conservation and Power of the Committee on Energy Commerce, U.S. House of Representatives, November, 1986, chaired by Edward Markey (D-MA).

possess such policies for their extramural research programs.[7] In order to evaluate experiments it also is necessary to understand the scientific or medical standards in effect during the period of their performance. What were they? How were they made known and put into effect?

Where would information be found that would show whether experiments were conducted for military, scientific, or medical purposes, or some combination, and thus would reveal the considerations of public benefit that went into their conduct?

Finally, when the facts and standards are assembled, by what factors is the past to be judged? By what criteria are wrongs to be assessed?

In each of these areas of inquiry, the well-lit streets and well-known landmarks had long since been altered beyond recognition or demolished. Where agency organization charts or other road maps existed to guide the way, the fragments at hand were often blurred beyond recognition.

B. BIOMEDICAL EXPERIMENTS: 1944-1974

1. Phase I: Mapping of Experiments and the World in Which They Were Set

The Committee has tried simultaneously to recreate both the world of experiments and the basic framework in which they were set and must be understood. These efforts have involved trying to get the Committee's arms around a potentially huge number of experiments, retrieving the ethical and scientific norms that were prevalent during the time experiments were conducted, and identifying and reconstructing the institutions that planned, funded, set policy for, carried out, and used data from the experiments.

a. Experiment Database

The aim of this activity is to provide a living electronic document that will serve as a central record on the identity of many (but by no means all) Government-sponsored human radiation experiments, with basic information on each experiment and keys to permit further research. To this end, the Committee created a form to collect standard information regarding

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[7] For example, in February 1994 the Congressional Research Service issued a report that fairly reflected prevailing understanding on the history of federal regulations for the protection of human subjects. The report begins the story of Executive Branch regulation in the 1960s, focusing on the activities at HHS' predecessor. "Protection of Human Subjects in Research," Irene Stith-Coleman, CRS Report 94-179 SPR, February 28, 1994. As discussed above, we now know the story starts far earlier, and involves DOD and the Department of Energy (DOE) predecessor, AEC, as well.

each biomedical experiment of which it became aware.[8] As of mid-October, the database comprised about 400 experiments that were conducted prior to 1975. In addition to the experiments in the database, the Committee has at least fragmentary data that may involve 1,000 or more further experiments.[9]

The core of the database is the experiments identified by the agencies.[10] However, it is now clear that these comprise only a portion of the research conducted, albeit a significant portion. The Committee seeks further sources to identify additional experiments and to provide missing data on those already identified. These include the following:

- Information provided by members of the public;
- Biomedical textbooks, histories, and journal articles, and bibliographies of radiation research;
- The Atomic Energy Commission (AEC, predecessor to the Department of Energy) listing of recipients of isotopes and other AEC reports;
- Documents provided by the agencies or located by staff in public or private archives or records centers (including, for example, agency program and budget documents, agency histories, and the minutes of relevant committees); and
- Presentations to Congress.

The database includes many categories of data with provision for electronic sorting by category. It was quickly apparent that data on some key categories of information (e.g., whether or not consent was obtained, who the subjects were, how they were selected) are lacking for most experiments. Given the fragmentary data presently available on most experiments, the database will not itself be the basis for evaluating individual experiments, but it will provide a guide or index for further research.

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[8] The form contains entries for the range of basic data that should be of importance to the Committee, the Interagency Working Group, and the public. For example, categories include (l) classification of the experiment by scientific and governmental purpose(s) (if any); (2) isotope and dosage; (3) source(s) of funding; (4) researcher(s) and institution(s); (5) provisions for consent, if any; (6) subject population and selection method; and (7) relevant publications.

[9] As discussed in this report, intentional releases are being catalogued separately.

[10] Appendix E discusses the number of experiments located in the case of each agency.

b. *Ethics Policies and Practices*

The aim of this effort is to determine what Federal and private sector research ethics policies and practices were in use prior to 1975. Following its first meeting, the Committee asked the agencies to provide basic information on the development of their research ethics policies and regulations. The retrieval of agency information is ongoing. The Committee is simultaneously searching private archives and conducting an interview program to trace private sector, as well as public sector, policies and practices.

It is now apparent that from the onset, the government engaged in high-level debates on human experimentation during the Cold War period. Committee staff, working with agency search staff, have attached high priority to tracing down the twists and turns in these debates and the development and implementation of policies that flowed from them.

i. *Department of Defense (DOD).* In the case of the military, documentation of consent policies predates the 1947 creation of DOD.[11] In February 1953, the Secretary of Defense issued, as a top secret document, a policy adopting the Nuremberg Code "to govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare."[12] Research questions for the Committee include the following:

- The extent to which the Secretary's policy, which was stamped "Top Secret", was known throughout DOD and by civilian researchers funded by DOD;
- Whether and how the Armed Services implemented the Secretary's policy;
- The extent to which implementing directives were actually applied to particular experiments;
- How the 1953 policy was interpreted: what research activities were considered to be covered by the directive and which were not? For example, how was research distinguished from training maneuvers? Were activities conducted by DOD contractors, as well as DOD employees, covered?; and
- The meaning of "human volunteers" in the context of military activities.

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[11] Most notably, Walter Reed employed a form of release in the turn of the century battle against yellow fever. The Navy has retrieved evidence of a relevant policy dating to the 1930's. Documentation obtained by the Committee staff shows discussion of consent policy in the World War II Committee on Medical Research, which coordinated the wartime medical research effort.

[12] The Nuremberg Code was the standard that was codified by the International Military Tribunal following the prosecution of Nazi doctors who engaged in human experimentation.

ii. *Central Intelligence Agency (CIA).* The Committee is seeking information on the relation between early ethics policies in DOD, HHS, and AEC, and experiments conducted by the CIA. In the 1970s, public and congressional attention focused on MKULTRA, and other programs of CIA experiments on mind control (most famously involving LSD), at least some of which involved unknowing subjects, including members of the public. Documents show that CIA officials who were involved in the predecessors to MKULTRA also were members of the DOD Committee on Medical Science and probable participants in the DOD Joint Panel on the Medical Aspects of Atomic Warfare, groups at which human experimentation planning and policy, among other items, were discussed.

iii. *AEC/Department of Energy (DOE).* At AEC, evidence for a consent policy dates to 1947, the year of AEC's creation. The Committee has been seeking to determine whether policies indicated in high-level documents were enacted as formal guidelines or rules, and whether these policies were put into practice by AEC-sponsored investigators.

iv. *Department of Health and Human Services (HHS).* The initial HHS policy appears to have been that applied to the National Institutes of Health (NIH) Clinical Center, which opened in 1953. The Committee has been researching the development and application of that policy. Policies governing extramural research were initiated during the 1960s.

v. *National Aeronautics and Space Administration (NASA).* NASA was created in 1958. The policies initially retrieved by NASA dated to 1972. At its birth, NASA drew upon the research work of other agencies, such as DOD. The Committee is researching how NASA developed these policies and the extent to which early NASA research relied upon ethics policies developed by others.

vi. *Department of Veterans Affairs (VA).* The recovery of policies related to experiments sponsored by the then-Veterans Administration has been limited. However, it appears that work done under VA auspices was often performed in coordination with other agencies or by investigators who also worked under DOD, AEC, or HHS (its predecessor) funding. The relation between the policies and practices of VA and those found elsewhere should be of interest.

In parallel with the reconstruction of Federal ethics policies and practices, the Committee is seeking to reconstruct the policies and practices that governed privately funded or performed biomedical research. This effort includes a search of relevant literature and records collections and an oral history project, described in more detail in Part II.B. below.

c. *Institutional Mapping*

The goal of this effort is to identify and understand the policies and programs in which experiments were set and to identify responsibility for these programs, policies, and ultimately experiments. A subsidiary goal is to provide the roadmap needed to ensure that as many experiments as possible can be identified, and to locate potential additional sources of information on those already known. The effort has already shown that headquarters-level records can aid in the reconstruction of the "big picture" in which experiments fit, as can be seen from the following examples.

From its creation in 1947, AEC had components that funded human experimentation and provided needed experimental tools (radioisotopes as well as equipment grants). AEC's Division of Biology and Medicine, created in 1948, awarded grants for research and set the overall biomedical research program agenda. Its Isotope Development Division distributed radioisotopes to researchers throughout the country, and its Human Use Subcommittee of the Committee on Isotope Distribution reviewed applications for the use of isotopes in human subject research. Documents reveal early policy debates and declarations on human experimentation. But as discussed at Committee meetings (and in related staff memoranda), the scope of ethics policies and the way in which they were translated from headquarters to field application remains to be reconstructed.

The Committee is also constructing a picture of DOD organizations, programs, and policies that provided high-level direction and oversight of human radiation experimentation. For example, in 1949, the Office of the Secretary of Defense created the Joint Panel on the Medical Aspects of Atomic Warfare. The Joint Panel included participation by private medical researchers and representatives of the AEC, Public Health Service (PHS), and probably the CIA. The Joint Panel served as a focal point for planning and information gathering on experimentation (including human experimentation) related to atomic warfare. At the same time, the Office of the Secretary of Defense also included the Armed Forces Medical Policy Council, whose work led the Secretary of Defense to issue DOD's Nuremberg Code policy and led the Joint Panel to consider human experimentation in connection with U.S. atomic bomb tests. The Committee has been following the trail of plans and policies formulated by these groups.

Mid-century debates and sponsorship of human experimentation often involved participation by multiple agencies. It is therefore necessary to understand relationships among agencies, as well as within them. For example, AEC and DOD (and their consultants), engaged in vigorous discussion over the need for human experimentation in connection with the nuclear-powered airplane (which was never built). Civilian agencies or their representatives also were involved in defense-related discussion and planning. Following World War II, the National Institutes of Health (NIH) inherited many of the research grants and contracts of the World War II Committee on Medical Research, the medical research and development component of the military effort. During the Korean War period, representatives of VA, NIH, and PHS, as well as AEC and DOD, were involved in the discussions of the Joint Panel on the Medical Aspects of

Atomic Warfare. PHS played an important role in monitoring bomb tests and conducting fallout measurement. When NASA was created in 1958, it was able to rely on a research heritage from agencies such as the Air Force and AEC. NASA established a joint research program in radiobiology with the AEC in the early 1960s.

d. *Scientific Standards Timeline*

The goal of this effort is to identify the scientific and medical standards that governed judgments about risks and potential benefits during the period in which experiments were undertaken. Areas of inquiry include the following:

- Determining the radiation standards that existed at the dawn of the Cold War, the manner in which they were set, and their basis;
- Examining the levels of risk developed and assumed by AEC's Isotope Development Division;
- Determining the extent to which the early research now under study played a role in the development of standards; and
- Identifying documents that contain key discussions of risks and potential benefits of human experimentation and reviewing risk/benefit discussions in contemporary literature.

2. Phase II: Focus on Specific Experiments and Their Context

While the reconstruction of the world of experiments continues, the Committee at its September meeting adopted a particular analytic strategy for focusing its efforts. This strategy involves two overlapping approaches that together capture as complete a picture as is reasonably possible. These approaches are (1) examining groups of biomedical experiments; and (2) examining the institutions that conducted and sponsored them. The program is ambitious, and its success will depend critically on the ability to retrieve needed information, as well as staff and Committee resources.

The first approach identifies for intensive study five groups of experiments (outlined below) covering the spectrum of human radiation research. Each group is anchored in one or more relatively well-publicized experiments. The second approach focuses on two institutions that were among several sites that were hubs of planning and research in human radiation research. Both approaches provide rich opportunities for exploring the nine overarching themes noted in the Introduction above.

a. Biomedical Experiments

i. *Biodistribution.* This group centers on the plutonium injection experiments. From those well-known experiments it reaches out to include (1) other experiments designed to test the biodistribution of isotopes with no clear immediate therapeutic or diagnostic potential; and (2) other experiments whose primary purpose was to advance the health and safety of those directly involved in weapons production, such as experiments related to toxicology or chelation therapy.

ii. *Total Body, Partial Body, and Local Irradiation.* This group includes the Cincinnati whole body irradiation experiments and other external irradiation experiments where the subjects were predominately persons who were ill.

iii. *Research Involving or Affecting Children.* This group is anchored in the Fernald School and Vanderbilt experiments. The Fernald School experiments were tracer studies using radioactive calcium in a population that included institutionalized mentally compromised children. Vanderbilt University conducted studies on pregnant women using radioactive iron to determine maternal-fetal iron exchange.

iv. *Radiation Research where Subjects were Predominately Healthy Adults.* This group includes the testicular irradiation of prisoners and other experiments on healthy adults (such as flash-blindness studies and other experiments related to atomic bomb tests) in which external sources of energy were applied with no potential for therapeutic or diagnostic benefit for the experimental subject.

v. *Radioisotope Research.* This group, which includes experiments at the Wrentham School, encompasses studies using radioisotopes that were products of the nuclear age and also had major medical applications in both diagnosis and therapy. Examples of these radioisotopes include iodine and iron. Unlike the biodistribution group, this group allows a purposive sampling of cases that include research on medical applications.

It is hoped that these five groupings, although by no means mutually exclusive, will serve as useful devices for organizing research and analytic efforts.

b. *Institutional Case Studies*

It now appears that these experiments took place in a world in which there was official debate at the highest level about human experimentation and the policies that should govern it. The primary purpose of the institutional inquiry is to advance the theme of management responsibility (see Introduction) by adding to our understanding of how decisions to experiment (or not) were made, and to answer questions such as:

- Where higher-level policies existed, how were they supposed to flow down from headquarters to research institutions and, ultimately, to investigators and subjects?

- Where did responsibility lie for determining the formal and practical reach of policies and the requirements for implementation?

- If policies were limited in coverage, or in their implementation, why was that the case?

- Where did responsibility lie for failure to implement and/or enforce policies and was a policy oversight process either in place or considered?

By focusing on institutions that sponsored or conducted many relevant experiments, the institutional case studies also should provide further basis for focusing on, and evaluating, particular groups of experiments, as well as other themes of interest to the Committee.

Staff researched a number of institutions as candidates for case studies, including AEC sites that conducted or sponsored research, such as Oak Ridge and Los Alamos; key DOD organizations, including the School of Aviation Medicine; and research centers funded by multiple agencies (such as the UCLA complex, which included work funded by the AEC, DOD, and VA, and similar complexes in the Boston and San Francisco areas). The Committee has decided to pursue two institutional case studies: the Oak Ridge complex and the Bay Area components of the University of California. Research on sites not chosen for case studies nevertheless continues to be of value in providing data on individual experiments, and on prevailing ethics policies and scientific standards.

C. INTENTIONAL RELEASES

The Committee's Charter includes 13 intentional releases of radioactive material into the environment.[13] These releases were generally related to radiation warfare tests, the gathering of intelligence, and the development of instrumentation. The category of intentional releases is now known to be larger, in variety and quantity, than the 13 releases identified in the Charter. For example:

- The Charter included 8 radiation warfare experiments; the number is at least 53.

- The Charter includes 4 Los Alamos, New Mexico, implosion tests involving radiolanthanum. DOE reports that the number of such tests approximates 250.

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[13] See Charter, section 3(2), Appendix B.

- The Charter includes one intentional release from a plutonium production facility (Green Run). Examples of further releases from nuclear production facilities have been found.

In addition to the types of releases identified in the Charter, other intentional releases include:

- Releases related to the development of nuclear rocket and nuclear aircraft technology;

- One-point safety tests of fission warheads at the Nevada test site that were performed to determine whether the accidental detonation of the high explosive at one point in a warhead would produce a nuclear yield;

- Radioecology tests, in which radioactive material was introduced into the environment to test for retention or transmission through the environment; and

- Tests of reactor safety and simulated accidents, such as reported by DOE's Idaho National Engineering Laboratory.

In addition to the intentional releases stipulated in its Charter, the Committee may also investigate examples of further intentional releases.

In general, the focus of efforts will be (1) to locate and retrieve for public release (where possible) information that may shed light on the planning of, and responsibility for, the releases; and (2) to determine whether releases that took place in the past, typically shrouded in secrecy, could be conducted today. As a complement to the Committee's overarching themes, the following questions are being pursued:

- What was the purpose of the release (e.g., bomb testing, reactor testing, long-range detection, environmental study)?

- How much radioactivity was released and in what form?

- Was radiation monitored on and off site? Who was responsible for the monitoring?

- Were there human biomedical studies in connection with the releases?

- Were participants and bystanders notified in advance of potential hazards?

- What measures were recommended or taken to minimize risks to participants and bystanders?

- What rules govern intentional releases today (for example, environmental impact regulations)?

- How would the historical releases be conducted today? For example, would environmental impact statements be required? Would there be public notice? Could all or portions of the review process be kept secret?

- What kind of releases are being conducted today, and what rules are being followed?

D. A NOTE ON SCOPE

At the outset, the Committee had to consider the scope of its activities. During its early meetings, the Committee heard public comments from veterans of the atomic bomb era and their families (military personnel exposed during atomic bomb tests), downwinders (for example, private citizens exposed to fallout from nuclear tests in Nevada), the Marshallese (inhabitants of the Marshall Islands, many of whom were exposed to radiation from bomb tests conducted in the Pacific), and representatives of uranium miners (who were exposed to radon as workers in AEC uranium mines). The Committee also received comments regarding once-common radium treatments and written communications or office visits from other individuals and groups.

The question of the scope of the Committee's activities was assigned to a subcommittee that recommended, and the full Committee agreed, that for purposes of inquiry hard and fast lines should not be drawn. In the absence of some degree of inquiry, the facts may be insufficient to determine whether human experimentation took place. The Committee's inquiry has revealed that, both in the past and at present, the factual and conceptual boundaries separating an experiment from other kinds of data gathering are not always clear. Finally, analysis of activities that may not be deemed experimental may shed important light on the conduct of human experimentation by showing why experimental data were needed.

In general, in cases of group exposure, the Committee directed the staff to review previously organized accounts, with an eye toward information that shows or suggests biomedical experimentation. Staff was also directed to focus on materials that have not previously been made public.

In piecing together the records of DOD's 1949-1953 Joint Panel on the Medical Aspects of Atomic Warfare, the Committee found a trail of discussion and planning that appears to have led to the conduct of at least some biomedical human experiments in connection with atomic bomb tests. These experiments are being pursued as part of the group of biomedical experiments involving subjects who are predominately healthy adults. The Committee asked staff to pursue this trail of inquiry, and at the Committee's request, DOD and DOE have agreed to locate and retrieve documentation related to actual or potential human experimentation in connection with atomic bomb tests. The areas of inquiry include:

- Documents related to the biomedical panels (or offices, committees, etc.) that planned the biomedical components of atomic bomb tests;

- Documents related to human subject data-gathering activities that, according to available documentation, may have been experiments (including, for example, flash-blindness testing, psychological observation or testing, the measurement of radioisotopes in body fluids, and the measurement of radiation doses to certain ground or aircrews, all in connection with weapon tests); and

- Documents related to DOD's ethics policies (particularly the 1953 Secretary of Defense Directive) to atomic bomb test activities.

In agreeing to search for the information, the agencies and the Committee reserve for future discussion whether particular activities constitute experiments. In conducting the search, the Committee will work with the agencies to ensure that previously retrieved data (such as that assembled for DOD's Nuclear Test Personnel Review) are used efficiently.

Public presentations also spurred Committee consideration of the concept of "experiment of opportunity," that is, situations in which the initial exposure to radiation may have been accidental (or, if premeditated, not for the primary purpose of human subject study), but the opportunity presented by the exposure led to an organized research effort. In discussing the concept, the Committee is mindful that, if only because of staff and resource limits, its mission cannot include the examination of human data gathering solely for safety monitoring purposes. However, the question of the boundary between such data gathering and experiments of opportunity is a focus of inquiry.

E. THE CONTEMPORARY STORY

As part of its mission, the Committee must establish the current status of the policies and practices related to human radiation research and make recommendations regarding future policies. In an effort to gain insight into this area, the Committee has undertaken three separate research projects aimed at describing contemporary practices related to the ethics of human subject research. The *Subject Interview Study* aims to discover the beliefs and attitudes of research subjects regarding their understanding and voluntary participation in research; the *Research Proposal Review Project* aims to discover the adequacy of current policies and practices in the protection of the rights of the subjects of research; and the *Agency Oversight Review* aims at assessing both the policies and practices of the agencies for oversight of the review and monitoring of human subject research supported or performed by them. The bulk of the work for these projects will be undertaken and completed during the remaining months of the Committee's term. Up to this point, work on the contemporary projects has consisted of seeking administrative approval (through the Office of Management and Budget), designing the projects, requesting the necessary information and materials from agencies, and preparing sufficient staff resources to successfully carry out the projects.

1. Subject Interview Study

The purpose of this project is to collect data concerning (1) the extent to which patients of radiation oncology, medical oncology, and cardiology services at both major research institutions and community hospitals believe they are participants in research; (2) the perceived voluntariness of this participation; and (3) subjects' reasons for agreeing to participate. This project will enrich the deliberations of the Committee with direct information about the contemporary experiences of some research subjects.

The project will proceed in three phases. Focus groups will be conducted (Phase I) to assist in development of a short survey, which will be administered to approximately 1,000 patients drawn from approximately 15 different institutions (Phase II), followed by a semi-structured interview to be administered to a subsample of approximately 150 subjects (Phase III).

Phase I: Focus Groups. Focus groups comprised of patients from two different institutions will be conducted by a professional facilitator. Issues to be covered in focus groups include:

- Voluntariness: did subjects feel as if they had a choice about whether to participate in an experimental protocol, and were others involved in the decision?
- Reasons for participating, including whether participation had been recommended and, if so, by whom?
- Understanding of what it means to participate, such as what it means for a drug or treatment to be experimental, and how being a patient in a research project differs from receiving regular medical care.

Phase II: Short Survey. Based on the focus group responses, a short survey, anticipated to take 5-10 minutes to complete, will be designed by Committee staff in conjunction with survey research consultants. The survey instrument will be designed to capture the following topics, provided as potential examples:

- Beliefs about being a research participant, such as whether the subject is currently receiving any treatments or drugs considered to be experimental, or participating in any research studies or proposals.
- Voluntariness (to be asked of those who believe they are currently participants in research), such as whether he/she believes there was a choice about whether to participate in research or experimental therapies, and why or why not.
- Reasons for participating, e.g., to receive state-of-the-art treatment; to help

advance science; to receive compensation; because someone recommended they should, etc.

- Understanding of what it means to participate in research, such as whether the subject understands what it means for radiation therapy to be experimental, the difference from regular medical care, whether everyone in their research proposal is getting the same therapy or treatment.

Phase III: In-Depth Interviews. Semi-structured, in-depth personal interviews then will be conducted with 10-15 patients who are participants in research at each of the 15 institutions. An interview guide will be developed with the help of the focus groups, and the same issues covered in the survey will be included in the interviews, with questions posed in an open-ended fashion and followup questions asked based on the subject's responses. Through this process, considerably more attention can be given to the relevant topics, such as the meaning of research participation for subjects.

2. Research Proposal Review Project

The project will evaluate the extent to which the rights and interests of persons currently involved as subjects of radiation research conducted or supported by the U.S. Government appear to be adequately protected in the proposal review process, and to compare this level of protection with that afforded the subjects of nonradiation research. The objectives of this project are (1) to determine, based on research proposal and IRB materials, whether harms and benefits, informed consent procedures, and selection of subjects appear to be appropriate; and (2) to determine whether research proposals and IRB materials provide sufficient information to make judgements about the protection of human subjects.

This project involves collecting the necessary documents from agencies and grantee institutions. To achieve these objectives, listings of pertinent research projects will be obtained from the Departments of Defense, Energy, Health and Human Services, Veterans Affairs, and NASA,[14] including:

- All human subject research proposals involving ionizing radiation that were newly approved and funded or renewed by the agency in fiscal year 1993, and a sample of such proposals from previous years.

- Human subject research proposals not involving ionizing radiation that were newly approved and funded or renewed during the same period as the ionizing

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[14] CIA maintains that it neither funded nor performed any human subject research involving ionizing radiation in fiscal year 1993. The Committee is currently determining whether CIA supported such research in 1990-1992.

radiation proposals, for the purpose of creating a comparison group.

Both intramural and extramural proposals in each category will be considered for review. Grantee institutions and the agencies will be asked to provide relevant documents for a sample of the radiation research proposals as well as a parallel sample of non-radiation research. A subset of Committee members and staff will review and evaluate the proposal materials based on evaluation criteria developed by Committee and staff. This team of evaluators will include persons with technical radiation risk and medical expertise, knowledge of the appropriate standards for informed consent and selection of human subjects, and any additional expertise necessary to address the objectives listed above.

3. Agency Oversight Review

In an effort to assess both the status and efficacy of current policies regulating human subject research, Committee staff has requested that each of the six agencies identified above (CIA, DOD, DOE, HHS, NASA, and VA) provide information related to oversight of research involving human subjects that it either conducts or supports, including any special procedures for oversight of research involving ionizing radiation. This includes information and materials related to the roles and responsibility of the appropriate office, personnel, process, and authority for oversight of human subject research review in each agency, as well as any applicable rules, regulations, or policies for the conduct, funding, or oversight of human subject research. Agencies also will be asked what procedures would be followed should it be determined that there is a need to bypass applicable research policies or regulations in the conduct of specific research projects. This information will be compiled, analyzed, and recommendations for future policy will be made during the next months of the Committee's work.

PART II. THE AGENCY SEARCH PROCESS AND OTHER METHODS OF INQUIRY: THE HUNT FOR PIECES OF THE PUZZLE

A. THE AGENCY SEARCH PROCESS

When the President established the Advisory Committee on Human Radiation Experiments, he also directed Federal agencies to provide it with the documentary information it needed to do its job. The Interagency Working Group created a subgroup to focus on document location and retrieval. Committee staff works with this group, and its representatives from each agency.

The Interagency Working Group has, collectively, devoted considerable time to these search efforts, which are ongoing. Numerous records collections, encompassing thousands of boxes of potentially relevant files in Federal Records Centers throughout the country, have been identified. Even where relevant collections are identified, however, the search process has been

arduous; dozens of boxes may yield only a handful of relevant documents, yet these documents may be of great value. Overall, the level of effort expended by the agencies, and the yield, has been significant.

1. Initial Reports

At the Committee's initial meeting, each agency reported on the status of their searches and invited Committee direction for continued search.

- CIA told the Committee in April, 1994 that its search had not found evidence that either showed CIA sponsorship or funding of human radiation experiments or information on human radiation experiments conducted by others.

- In January, DOD components had been charged to locate entities that conducted or sponsored experiments, and documents related to those experiments. DOD reported that many experiments had been identified.

- DOE explained that the first phase of its search was an attempt to inventory all potentially relevant records possessed by the agency and current contractors, in order to identify specific experiments and collections that would merit further review. The second phase would be an attempt to focus, based on what had been found, on the policy or contextual documents surrounding the experiments. (DOE had previously provided documents relating to human radiation experimentation in response to congressional inquiry and other investigations.[15])

- HHS reported that data on the many thousands of grants for earlier years were limited to skeletal grant records, which did not always make clear whether research involved human subjects. HHS was working on targeted approaches to locate documents of relevance to the Committee and to develop more complete data on intramural research.

- NASA's initial search resulted in the identification of about 200 reports and publications describing six specific studies and three large categories of research.

- VA's initial search focused on a survey of 172 medical centers throughout the country and a review of reports at the central office. There was no formal effort to

[15] These documents, along with materials collected by DOD relating to the Cincinnati total body irradiation experiments, were the bulk of documentation about specific experiments available at the onset of the Committee's work.

identify and list experiments. VA told the Committee it would search for further information on its confidential Atomic Medicine Division, which was created in 1947.

In addition to document searches, a number of the agencies interviewed former officials who might have knowledge of experiments (or related records) and sought to make use of Radiation Helpline telephone information.

2. Committee Assessment

In the first days and weeks of work, staff met with the search teams from each agency to learn of progress in and obstacles to the search. Search plans and status, as reported in detailed staff memoranda to the Committee, varied from agency to agency. In most cases, however, their progress demonstrated the inevitable difficulty of retrieving complete, detailed records on specific activities after the passage of up to half a century:

- To the extent experiments had been identified, only fragmentary further information had been provided (or was available).
- The volume of potentially relevant records is enormous, particularly because records often have been consigned to records centers or the National Archives with little useful indexing.
- Agencies had not always searched for headquarters-related documents, including those showing the nature and development of research ethics policies.
- Agencies had not always searched for documents retired to the National Archives (which are technically not within agency possession) and only sporadically searched for documents located in Federal Records Centers.
- While the agency searches produced surprising new information on early ethics policies, there was much less information on the implementation of these policies in the case of particular experiments.
- After the passage of many years, agency components responsible for human experimentation have been renamed, reorganized, or abolished, making it difficult to determine which records collections to search.

3. Committee Work with Agencies on Search Strategy

The initial agency searches provided a start in identifying experiments and an appreciation for the difficulty in retrieving substantial data about the experiments. With this data and experience in hand, the Committee sought to determine how to assist agencies in directing

the searches. The particulars of these activities are discussed in more detail in Appendix E and in staff memoranda and related Committee discussion concerning each agency.

In general, agencies were asked to refocus their searches. From the "dragnet" searches to identify experiments, it was suggested that focus be placed on identifying and retrieving headquarters-level collections that could provide context for particular experiments. The Committee expected that once more was known about the planning, funding, and use of experiments, it would be able to better advise the agencies on the particular experiments (or groups of them) for which a more intense field-level search would be requested. (It was also expected that the higher-level documents would help identify further experiments.) Agencies also were asked to look for documentation of the development and implementation of ethics policies governing human experimentation.

The Committee's archivists and historians, in conjunction with agency historians and records specialists, identified headquarters-level records collections to be searched and the likely location of these collections in the National Archives or Federal Records Centers. Agencies were also asked to give high priority to locating readily available documentation, such as agency histories, that could serve as guides to further searches.

In summary, and with further detail provided in Appendix E, considerations that were raised with each agency are discussed below.

a. *CIA.*

Documentation provided by DOD and DOE, and located by staff in the National Archives, confirmed that CIA was a participant in the mid-century DOD groups at which biomedical human experimentation, among other matters, was discussed and planned. Other data obtained by the Committee from members of the public confirmed that CIA contracted for work with, at least, DOE radiation research facilities. As a consequence, the Committee has asked CIA to search for documentation related to further evidence of CIA's association with human radiation experimentation.

b. *DOD.*

The Committee proposed that DOD agencies[16] look for headquarters-level planning, programming, and budgeting documentation. The headquarters-level ethics and policy documentation located as a result of this effort did reveal important documentary trails. For example, the records of the Joint Panel on the Medical Aspects of Atomic Warfare include debate on the need for human experimentation, plans for experimentation, and digests of

[16] Including the Office of the Secretary of Defense and the Defense Nuclear Agency, as well as each of the military services.

experiments. Similarly, the Armed Forces Medical Policy Council initiated discussions in 1951 that led to both the Secretary of Defense's February 1953 issuance of the top secret version of the Nuremberg Code for human experimentation and to the Joint Panel's consideration of experimentation in connection with atomic bomb tests.

DOD will continue to search for the location and retrieval of the records of relevant headquarters-level groups (through at least 1974), and the location and retrieval of documents relating to the development and implementation of its 1953 Nuremberg Code policy. It is also refocusing field-level searches in light of the new understanding that has been gained.

c. *DOE.*

In initial discussions, DOE proposed to continue its Phase I effort to locate and provide a comprehensive inventory to all relevant record collections. This effort should yield a publicly available index to extensive and previously disorganized public records. In the course of this review, experiments would be identified and some records retrieved. The Committee agreed to this proposal, with the expectation that the inventories would be available in the timeframe required by the Committee to retrieve documents for its work.

The Committee's initial review of DOE efforts led to specific Committee requests that DOE (l) locate the files of the AEC Intelligence Division, which may have contained data on work performed for other agencies and on intentional releases; (2) locate the collection of 250 documents that underlay DOE's 1974 reports on the plutonium injection experiments; and (3) arrange for the retrieval of documents from the three universities involved in the plutonium injections (University of Chicago, University of Rochester, and University of California--San Francisco). DOE is currently retrieving materials from the universities, but it reported that the files of the AEC's Intelligence Division had been destroyed and that the collection associated with the 1974 report could not be located. As discussed in Appendix E, the volume of documents that remain to be examined is large. On an ongoing basis, DOE and Committee staff are working to identify headquarters and field collections for priority retrieval.

d. *HHS.*

Initial review by HHS produced a computer-generated list of experiments that apparently involved both ionizing radiation and human subjects, but only for research initiated in and after 1962. Although components of the agency and its predecessor conducted or funded numerous human radiation experiments before 1962, a complete review of potentially relevant records was determined not to be feasible, because the extant records of earlier research are fragmentary. Once a listing of experiments reviewed by the NIH Radiation Study Section was produced, the systematic search for early experiments focused on archival research into organizational, policy-related evidence, and project specific documentation when available. More recently, the Committee and HHS have agreed that the Radiation Study Section list, with completed project titles, could serve as a reasonable proxy for a comprehensive search of pre-1962 experiments.

This approach is reasonable because many, if not most, of the experiments of interest likely were reviewed by this study section. This approach will be complemented by review of a more complete listing of intramural human radiation research conducted at the NIH Clinical Center.

e. *NASA.*

The Committee has asked NASA to provide a comprehensive inventory of potentially relevant record collections and locations. Several areas for focused inquiry have been identified: the development of NASA ethics practices; total body irradiation work conducted at Oak Ridge and supported by NASA; and space-related research performed in coordination with AEC and/or DOD.

f. *VA.*

VA's initial effort focused on a survey of field locations, in response to which some data were provided. There was only limited review of headquarters-related documents and no provision for the systematic identification of experiments conducted or sponsored by VA. Following review of the responses to the survey, the Committee and VA agreed to search headquarters records and, as that search proceeded, focus on a sample of field sites. In July, VA committed to a search of the approximately 1,800 Washington, D.C.-area record boxes that may contain relevant information. The present estimate is that the review will be completed by mid-November. The Committee simultaneously identified a number of field offices from which additional information was requested.

As noted previously, VA intends to find the purpose of its Atomic Medicine Division, which apparently included confidential activities. In October, VA asked the Office of the Inspector General, because of its expertise in records examination and search, to assist in this search.

4. Classified Documents

From the outset, the Committee was concerned about the limits that classification may put on its ability to review documents and to report on them to the American public. The Committee's policy is to seek declassification of relevant documents.

In the cases of DOD, DOE, and CIA, while documents have been declassified, significant collections of relevant material are still classified.[17] The Committee sought, and

[17] HHS initially stated that it did not have classified documents. HHS subsequently reported that it reviewed classified documents still within its possession and did not find any of relevance. VA similarly reported that it lacked original classification authority and that it does not possess any relevant classified documents. More recently, VA has found that President Truman in 1951 gave VA original classification

received, written assurance that reasonably discrete requests for declassification would be acted upon within three weeks. Where large classified collections of documents remain to be searched, Committee and staff may review the collections to identify priorities for declassification requests. This process has been impeded because of delays in the receipt of security clearances. By mid-October, only the Chairperson and six staffers had received interim clearance.

Agencies have stated that biomedical research materials should, in general, no longer be classified. However, they have also stated that some information of importance to the Committee, particularly that related to some intentional releases, will continue to require classification.[18] For example:

- DOD has stated that information related to the planning and purpose of the Green Run intentional release must still remain classified; and

- DOE has stated that much documentation related to the 250 radioactive lanthanum intentional releases conducted at Los Alamos must remain classified.

B. ADDITIONAL METHODS OF INQUIRY

In addition to documentation available from the agencies, the Committee seeks to locate information from all other feasible sources. Towards that end, it is conducting additional documentary searches, an interview project, and an oral history project.

1. Documentary Search

This search for information includes:

- *Members of the public.* Many members of the public have provided the Committee with important data, including documents gathered through personal research.

- *Published literature.* As noted elsewhere, the Committee staff is assembling published material from a wide variety of sources.

- *Congressional materials.* Staff has compiled a chronology of congressional hearings related to human research involving radiation going back to 1948. The materials are a valuable research tool.

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authority; VA lost this authority in 1972, apparently due to non-use.

[18] The Committee will explore the further possibilities for declassification.

- *Universities*. The Committee is contacting universities that may house documents of relevance. With DOE's assistance, for example, the Committee is retrieving documents from universities where researchers participated in the plutonium injection experiments. The Committee is also working with universities that have undertaken to review human radiation research conducted at their institutions. As the Committee focuses on additional experiments, further inquiries will be made.

- *Collections*. The Committee seeks to locate and review relevant collections of personal papers. For example, Committee members and staff have reviewed portions of papers of the medical director of the Manhattan Project (located at University of California - Los Angeles), the first head of the AEC Isotope Development Division (Texas A&M University), an early director of the AEC Division of Biology and Medicine (Boston University), the 1950-1951 chairman of the Armed Forces Medical Policy Council (Ohio State), the chairman of the DOD's Joint Panel on the Medical Aspects of Atomic Warfare (Harvard), and other members of mid-century radiation research review committees (University of California, Case Western Reserve University), as well as DOD-funded researchers at the Medical College of Virginia, the World War II Committee on Medical Research (University of Pennsylvania), and Henry Beecher, whose 1966 *New England Journal of Medicine* article was a watershed in the discussion of the ethics of biomedical research (Harvard University).

2. Ethics Oral History Project and Interview Project

In addition to collecting documentation, the Committee has embarked upon an Ethics Oral History Project in order to understand the evolution of ethical norms and research practices in human experimentation from World War II onward. Oral histories are essential, since information from other primary and secondary sources will be incomplete. Approximately 10 to 25 senior research scientists active in both radiation and nonradiation research from 1944 to the present are being interviewed by experienced interviewers from the Advisory Committee and its staff. Interviewees are being selected from two age groups: (a) clinical researchers who began their careers in the 1940s or 1950s, and (b) those whose careers began in the early 1970s.

In developing this project, the Committee has consulted with independent experts (ethicists and historians) concerning both whom to interview and how to conduct an oral history. Because the project involves the collection of information from human subjects, and the Committee seeks to draw generalizable conclusions from this information, the project was submitted to an institutional review board (IRB) from Pennsylvania State University College of Medicine (the home institution of the Committee member directing this effort). With IRB approval granted September 26, 1994, the Committee began interviewing on September 30, 1994. All interviews are being tape-recorded and transcribed; interviewees will be offered the opportunity to review transcripts before they are evaluated by the Committee.

The Committee also is interviewing individuals connected with particular experiments that the Committee is studying, and the government programs related to the experiments. Those interviewed to date include individuals connected with the plutonium injection and Cincinnati TBI experiments, attorneys who worked in the AEC Office of General Counsel at its creation, the military assistant to Secretary of Defense Wilson, and Glenn Seaborg (discoverer of plutonium). Finally, the Committee is seeking transcripts of interviews conducted by others. For example, DOE provided the Committee with (DOE-funded) interviews conducted by J. Newell Stannard on behalf of his history of radiation research and the Committee has reviewed interviews conducted by the American Institute of Physics.

PART III. OUTREACH

The Committee's outreach effort is designed to accomplish two goals: to gather information from sources outside the agencies whose records constitute its primary data base, and to publicize the Committee's work so that the public will have full access to its deliberations.

Every Federal advisory committee is an experiment in open government. In this case, the Committee is conducting an inquiry into the Nation's past. To engage with the past, it is essential to locate, hear, and learn from those who made and were affected by the history that the Committee is studying. If the Committee wants the past to connect with the present and future, it must also hear and learn from those concerned with human experimentation today. The Committee has many diverse constituencies, each of which it is seeking to reach.

At the core of the Committee's efforts are those who participated (or participate now) in human radiation experiments. This group includes all living human subjects of federally-funded experiments involving ionizing radiation, and family members (or other representatives) of subjects who are no longer alive. It also includes biomedical scientists and policymakers who were or are involved in human radiation experiments. The Committee has sought to contact these groups and individuals in a number of ways. Letters inviting participation in Committee meetings and soliciting relevant documents and information were sent to more than 50 groups representing subjects and families and to 15 professional societies.[19]

In addition to the public comment period that is a component of every Committee meeting, the Committee will hold several meetings outside of Washington with the purpose of hearing from the public. The October meeting of the full Committee was held in San Francisco

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[19] Some responded by attending Committee meetings and addressing the Committee during the public comment period, others have supplied documents, and some have done both. In a number of cases, the Committee has received valuable information in this way that it has not obtained by other means.

so that interested parties in the Western part of the United States could attend a meeting and express their views directly to the Committee. The Committee also has scheduled three small-panel meetings, in Cincinnati (October 21), Spokane (November 21), and Albuquerque or Santa Fe (January 30, 1995). As time permits, the Committee may seek to use portions of its future full Committee meetings to engage representatives of the various constituencies in discussions of particularly knotty questions that the Committee must address.

The Committee, as noted, is conducting interview projects to capture the voice of past and present investigators and subjects. To further identify subjects (or family members), staff has reviewed close to 20,000 telephone calls to the Radiation Helpline maintained by the Interagency Working Group and is reviewing several thousand letters received by DOE. Many of these callers and correspondents appear to have information or perspectives of particular value and the Committee has undertaken to contact them.[20]

Committee staff and Committee members meet regularly with individuals who contact the Committee and respond to calls and letters. When time and location permits, staff and Committee members are available to speak at conventions, professional conferences, or other meetings. The Committee is seeking to provide the public with the results of the documentary inquiry as soon as possible, in hope that members of the public will continue to provide analyses and reflections that the Committee can draw upon. Finally, the Committee seeks to engage Congress and the press.

Outreach efforts to date have yielded a substantial number of useful documents from private collections, including those of families of atomic veterans and of researchers who played important roles in the early days of radiation experimentation. Also as a result of the Committee's outreach program, members have heard testimony from many persons with relevant radiation-related experience. Through its interview project the Committee so far has collected valuable information from researchers and others in their own voices. Committee and staff members have spoken at public meetings and met with many individuals and groups to explain the Committee's work and report on its progress.

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[20] In establishing the Helpline, DOE stated that calls would be handled in confidence. The data on 20,000 calls, therefore, was reviewed by Committee staff following DOE redaction of the identification of the callers. DOE has sent letters to callers identified by the Committee, noting the Committee's interest in communication. (The sample focused on individuals who appeared to have specific information related to experiments that the Committee has been addressing or might address.)

PART IV. INFORMATION MANAGEMENT AND PUBLIC ACCESS

Information is the lifeblood of the Committee's work, and this imposes two fundamental tasks. First, data must be organized to be useful to the Committee and the public during the Committee's term. Second, data must be organized to be available to the public and the Interagency Working Group following the completion of the Committee's work. As of mid-October, progress includes the following:

- Well over 370 individual document accessions, ranging in size from 1 or 2 documents to several thousand, had been received or retrieved from a wide variety of public and private sources.

- Data (often fragmentary, as noted) had been received on many hundreds of experiments.

- Almost 2,000 journal articles, Congressional reports, and secondary sources that bear on experiments or experimentation have been assembled.

As discussed above, the Committee is simultaneously engaged in many projects dependent upon the compilation and organization of additional data. Of necessity, the creation of a system to permit efficient use of data has been a central focus of staff effort. The details of the information systems available to the Committee and the public are provided in Appendix F; highlights include the following:

- The Committee has an interactive network based on Lotus Notes, for use by staff. The Committee expects to shortly connect with the public via the Internet. The network should provide direct public access to the index of document collections possessed by the Committee, and to the experiment database.

- The Committee has established a public reading room. Basic committee materials (e.g., transcripts and briefing books for each meeting) are available. As they are assembled by staff, collections of historically important material (e.g., minutes of important committees, histories of relevant programs) are being organized and made available in the reading room .

PART V. TAKING STOCK: SOME INITIAL OBSERVATIONS

The Committee has accomplished a good deal. It has made significant progress towards identifying and organizing the world of past experiments and reconstructing the framework needed to evaluate them. It has sought and has begun to receive the advice and assistance of groups and individuals interested in its work. It has initiated projects to evaluate the conduct of experiments today. And, with the agency search teams, it is recovering documentation of our past, which is being archived for use following the conclusion of the Committee's work.

A. OPENNESS

The President's request that Federal agencies open their Cold War files to the Committee, and the public, was ambitious. There were many reasons for skepticism: the enormity of Federal records collections, the disorganization of many collections, the large number of classified records, and the potential for bureaucratic delay. These factors remain real, yet the Committee and the agency search teams have been able to locate significant collections of material. Of greater importance, the work has produced a road map that will permit the completion of a substantial search within the Committee's life, and will remain as a guide to national records that will serve public, Congress, the press, and Government agencies in years to come. For example:

- At the Committee's request, the Defense Nuclear Agency has declassified the table of contents of its more than 500 histories, on the basis of which declassification of portions of these histories is being requested. The histories of this agency, which has been at the center of nuclear weapons research and development, had previously been available only on a limited basis.

- The Committee is organizing the minutes and related records of the AEC Advisory Committee on Biology and Medicine and several DOD committees that were central to biomedical research related to atomic warfare.

- The Committee has located and is assembling documentation of the mid- century relationship between the civilian health research agencies (predecessors to the current HHS) and defense agencies.

- The Committee is assembling histories of military research organizations and activities. (DOD, for example, has provided multivolume histories of the Air Force's School of Aviation Medicine, the Naval Radiological Defense Laboratory, and a history of the Atomic Cloud Sampling Program.)

B. ORGANIZING THE SECRET AND PUBLIC WORLDS OF HUMAN RADIATION EXPERIMENTS

The Committee is learning that secrecy is not necessarily the primary bar to comprehending our past: a vast amount of relevant information is public but scattered. In tandem with the task of opening up that which was secret, the Committee places a premium on collecting and organizing that which is public. For example, the reconstruction of the story of human radiation experimentation in connection with the atomic bomb tests requires the piecing together of previously disconnected public and secret data, including: (1) facts that have, to some extent, long been public and relatively well known--such as the performance of psychological testing in connection with atomic bomb tests, or the manned flythrough of atomic clouds; (2) facts that were initially secret, had to some extent become public, but have not been relatively well known--such as the existence of the 1953 top secret Secretary of Defense ethics policy; and (3) facts that were initially secret, have been partially declassified, and are still being discovered, such as the biomedical planning related to atomic tests, and the relationship between this planning and DOD ethics policy and test activities.

The lists of experiments provided by the agencies are forming the core of the Committee's database of experiments. This database, in turn, is the starting point for the addition of new experiments, new data, and new information from the further sources that are currently being canvassed. Following the Committee's expiration, this database will remain as a "living electronic document."

C. HISTORICAL DISCOVERY

The work of the Committee is the work of a national government looking into its own past. Among the most important findings and implications of this search have been the following:

1. Government Ethics Debate and Policy

While full evaluation must await the final report, it already is clear that the information developed by the Committee should require a significant revision of our understanding of the history of research ethics. (This information is detailed in staff memoranda.)

2. Discovery of the Present in the Past

When the Committee began its work six months ago, it might reasonably have been presumed that human experimentation conducted in the mid-century world was so different from current research that its relevance to the present day would be limited. The examination of the past was, and remains, an end in its own right. However, the story that is unfolding appears to have far greater relevance to the contemporary questions faced by the Committee than might have been expected. For example:

- It might have been assumed that the mid-century was marked by the complete absence of debate on consent, much less formal consent policies. Documents now show that discussion took place and policy statements were issued. Then, as now, a key question is the way in which bureaucracies translate policies into practice and the extent to which policies that have been implemented are adhered to or enforced.

- Similarly, it appears that the meaning and reach of policies that were intended to govern experimentation were then, as now, not always clear. Where policies did exist, what were they intended to cover? Did they cover sick patients undergoing experimental therapy, as well as healthy volunteers? What was the assumed boundary between experimentation with healthy volunteers and occupational safety monitoring?

- Then, as now, questions include the assignment of responsibility for policies designed to ensure basic rights of subjects. Where experiments involved multiple agencies and institutions, how was responsibility for ensuring rights assigned? When the decisionmakers included medical professionals, government officials, military officers, and civilian administrators, what rules and expectations governed the conduct of the differing professions?

- Documents show that, faced with critical decisions concerning the safety of workers, soldiers, and the public health, Cold War experts were eager for opportunities to gather data on radiation. Then, as today, there was tension between the role of the physician as healer and as seeker of new knowledge. What can the study of the resolution of this tension in the past tell us about its resolution in the present?

- A conflict of interest may also exist within institutions that have dual responsibility for promoting human subject research and assuring health and safety. Biomedical offices or committees vested with responsibility for ensuring that health standards were met also promoted the exposures needed to learn about the appropriate standards. What can this experience tell us about the desired relation of promotional and regulatory roles today? What difference did it make when the promotion and regulation were conducted, at least in part, in secret? What can this experience tell us about the future organization of research that involves secret components?

3. Government Rediscovery of its Past

The events that the Committee is studying often predate the working careers, even lives, of those now staffing the agencies. The search process has involved the continued discovery of a heritage that had been lost even to those to whom it had been bequeathed. Consequently, the

search has been an opportunity to rediscover this past. For example, there was limited recollection of the extent to which the Cold War linked the activities of civilian and military agencies. The reconstruction of the intertwined Cold War roots of civilian and defense agencies requires the piecing together of documents and memories from many sources.

D. PUBLIC ACCESS TO THE RECORDS OF OUR PAST

As discussed above and in Appendix F, the Committee is devoting considerable resources to organizing important record collections so that they can be made available to the public during the Committee's lifetime. This effort includes the organization of collections (in paper form) and the development of databases for electronic access via Internet.

E. CHALLENGES TO RECONSTRUCTING THE PAST

The primary challenge to the Committee's task is its daunting nature. Agency searches are time consuming, data on experiments are fragmentary, some important document collections have been lost or destroyed, and declassification is slow and uncertain.

1. Agency Searches Are Time Consuming

While the process of identifying and retrieving documents remains overwhelming, the basic contours of the search have been established. As discussed in detail in Appendix E, agency searches have now located many headquarters-level collections that are likely to contain relevant information. The effort is currently directed at the retrieval of these documents. At the same time, effort will be required to access field collections that appear most promising. These efforts will take more time, but they should be relatively well-defined tasks--the time should not be open-ended.

2. Data on Experiments are Fragmentary

In the case of many experiments, only fragmentary data are available from government and public sources (e.g., journal articles). Data on key questions, such as consent practices and subject selection, are often lacking. Additional information may be available from the institutions that conducted the experiments, the investigators who conducted them, and the subjects themselves. The Committee will seek to focus its efforts on cases where access to additional information is more likely. However, the reconstruction of experiments will be time consuming and its success uncertain. The problem of fragmentary data also applies to intentional releases, where in some cases pertinent information remains classified.

3. Loss or Destruction of Important Document Collections

Even when important document collections have been identified, they can rarely be recovered *in toto*. In some cases, significant collections appear to have been lost or destroyed.

(The destruction may well have been in accord with standard records retention practices; however, at many years remove, it is often difficult to know the precise circumstances of destruction.) For example:

- CIA acknowledged that the charter of its MKULTRA program of experiments included radiation research; however, as CIA previously reported, Director of Central Intelligence ordered MKULTRA files destroyed in 1973.

- As noted above, documents provided by DOD and DOE, and/or located by staff in the National Archives (in the files of HHS predecessors) show that CIA played a role in the mid-century DOD committees that debated and planned for, among other things, human experimentation. CIA, however, has not yet located any materials related to these groups in its own files.

- In issuing his Nuremberg Code directive in 1953, Secretary of Defense Wilson required the advance approval of covered human experimentation by the Service Secretaries. With limited exceptions, the files containing such approvals have not been located.

- The Naval Radiological Defense Laboratory (NRDL) was established in 1947 to study contamination problems posed by the use of the atomic bomb. At the time of its "disestablishment" in 1969, its library of research reports was evidently dispersed, and basic records were apparently destroyed. The Navy continues, however, to search for surviving NRDL materials.

- DOE was unable to locate the pre-1970s files of its Intelligence Division, which could have provided critical data on intentional releases and work done for others. In response to Committee request, a DOE investigation revealed that these files were substantially purged during the 1970s and as late as 1989.

- In the early 1970s, DOE's predecessor (AEC) conducted an extensive inquiry into the plutonium injection experiments. The resulting reports referenced a collection of 250 documents that were gathered and used in the reports. DOE has not yet been able to locate this potentially important collection.

- Requests for the use of isotopes for human experiments, as well as other purposes, required the approval of the AEC Isotope Development Division. However, DOE has been unable to locate much of the basic licensing documentation, which would provide fundamental data on human experimentation conducted with isotopes.

- At the outset, HHS reported that, except for skeletal records of grants, there was a paucity of information on experiments for the years through the early 1960s.

- In the 1960s, NASA contracted with DOE's Oak Ridge operations to perform a retrospective study of whole body irradiation. The study encompassed over 3,000 radiation exposures at over 40 institutions. If recoverable, the data would be an essential source on whole body irradiation. However, in 1981 congressional testimony, NASA stated that the data had been destroyed in the routine course of business.

- At the time of the Committee's creation, VA announced its intent to learn about the purpose of a confidential "Atomic Medicine Division," that, according to a 1952 report, was created in 1947. VA has located only a handful of additional relevant documents that might shed light on any activities of this confidential division. However, as noted, VA has asked its Inspector General to assist in the search.

4. Classification

As noted, a substantial amount of material of relevance to the Committee remains classified. The declassification process slows the document retrieval process. The Committee has sought and received written assurance that declassification decisions will be made within a short time frame. Possessed of security clearances, Committee and staff will be able to review documents and earmark those meriting speedy declassification. However, security clearances have been received only recently and on a limited basis. In addition, as noted earlier, agencies have stated that in some cases declassification requests will not be granted.

PART VI. THE NEXT SIX MONTHS

A. WORK TO BE DONE

In the next six months, the Committee will continue with the tasks of data gathering and organization. The focus of the Committee's work, however, will shift to developing (1) the ethics criteria for evaluating historical and contemporary experiments, policies, and procedures, and (2) the criteria for determining appropriate Federal responses where wrongs or harms have occurred. Based on what the Committee has learned about both past and present experiments, the Committee then will make specific recommendations regarding policies for the future.

1. Continuation of Present Tasks

- Continuing Phase I of the inquiry: identifying experiments and mapping the world in which they were set (1944-1974).

- Implementing Phase II of the inquiry: focus on specific experiments and their

context (1944-1974).

- Implementing the three projects designed to gather data about the current state of human radiation research.

- Continuing the agency search process.

- Continuing other methods of inquiry, including documentary search efforts from members of the public, published literature, congressional materials, universities, and collections of personal papers.

- Continuing to interview individuals connected with particular experiments and Government programs, and continuing with the oral history project.

- Continuing outreach efforts.

- Continuing to develop and make available public archives.

2. Identification of Relevant Ethics Standards

Based on the work done in the investigation of research policies and practices (and, as relevant, scientific and medical standards and practices), the Committee will identify the relevant ethics criteria for judging past and present experiments. This will require discussion and analysis of issues related to the appropriate standards and concepts by which retrospective judgments about ethical issues are to be made, including the selection of subjects of research, balancing of risks and benefits, standards of informed consent, voluntariness of participation, and prior review. This also will require careful discussion of knotty questions about whether and how we ought to judge the conduct of those who have preceded us.

3. Considerations and Criteria for a Range of Remedies

The Committee will make recommendations on criteria for the range of remedies that may be appropriate where wrongs or harms have occurred. These criteria will be based on an analysis of past experiments in light of the ethics standards adopted by the Committee. The criteria also will reflect the Committee's consideration of alternative forms of remedy, including responses such as explicit governmental acknowledgement of the wrong done, medical monitoring and followup, access to personal information, compensation, or other potentially appropriate responses.

4. Recommendations on Policies for Future Research

Based on the understanding gained through investigating and analyzing past and present practices and policies concerning human radiation research and intentional releases, the Committee will make specific recommendations on policies for future research.

B. TIMING OF FINAL REPORT

The Committee takes the year term in its Charter as a serious indication of the Interagency Working Group's, and the public's, interest in a timely final report. A substantial start-up time has been required to assemble Committee staff, to chart and master the vast quantities of Federal records, to develop databases needed to manage this ocean of data, and to communicate with the Committee's many constituencies. While the learning curve has been steep, considerable efficiencies should now be experienced. The Committee will seek to meet the April 1995 deadline. While an extension of several months may be required, the Committee has no intention of seeking a significantly longer term.

APPENDIXES

APPENDIX A

EXECUTIVE ORDER

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 18, 1994

EXECUTIVE ORDER

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

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

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

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

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

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

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

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

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(OVER)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

# # #

APPENDIX B

CHARTER

CHARTER

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

1. Committee's Official Designation

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

2. Authority

Executive Order No. 12891.

3. Objectives and Scope of Activities

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

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

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

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

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

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

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

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

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

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

4. Description of Duties for Which Committee is Responsible

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

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

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

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

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

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

5. To Whom the Advisory Committee Reports

The Advisory Committee shall report to the Interagency Working Group.

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

6. Duration and Termination Date

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

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

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

8. Estimated Annual Operating Costs

$3 million.

9. Estimated Number and Frequency of Meetings

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

10. Subcommittee(s)

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

11. Members

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

12. Chairperson

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

APPENDIX C

COMMITTEE ROSTER

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

APPENDIX D

PUBLIC MEETINGS

PUBLIC MEETINGS OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Meetings for the Advisory Committee on Human Radiation Experiments are scheduled as follows:

1. **April 21-22, 1994**
   Ramada Plaza Hotel
   Washington, DC

2. **May 18-19, 1994**
   Ramada Plaza Hotel
   Washington, DC

3. **June 13-14, 1994**
   Ramada Plaza Hotel
   Washington, DC

4. **July 5-6, 1994**
   Washington Vista Hotel
   Washington, DC

5. **July 25-26, 1994**
   Stouffer Mayflower Hotel
   Washington, DC

6. **September 12-13, 1994**
   Ramada Plaza Hotel
   Washington, DC

7. **October 11-13, 1994**
   The Press Club of San Francisco
   San Francisco, CA

8. **November 14-15, 1994**
   Renaissance Hotel
   Washington, DC

9. **December 15-16, 1995**
   Omni Shoreham Hotel
   Washington, DC

10. **January 19-20, 1995**
    Omni Shoreham Hotel
    Washington, DC

11. **February 16-17, 1995**
    Location not yet determined

12. **March 16-17, 1995**
    Location not yet determined

13. **April 10-11, 1995**
    Location not yet determined

SMALL PANEL MEETINGS

1. **October 21, 1994**
   Regal Cincinnati Hotel
   Cincinnati, OH

2. **November 21, 1994**
   West Coast Ridpath Hotel
   Spokane, WA

3. **January 30, 1995**
   Albuquerque or Santa Fe, NM
   Location not yet determined

APPENDIX E

SUMMARY OF AGENCY RECORDS RETRIEVAL

CENTRAL INTELLIGENCE AGENCY

DEPARTMENT OF DEFENSE

DEPARTMENT OF ENERGY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF VETERAN AFFAIRS

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

CENTRAL INTELLIGENCE AGENCY

History and Organization of the Central Intelligence Agency

The Central Intelligence Agency (CIA) was created in 1947 by the National Security Act, which also established the Department of Defense (DOD) and the National Security Council (NSC). CIA was modeled largely after the Office of Strategic Services, which served as the principal U.S. intelligence organization during World War II. The newly created agency was authorized to engage in foreign intelligence collection (i.e., espionage), analysis, and covert actions; it was, however, prohibited from engaging in domestic police or internal security functions. Nonetheless, CIA engaged in a program of domestic human experimentation from the 1950s into the 1970s.

CIA components most likely to have been associated with any experiment are the Office of Scientific Intelligence (OSI) in the Directorate of Intelligence; the Office of Security; the Technical Services Division (TSD) in the then-Directorate of Plans (DDP, now Directorate of Operations); and (at least from 1962) the Office of Research and Development (ORD) in the Directorate of Science and Technology. Beginning in the late 1940s, OSI analyzed and disseminated foreign scientific, and medical intelligence concerning the development and testing of atomic weapons and interacted with DOD and the Atomic Energy Commission (AEC) on these issues. TSD ran Project MKULTRA, discussed below. Human experimentation was done prior to MKULTRA by OSI and the Office of Security and, after MKULTRA, by ORD.

Experiments

To date, CIA has found no records or other information indicating that it conducted or sponsored human radiation experiments.

Records Search

In response to the January 1994 presidential directive, CIA conducted an agency-wide search for information about human radiation experiments that it may have conducted.[1] At the Committee's initial meeting in April 1994, CIA stated that the search encompassed an electronic review of approximately 34 million documents, a manual review of 480,300 documents, and nearly 50 interviews. CIA also stated that it had found no documents relating to experiments conducted by other agencies. The Committee, however, has since found records indicating that CIA officers did participate in DOD groups in which human radiation experiments, including those involving the placement of troops at atmospheric weapons tests, were discussed and planned. As discussed below, CIA is continuing to search for documents relating to these and other activities.

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[1] In contrast to all other agencies, CIA maintains custody of virtually all of its records; only a small number have been transferred to the National Archives and none to any Federal Records Center. No publicly available index or inventory describes the size and organization of the records that CIA maintains.

Beginning in the early 1950s, CIA engaged in an extensive program of human experimentation, using drugs, psychological, and other means in search of techniques to control human behavior. CIA has so far found no evidence that radiation experiments on humans were part of this program. CIA documents and a 1963 CIA Inspector General (IG) report, however, state quite clearly that MKULTRA was a program "concerned with research and development of chemical, biological, and *radiological* materials capable of employment in clandestine operations to control human behavior." (emphasis added) The IG report states that "additional avenues to the control of human behavior had been designated . . . as appropriate to investigation under the MKULTRA charter, including *radiation*, electroshock, various fields of psychology, sociology, and anthropology, graphology, harassment substances, and paramilitary devices and materials." (emphasis added)[2] The program included unwitting experimentation on humans with LSD (lysergic acid diethylamide), brainwashing, and other interrogation methods.

CIA's human behavior program originated in 1950 and was motivated by Soviet, Chinese, and North Korean use of mind control techniques. It began under the code name BLUEBIRD (and was later known as ARTICHOKE) and was operated by the Office of Security and OSI with support from other offices. MKULTRA formally began in April 1953 as a special, clandestine funding mechanism for DOD human behavior research. The program was the subject of investigations by the Rockefeller Commission in 1975, the Senate Church Committee in 1976, and hearings by Senator Kennedy in 1975 and 1977; however, these committees did not focus on radiation experiments, and no such information was found by them.

CIA has told the Committee that MKULTRA involved human experimentation using every research "avenue" listed in the MKULTRA document except for radiation.[3] The agency also noted that most of the MKULTRA records were deliberately destroyed in 1973 by the order

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[2] A redacted version of the IG report was reprinted in Joint Hearings on Biomedical and Behavioral Research, 1975, before the Subcommittee on Health of the Senate Labor and Public Welfare Committee and the Subcommittee on Administrative Practice and Procedure of the Senate Judiciary Committee, 94th Cong., 1st Sess., at 877 (the complete report is still classified); *see also* "Final Report of the Senate Select Committee to Study Governmental Operations with Respect to Governmental Operations, Book I" at 389-90, 94th Cong., 2d Sess., No. 94-755 (Apr. 26, 1976)("Church Committee").

[3] CIA did investigate the use and effect of microwaves on humans in response to a Soviet practice of beaming microwaves on the U.S. Embassy but determined that this was outside the scope of the Committee's purview. CIA also sponsored radioisotope tracer experiments involving irradiated LSD and other chemicals on laboratory animals as part of MKULTRA. The Army conducted similar tracer studies on humans at Edgewood Arsenal in Maryland during this period. Beginning in 1967, CIA's Office of Research and Development and the Edgewood Arsenal undertook a joint program for research in influencing human behavior with drugs, which included human experimentation (including on prison inmates) and was performed by the same University of Pennsylvania researchers who had performed the tracer studies. It is not known whether the joint program included radioisotope tracer studies on humans.

of then-Director of Central Intelligence Richard Helms.[4] In early September 1994, the agency found a document that summarized work done for ARTICHOKE, which states that "[i]n addition to hypnosis, chemical and psychiatric research, the following fields *have been explored*: . . . 7) other physical manifestations, including heat and cold, atmospheric pressure, *radiation.*" (emphasis added) Although there is no indication from this document that radiation was explored on humans directly, it makes clear that CIA did "explore" radiation as a possibility for the defensive and offensive use of brainwashing and other interrogating techniques.[5]

In another MKULTRA project, CIA secretly provided funding for the construction of a wing of Georgetown University Hospital in the 1950s so that it would have a locale to carry out clinical testing of its biological and chemical programs. Dr. Charles F. Geschickter, a Georgetown doctor who conducted cancer research and experimented with radiation therapy, acted as cover for CIA financing.[6] CIA also tried unsuccessfully to enlist AEC to cofund the project by appealing to its interest in Geschickter's radiation research. Geschickter testified before Congress in 1977 that CIA money helped fund his radioisotope lab and equipment. Thus, CIA money seems to have helped fund radiation-related medical research as a cover for the agency's real interest in chemical and biological research.

Records obtained from DOD and the Department of Energy (DOE) and by Committee staff from the National Archives show that CIA was represented in key DOD biomedical groups in which both human experiments and experimental ethics policy were discussed and planned. At least three CIA officers were members of DOD's Committee on Medical Sciences (CMS) from 1948 to 1953 and attended meetings and received the "program guidance" of the DOD Joint Panel on the Medical Aspects of Atomic Warfare. As reported elsewhere,[7] the Joint Panel was the center for information gathering and planning for medical experimentation, including human experiments, relating to atomic warfare; for example, this panel helped coordinate the program of placing troops in the vicinity of atmospheric nuclear weapons tests. In 1948 CIA also participated in discussions regarding the proposed formation of an Armed Forces Medical Intelligence Organization, during which it was suggested that CIA would be in charge of foreign

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[4] Helms testified in 1975 that he ordered the records destroyed because "there had been relationships with outsiders in government agencies and other organizations and that these would be sensitive in this kind of a thing but that since the program was over and finished and done with, we thought we would just get rid of the files as well, so that anybody who assisted us in the past would not be subject to follow-up questions, embarrassment, if you will." Church Committee, Book I, at 403-04.

[5] CIA officials have suggested this reference to radiation might have meant "ultrasonic radiation" because they found another document in which the possibility of using "ultrasonics and other radiant energy" was proposed and rejected. This suggestion, however, seems unlikely because the summary document also lists "sound" as a field that was explored in addition to radiation.

[6] The Geschickter Fund for Medical Research served as a principal "cut-out source" for CIA's secret funding of numerous MKULTRA human experiment projects.

[7] See discussion in Part I of the Interim Report.

atomic, biological, and chemical intelligence from a medical sciences viewpoint.[8]

CIA representatives on CMS worked for OSI (and its precursor, the Scientific Branch). This office had principal responsibility for analyzing and disseminating foreign atomic energy intelligence. It chaired the Joint Atomic Energy Intelligence Committee (JAEIC, also known as the Joint Nuclear Intelligence Committee), an interagency body that helped coordinate analyses and activities by Departments responsible for monitoring foreign nuclear weapons programs. It also chaired the interagency Scientific Intelligence Committee as well as the Joint Medical Sciences Intelligence Committee, both of which coordinated scientific and medical intelligence for the Government. These two committees provided medical intelligence to the Armed Forces Medical Policy Committee, which also played an active role in planning and overseeing radiation research and human experimentation for DOD. This office also worked on Projects BLUEBIRD and ARTICHOKE; at least one of the officers who attended CMS meetings also analyzed medical intelligence for the Office of Security's human experimentation activities under BLUEBIRD and ARTICHOKE.

CIA historically has employed the facilities of other agencies, including DOD and DOE (and its predecessors) to assist in agency research. For example, in 1965 CIA entered into a Memorandum of Understanding with AEC's Lawrence Livermore Laboratory to perform a number of projects for CIA's Office of Scientific Intelligence. CIA has been asked to search for documents specifically related to the work performed under this agreement that might relate to human radiation experiments.

With regard to the history of CIA's ethics policies, the MKULTRA experiment program gestated from 1951 to 1952. This was the very period in which DOD's CMS, with CIA participation, engaged in discussions that led to the Secretary of Defense's 1953 enactment of an ethics policy for human experiments based on the Nuremberg Code. The relationship between these Nuremberg Code discussions (and policy) and CIA's MKULTRA activities is a subject of the Committee's inquiry.

Through the course of MKULTRA, CIA sponsored numerous experiments on unwitting humans. After the death of one such individual (Frank Olson, an army scientist who was given LSD in 1953 and committed suicide a week later), an internal CIA investigation warned about the dangers of such experimentation. Ten years later, a 1963 IG report recommended termination of unwitting testing; however, Deputy Director for Plans Richard Helms (who later became Director of Central Intelligence) continued to advocate covert testing on the ground that "positive operational capability to use drugs is diminishing, owing to a lack of realistic testing. With increasing knowledge of the state of the art, we are less capable of staying up with the Soviet advances in this field." The Church Committee noted that "Helms attributed the cessation

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[8] Although this organization apparently was never created, the basic division of labor between CIA and DOD suggested here seems to have been maintained by the Armed Forces Medical Policy Committee.

of the unwitting testing to the high risk of embarrassment to the Agency as well as the 'moral problem.' He noted that no better covert situation had been devised than that which had been used, and that 'we have no answer to the moral issue.'"[9]

Following revelations of MKULTRA and other unethical CIA practices, President Gerald Ford issued the first Executive Order on Intelligence Activities in 1976, which, among other matters, prohibited "experimentation with drugs on human subjects, except with the informed consent, in writing and witnessed by a disinterested third party, of each such human subject and in accordance with the guidelines issued by the National Commission for the Protection of Human Subjects for Biomedical and Behavioral Research." Subsequent Executive Orders by Presidents Jimmy Carter and Ronald Reagan expanded the directive to apply to any human experimentation: "No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education, and Welfare. The subject's informed consent shall be documented as required by those guidelines."[10] CIA has issued guidelines implementing the Executive Order and has provided them to the Committee.[11]

Remaining Tasks

The primary focus of CIA's initial search was records on the use of ionizing radiation on humans by the U.S. Government. The agency did not initially search specifically for information on such topics as the 1949 "Green Run" release (an intentional release of radiation in Hanford, Washington) or the activities of the JAEIC, CMS, or Joint Panel on the Medical Aspects of Atomic Warfare. Nor did CIA initially focus on activities of the Soviet Union and other countries that may have prompted U.S. agencies to consider human radiation experiments (e.g., when the Soviet Union sent approximately 40,000 troops to a test area to conduct military exercises 30 minutes after an atomic bomb test in Totsk, Kazakhstan, on September 14, 1954).

In response to specific Committee queries, CIA has provided documents that describe activities of the OSI. CIA continues to search for records in light of five Committee requests. These requests include: (1) records on CMS, the Joint Panel on the Medical Aspects of Atomic Warfare, and other DOD and/or interagency medical intelligence organizations involving human

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[9] Church Committee, Book I, at 402. The Church Committee noted that "the project involving the surreptitious administration of LSD. . .was marked by a complete lack of screening, medical supervision, opportunity to observe, or medical or psychological followup. The intelligence agencies allowed individual researchers to design their project. Experiments sponsored by these researchers...call into question the decision by the agencies not to fix guidelines for the experiments."*Id.*

[10] Executive Order 11905 (Feb. 19, 1976) (Ford); Executive Order 12036, § 2-302 (Jan. 26, 1978) (Carter); Executive Order 12333, § 2.10 (Dec. 4, 1981) (Reagan).

[11] One section of the most recent guidelines originally was classified, i.e., HR 7-1a(6)(c)(4), but was declassified upon the request of the Committee.

experiments; (2) foreign medical intelligence records on human radiation experiments; (3) records on work done by other agencies; (4) records on ethics policies; and (5) records on the Green Run and other intentional releases.

The Committee awaits completion of ongoing records searches that CIA has been conducting on the above and other topics raised by the Committee.

DEPARTMENT OF DEFENSE

FIVE COMPONENTS OF THE DEPARTMENT OF DEFENSE

Five relevant components of the Department of Defense (DOD) have been involved in human radiation experiments: the Office of the Secretary of Defense (OSD), the Department of the Air Force (Air Force), the Department of the Army (Army), the Department of the Navy (Navy), and the Defense Nuclear Agency (DNA). The searches performed are described below.

OFFICE OF THE SECRETARY OF DEFENSE

History and Organization

DOD replaced the War and Navy Departments in 1947. OSD, established concurrently, consisted of the Secretary of Defense, his deputies and assistants, and various advisory boards and committees, including the Research and Development Board (RDB). Responsibilities of the RDB included preparing an integrated military research and development (R&D) program and coordinating R&D among the military services. Under the former War and Navy Departments, these tasks had been performed in part by the Office of Scientific Research and Development (1942-1945), National Research Council (1945-1946), and the Joint Research and Development Board (1946-1947).

To accomplish its assigned responsibilities, RDB created numerous committees whose members included military personnel and civilians. There are at least three committees or panels whose work is particularly relevant: (1) Committee on Medical Sciences (CMS), (2) Joint Panel on the Medical Aspects of Atomic Warfare (which reported to both CMS and Committee on Atomic Energy), and (3) Committee on Human Resources.

With the disestablishment of RDB in 1953, its responsibilities were apparently assigned to the newly created Assistant Secretary of Defense for R&D for several years and then to the Defense Director of Research & Engineering (DDR&E) in 1958. At least during the 1950s these offices had their own advisory committees and panels. The records of at least three such panels (i.e., CMS, Committee on General Sciences, and Committee on Atomic Energy) may be of interest.

Another advisory board during this period, the Armed Forces Medical Policy Council (AFMPC), drafted and recommended to Defense Secretary Wilson the policy on consent for certain human experiments that he adopted in February 1953. AFMPC succeeded the Office of Medical Services in early 1951 but appears to have been disestablished in 1953. At some point thereafter, the office of the Assistant to the Secretary of Defense for Health was created, and it is believed that this office assumed some, if not all, of the functions of AFMPC.

Experiments

OSD reviewed and either approved or disapproved specific programs and projects of the four military services and the Defense Nuclear Agency and its predecessors (see below).

Records Search

The initial DOD search did not encompass OSD. DOD agreed to search OSD files at the Committee's request and has been engaged in an effort to locate and retrieve the files of relevant groups, as discussed above or further identified in the course of ongoing search. Most records of the RDB's CMS, Joint Panel on the Medical Aspects of Atomic Warfare, and Committee on Human Resources that are in the OSD collection (Record Group #330) at the National Archives (NARA) in Washington, D.C., have been examined. Some significant records, however, are not in this collection and may not exist. For example, although there are verbatim transcripts of the meetings of CMS and the Committee on Human Resources, only summary minutes exist for the meetings of the Joint Panel on the Medical Aspects of Atomic Warfare. Most records of AFMPC and its predecessors in this collection also have been reviewed. OSD has also started to identify and review pertinent collections in the OSD holdings at the Washington National Records Center (WNRC) (Record Group #330); these are estimated to comprise approximately 2000 boxes.

Remaining Tasks

Most records of two RDB predecessors, the Office of Scientific Research and Development (Record Group #227) and the Joint Research and Development Board (Record Group #330), are declassified and housed at NARA in Washington, D.C. The records of the committees with jurisdiction over biomedical research must be examined. Most of the records of the National Research Council are either unclassified or declassified and housed at the National Academy of Sciences in Washington, D.C. Similarly, the records of the committees with jurisdiction over biomedical research must be reviewed.

With respect to the OSD records at NARA, the following remains to be done: (1) Committee Staff will complete the examination of the records of the CMS, Joint Panel on the Medical Aspects of Atomic Warfare, and Committee on Human Resources; (2) Committee staff will complete the examination of the monthly, quarterly, and annual progress reports submitted by the four military services and Armed Forces Special Weapons Project (AFSWP) to RDB; and (3) Committee staff will complete the review of the records of AFMPC and its predecessors. For the most part, these records are declassified.

With respect to the OSD records at WNRC (Record Group #330), DOD must (1) complete the identification and review of any relevant RDB records (including, among other things, any correspondence files of the Joint Panel on the Medical Aspects of Atomic Warfare and any verbatim transcripts of its meetings), (2) complete the identification and examination of

the pertinent records of the Assistant to the Secretary of Defense for R&D and DDR&E, (3) complete the identification and review of records of any other OSD office that had any role in human experiments, and (4) complete the identification and examination of any relevant records of AFMPC and its successor(s). Committee staff will assist OSD in this process. Most of the OSD records at WNRC are still classified. DOD must also identify and review any relevant OSD records still remaining.

DEPARTMENT OF THE AIR FORCE

History and Organization

The Air Force was established in 1947 under the new DOD. Prior to this it had been part of the U.S. Army under the War Department.

Several Air Force components have been involved in biomedical research, including the Office of the Surgeon General (OSG), which has general oversight responsibilities. Another, the School of Aviation Medicine (SAM), was a subordinate command of the Air University in the 1950s and 1960s and is now part of the Human Systems Center. A third component is the Medical Centers attached to operational commands where clinical investigations are conducted.

Experiments

The Air Force provided a list of more than 600 human radiation experiments, approximately 90 of which predate 1975. Committee staff has asked the Air Force to provide available backup material it has identified regarding pre-1975 experiments. SAM was a primary sponsor of the majority of the pre-1975 experiments, and the Air Force has provided histories of SAM. The Air Force reports that additional material is warehoused at SAM's Texas facilities; however, records of many individual experiments appear to have been destroyed or taken by the investigators.

Records Search

With respect to headquarters documents, selected files in the Secretary of the Air Force (Record Group #340) and Headquarters, Air Force (Record Group #341) collections at NARA and WNRC have been examined. All periodic and programmatic histories of OSG have been examined, and pertinent portions provided (this effort extensively involved the U.S. Air Force Historical Research Agency).

The minutes, agendas, and reports of the panels and committees of the Scientific Advisory Board (SAB) dealing with biomedical research in Record Group #341 at WNRC have been reviewed. SAB was established in 1947 and advises the Secretary of the Air Force and the Chief of Staff on research and development.

In response to the DOD-wide January search directive, the Air Force sought to identify experiments (and related documentation) at field sites that may have conducted or sponsored experiments. This effort entailed several queries to all Air Force commands, including each individual clinical investigation facility (Travis AFB, Lackland AFB, Keesler AFB) and those conducting clinical investigation programs (Anderson AFB, Wright-Patterson AFB, Scott AFB). Command historians, as well as the Office of Air Force History, were also queried. The Air Force reports that over 6,000 person-hours have been spent reviewing selected files at the National Personnel Records Center in St. Louis; the holdings at Strughold Library at Brooks AFB; and the Geophysics Laboratory Library at Hanscom Field.

Remaining Tasks

Further review may be needed of selected files in Record Groups #340 and #341. The post-1953 records of OSG must be located and reviewed. Committee staff will continue to work with the Air Force to examine pertinent records of important nonheadquarters commands, particularly SAM.

Although evidence exists that the Air Force received notice when the Secretary of Defense issued his Nuremberg Code directive in February 1953, little or no evidence exists of its implementation in specific cases. The Committee believes that the search will locate relevant materials on implementation.

The Committee also has asked the Air Force to search for materials relating to (1) consent practices used for those involved in flash-blindness tests and atomic cloud air sampling activities conducted in connection with atomic bomb tests, and (2) the development and application of a 1958 Air Force policy regarding ultrahazardous research.

DEPARTMENT OF THE ARMY

History and Organization

The Army was established in 1947 under the new DOD. Prior to this the Army was under the War Department, which DOD replaced.

One component conducting biomedical research was the Office of the Surgeon General (OSG) and its many subordinate commands. These commands included hospitals (e.g., Letterman General Hospital in San Francisco) and research centers (e.g., the Medical Research Laboratory at Fort Knox). Beginning in the 1940s, OSG created a Medical Research and Development Board to review all biomedical research conducted by OSG and its many contractors. It is not known how long the board existed, but in 1958 OSG established the Army Medical Research and Development Command, which evidently had the same responsibilities.

A second component conducting biomedical research is the Chemical Corps and its

successor(s). The Chemical Corps replaced the Chemical Warfare Service in the mid-1940s, and it in turn was disestablished and had its responsibilities assigned to the Assistant Chief of Staff for Force Development in 1963. At least during the late 1940s and early 1950s, it appears that the majority of biomedical research was conducted by or for the Medical Division of the Army Chemical Center (one of three major centers in the Chemical Corps during this period).

Another significant component might be the Scientific Advisory Panel and any successor(s). In 1951 this panel was established to advise the Secretary of the Army and the Chief of Staff on R&D the Army should undertake. Its responsibilities may have included R&D in the biomedical field.

Experiments

In September 1994 the Army provided the Committee with a listing of several hundred experiments. The Committee has asked the Army to identify all pre-1975 experiments and provide all available supporting documentation for each one.

Records Search

With respect to headquarters documents, the Army currently is reviewing the periodic and programmatic official histories of OSG and the Chemical Corps and its successor(s) at the Center for Military History. The tables of contents and relevant portions of any of interest will be provided to the Committee. All histories of the Chemical Corps and its successor(s) are classified. With the exception of records from 1952 to 1953, which could not be located, OSG records (Record Group #112) at WNRC for 1951 to 1958 have been reviewed. OSG records at WNRC for the years following 1958 currently are being examined.

In response to the January 1994 DOD-wide search directive, the Army asked field sites that may have conducted or sponsored experiments to identify them and the location of related data. The Committee does not have a clear definition of the extent of this inquiry yet.

Remaining Tasks

The review of the histories of OSG and the Chemical Corps and its successor(s), as well as the remaining OSG records at WNRC, must be completed. Any OSG records at the National Archives or still housed at OSG must be identified and reviewed.

The large collection of records of the Chemical Corps at WNRC (Record Group #175) and any possibly still with a successor must be identified and examined. (These include records related to radiation warfare experiments conducted at Dugway, Utah, or elsewhere.) The records of the Scientific Advisory Panel and any successor(s) must be located reviewed.

In June 1953 the Secretary of the Army implemented in a separate order the Secretary of Defense's Nuremberg Code directive from earlier that year. A 1975 Army Inspector General

report details the extent of its implementation in research involving psychoactive chemicals, but there is little documentation regarding its implementation in research involving ionizing radiation. The Committee has asked the Army to place a priority on locating this material. The Committee has also asked the Army (as well as other services) to provide all documents related to human experimentation planned or conducted in connection with atomic bomb tests, including documentation relating to the biomedical components of tests, and consent procedures for those involved in troop maneuvers, psychological observation, body fluid sampling, or other human subject tests. The Army has agreed to provide all such materials.

DEPARTMENT OF THE NAVY

History and Organization

The Department of the Navy (Navy) was established in 1947 under the new DOD. Prior to this the Navy was under the Navy Department, which DOD replaced.

One component conducting biomedical research is the Bureau of Medicine (BUMED) and its many subordinate commands. BUMED through the years has conducted research at its own facilities and through contractors. A second component involved in biomedical research is the Office of Naval Research (ONR). Most of its research has been performed by contractors. BUMED and ONR existed at the time the Department of the Navy was established. A third component performing biomedical research was the Naval Radiological Defense Laboratory (NRDL) which existed from 1946 to 1969. NRDL was established in the aftermath of contamination problems experienced following the 1946 Bikini atomic bomb test Baker. A fourth possible important component is the Naval Research Advisory Committee. Established in 1946, its role has been to advise the Secretary of the Navy and Chief of Naval Operations on research and development. Its responsibilities may have included advising on biomedical research and development.

Experiments

The Navy has identified approximately 800 experiments, of which about 150 predate 1975. (Additional experiments are still being located.) The Navy provided the Committee with available documentation on these experiments, but in many cases, particularly for pre-1975 experiments, data are fragmentary. The Navy and the Committee will work to identify further data on selected experiments.

Records Search

The Navy reports that over 1,800 person-days have been expended in the records search. With respect to headquarters documents, relevant portions of the records of the Secretary of the Navy in Record Group #428 at NARA and WNRC, and at the Office of the Secretary of the Navy have been reviewed in part.

Relevant portions of the records of BUMED at NARA (Record Group #52) and at BUMED have been reviewed in part. BUMED histories have been examined. Relevant portions of ONR records still housed at ONR have been reviewed. ONR records in Record Group #298 at NARA and WNRC are being examined.

In response to the DOD-wide January search directive, the Navy sought to identify experiments and related records at numerous field sites. Selected files in the only known location of NRDL office files (the NARA and Federal Records Center in San Bruno, California) have been, or are being, examined. Certain technical reports from NRDL's library were sent to the Armed Forces Radiobiology Research Institute (AFRRI) and to the Naval Surface Weapons Center in White Oak, Maryland, and they have been reviewed. Unclassified NRDL histories have been provided. However, the Committee understands that many other NRDL records or reports were destroyed when NRDL was disestablished, and has requested a report on this matter.

At the Federal Personnel Records Center in St. Louis, records were examined on the following commands: Naval Submarine Medical Research Center; Naval Hospital and Naval Submarine Base, Groton; Naval Hospital, Chelsea; Naval Hospital, St. Albans; and Naval Hospital and Naval Medical Research Institute, Taiwan.

Remaining Tasks

Further review of selected records of the Secretary of the Navy, BUMED, and NRDL may be necessary. Classified NRDL histories were once housed at the Naval Historical Center. Additionally, a review of the holdings of the Naval Historical Center should be made for other relevant periodic and programmatic histories, as well as relevant records collections. The records of the Naval Research Advisory Committee must be located and reviewed.

The Navy has found evidence of consent policies dating to the 1930s. For the period through the mid-1960s, the Navy has located documentation of this process for some experiments. Only approximately six of these experiments involved ionizing radiation, however, while the Navy reported over 100 such experiments from this period. The Committee hopes that the Navy will be able to locate further information regarding these additional experiments, including information relating to any review process.

DEFENSE NUCLEAR AGENCY

History and Organization

DNA is the successor to the Armed Force Special Weapons Project (AFSWP) and the Defense Atomic Support Agency (DASA).

Since the establishment of AFSWP in 1947, the responsibility for biomedical research

conducted for AFSWP and its successors has lain primarily with a small medical division at the headquarters. The Armed Forces Radiobiology Research Institute (AFRRI, discussed below), has also had some responsibility in this area. Again, except for AFRRI, biomedical research of AFSWP, DASA, and DNA actually has been performed by a contractor or another Government agency.

In the early 1960s. DASA assumed control of AFRRI from the Navy. AFRRI has conducted almost exclusively research at its own facilities.

Experiments

DNA initially identified approximately one dozen pre-1975 experiments. DNA's research has identified further experiments funded or organized by DNA.

Records Search

DNA has committed to reviewing all of its and its predecessors' records (Record Group #374) at NARA and WNRC, as well as those still housed at its headquarters and one field command. Apparently, these are the only four repositories that hold any such records, almost all of which are classified. A number of relevant documents have been and are being declassified and will be provided to Committee staff. Committee staff has asked DNA, and DNA has agreed, to include any documentation related to potential human experimentation connected with atomic bomb tests.

DNA reports that some records have been destroyed. A key collection in this category is the contract files for the biomedical research sponsored by AFSWP and DASA during the 1950s and 1960s. Moreover, few records of some key offices (most notably the medical division at headquarters) have been located.

DNA has examined all official periodic and programmatic histories of AFSWP, DASA, and DNA, all of which are classified. Tables of contents and pertinent portions have been declassified and furnished to Committee staff, who, after reviewing them, requested further portions. DNA has also provided the periodic histories of AFRRI, as well as the minutes of the meetings of its Board of Governors. All of these items were unclassified.

DNA is reviewing selected classified materials it has collected that are connected to the histories of the nuclear weapons tests prepared for the Nuclear Test Personnel Review (NTPR) program. In conducting the DNA search, the Committee is mindful of previous DNA (and DOD) work connected with the NTPR program. That program sought, among other goals, to collect documentation on U.S. nuclear tests; it also prepared a series of test histories. Committee staff is availing itself of the public NTPR materials and has asked for declassification of many NTPR source documents that may remain classified.

Remaining Tasks

Committee staff has received significant documentation as a result of DNA's research, and, based on DNA's commitment, expects provision of the remaining information in the immediate future. DNA is preparing an index of the records at NARA, WNRC, and its headquarters and field command. Based on the materials provided from the search and this index, Committee staff will request further information. The areas of the requests will include specific biomedical experiments, intentional releases, and human experimentation connected with atomic bomb tests.

DEPARTMENT OF ENERGY

History and Organization of the Department of Energy

The Department of Energy (DOE) is the successor to the Manhattan Engineer District (MED), Atomic Energy Commission (AEC), and Energy Research and Development Administration (ERDA).

MED was established within the U.S. Army in 1942 to build the atomic bomb. Although biomedical research was conducted at individual project sites from the first days of MED, in August 1943 the Medical Section was created partly to coordinate such research. The biomedical research program was conducted both at Government-owned, contractor-operated laboratories (e.g., Clinton Laboratory, now Oak Ridge, and Los Alamos Laboratory) and by contractors (e.g., the University of Rochester and the University of California Radiation Laboratory). The Medical Advisory Committee was created in mid-1946 to advise MED on a number of issues, including future biomedical research programs that the atomic energy program might adopt. In 1946, MED began to distribute radioisotopes produced at Clinton Laboratory to researchers outside of its own laboratories and contractors. The Interim Advisory Committee on Isotope Distribution was set up to advise MED on policies and guidelines in this area, including the use of radioisotopes in humans.

AEC came into existence as an independent agency within the executive branch on January 1, 1947. At the outset, AEC had no division or office responsible for biomedical research. Early in 1947 the Interim Medical Advisory Committee (IMAC) was created to advise AEC on its biomedical research effort, and most of the existing programs and contracts simply were continued. The Medical Board of Review, a successor to IMAC set up in mid-1947, recommended the creation of a division specifically responsible for biomedical research and a permanent advisory group of physicians from outside the Government to assist that division. Based on these recommendations, the Advisory Committee on Biology and Medicine (ACBM) was formed in September 1947, and the Division of Biology and Medicine (DBM) in early 1948. Under AEC, the biomedical research program increased dramatically both at Government-owned laboratories and at contractor sites. Virtually all of this effort was managed and directed by DBM, with the assistance of ACBM.

The Division of Military Application (DMA) had substantial responsibilities involving the military use of atomic energy. During the late 1940s, and possibly later, DMA had a Radiological Branch that worked extensively in the radiological warfare field. DMA funded some biomedical research in the 1950s concerning fallout and also may have funded other biomedical research.

The distribution of radioisotopes grew rapidly under AEC. Once production difficulties were overcome in 1947, distribution was expanded to users in industry and agriculture. The Isotopes Branch and its successors ran the isotope production and distribution program. The Advisory Committee on Isotope Distribution was created in 1948 to replace the interim committee of the same name, and the Subcommittee on Human Applications was established thereunder to set guidelines and policies for the Isotopes Branch governing use of AEC-supplied

radioisotopes in humans. In 1958 the Advisory Committee on Medical Uses of Isotopes succeeded the Subcommittee on Human Applications.

ERDA assumed most of the responsibilities of AEC in 1974; the civilian nuclear power and isotope distribution functions of AEC were transferred to the newly created Nuclear Regulatory Commission. The Biology and Environmental Research Division was established to continue the work of DBM.

Experiments

DOE-identified experiments include (1) experiments identified in the mid-1980s and included in the Markey report and (2) further experiments DOE identified in June 1994. Additional experiments are being identified by the DOE headquarters Office of Human Radiation Experiments (OHRE), to which DOE has given final responsibility for identifying experiments. OHRE works independently, and in conjunction with other DOE elements, to identify experiments. In mid-October, OHRE reported that it had identified information pertaining to over 80 separate human experiments. Further DOE experiments continue to be identified in documents provided by DOE and in other sources located by the Committee.

Records Search

In mid-October DOE reported that it had released approximately 115,000 pages of documents. DOE has issued written guidance to all DOE and contractor elements directing them to search for all records with information about human radiation experiments. The present aim of the search is to provide (1) inventories of relevant record collections ("series descriptions") and (2) copies of the documents. DOE created OHRE, among other matters, to serve as a central collection point and perform quality control.

Series descriptions are complete for Lawrence Berkeley Laboratory, Argonne, and Oak Ridge; those for Los Alamos, Brookhaven, Hanford, and Idaho are being revised. The series descriptions indicate that approximately 75 percent of the relevant collections are unclassified or declassified. Committee staff has asked DOE to annotate series descriptions to indicate which records therein have been reviewed.

In addition to MED and early AEC headquarters records at Oak Ridge, numerous headquarters records remain at various DOE headquarters offices and at the National Archives (NARA) and the Washington National Records Center (WNRC) in the Washington, D.C., area.[1] The relevant Oak Ridge and MED/early AEC headquarters records at the Atlanta NARA in Record Group # 326 have been reviewed by DOE and Committee staff.

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[1] Records transferred to National Archives and Records Administration are no longer under agency control. However, DOE is committed to assisting the Committee in the identification and retrieval of relevant collections.

At the Committee's request, DOE is retrieving records related to human experimentation from the universities involved in the plutonium injection experiments (i.e., the University of Rochester, University of California, and University of Chicago).

A number of records of interest remain classified. The Committee has sought to limit and prioritize declassification requests. Initially, the Committee asked DOE to locate and declassify relevant files of the AEC's Division of Intelligence, which were understood to include information on intentional releases and "work for others" (e.g., experiments performed for other agencies at DOE labs). Following an extensive search, DOE reported that these files--through the early 1970s--probably have been destroyed. At the Committee's request, DOE conducted an inquiry and prepared a report on this matter.

Currently, the Committee has assigned priority to OHRE to declassify portions of the periodic reports of AEC to the Joint Committee on Atomic Energy (the congressional oversight committee) and portions of the periodic reports of AEC's divisions to the General Manager. A declassification request for selected files in the 1947-1951 and 1952-1958 Executive Secretariat files (i.e., the files of the five-member Commission) has been made to the DOE declassification team at NARA.

Remaining Tasks

With respect to headquarters materials, numerous collections in the Washington, D.C., area must be reviewed. Where detailed finding aids and inventories exist, individual files (instead of entire boxes or collections) often can be targeted for review. Committee staff will seek to work with DOE staff to assure the timely and efficient review and retrieval of documents. Specific collections of interest include the following:

- *Isotope Branch (and its successors)* - Despite an extensive search by DOE staff, no collections of these records have been located. However, some documents have been found in other collections regarding the isotope production and distribution program.

- *Insurance Branch* - Documents indicate that the Insurance Branch may have been a driving force in the development of rules relating to human experiments. Despite an extensive search by DOE, the records of this Branch have not been located.

- *Atomic Bomb Test Biomedical Planning Groups* - DOE staff has located, and will soon provide, the files of these panels, which planned and reviewed biomedical research connected with atomic bomb tests.

- *Division of Military Application* - Inventories for DMA collections at WNRC and DOE headquarters have been provided. Selected files in these collections must be reviewed and relevant individual documents declassified.

- *General Manager* - The inventory for the General Manager collection at the History Division has been provided. Selected files in this collection must be reviewed and relevant individual documents declassified.

- *Office of General Counsel* - Inventories have been furnished for collections at WNRC and NARA, but there appear to be no pertinent files there. The History Division has a large collection for which there is no inventory, but DOE staff's initial examination indicates that this collection contains relevant materials. Selected files must be examined and pertinent individual documents declassified.

- *Commission Minutes* - Committee staff has examined the small collection of declassified minutes at the History Division. The much larger declassified collection in Record Group #326 at NARA must be reviewed.

- *General Advisory Committee* - Committee staff has examined the small collection of declassified agendas, minutes, and reports at the History Division. The much larger declassified collection in Record Group #326 at NARA must be reviewed.

- *Division of Biology and Medicine* - Committee staff has examined the declassified portions of the collections at the History Division and the collection on fallout in Record Group #326 at NARA. Both collections have files that must be declassified. Inventories have been provided for these and other DBM collections at NARA, WNRC, and DOE headquarters. All other collections are completely unclassified; selected files therein must be examined.

- *Advisory Committee on Biology and Medicine* - Summary minutes of all ACBM meetings have been furnished, as well as some verbatim minutes.

- *Executive Secretariat Files* - Committee staff has examined only a limited number of declassified files in the 1952-1958 collection in Record Group #326 at NARA. As noted above, a declassification request is pending for other files in this collection and the 1947-1951 collection at NARA. Inventories have been provided for the 1958-1974 collection, which is at the History Division; selected files must be reviewed, and relevant documents declassified.

- *Periodic Division Reports to the General Manager/Periodic AEC Reports to the Joint Committee on Atomic Energy* - As noted above, these are being declassified by DOE and will be furnished shortly.

- *Individual Commissioner Files* - These collections are at NARA, WNRC, and at DOE headquarters. A small number of selected files must be reviewed, and pertinent individual documents declassified.

There are some indications that a significant percentage of the 1958-1974 records of the Isotopes Branch were transferred to the Nuclear Regulatory Commission. If true, these might be in Nuclear Regulatory Commission collections at a NARA or Federal Records Center or possibly still at the Nuclear Regulatory Commission.

The Committee has requested the supporting documents used by the Division of the Inspector General in writing the 1974 report on the plutonium injections. DOE reports that it continues to search for these documents.

While both headquarters and some laboratories had policies governing informed consent beginning in the late 1940s, few documents have been found thus far on the scope and implementation of these policies. Committee staff believes that DBM and Office of General Counsel collections, as well as those of the Insurance Branch, might have pertinent information.

Finally, a number of unclassified periodic and nonperiodic AEC publications must be reviewed. These range from AEC semiannual and annual reports to congressional reports to annual reports of the Oak Ridge Institute of Nuclear Studies.

In the field, series descriptions for several sites must be revised. The progress in examining records varies: some sites (e.g., Los Alamos and the Oak Ridge Operations Office) have completed or nearly completed the initial review, while others have not. Committee staff is working with DOE on targeted inquiries at several sites, including Brookhaven, Los Alamos, Oak Ridge, Richland, and the historic University of California contracts. DOE is seeking to locate and review records of several private and public institutions that performed important biomedical research for the AEC (e.g., the University of California at Los Angeles and San Francisco and the Universities of Chicago and Rochester).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

History and Organization of the Department of Health and Human Services

The Department of Health and Human Services (HHS) is the Federal agency most directly concerned with public health and health-related research. The landmarks for the organization as a whole were the creation of the Federal Security Agency (FSA) in 1939, the establishment of the Department of Health, Education, and Welfare (HEW) in 1953, and HEW's reorganization into HHS in 1980.

The U.S. Public Health Service (PHS), one of the five major operating divisions of HHS, has conducted and sponsored radiation research. From 1944 to 1967, PHS included the Office of the Surgeon General, the National Institutes of Health (NIH), the Bureau of State Services (BSS), and the Bureau of Medical Services. After reorganization in 1968, PHS--including NIH, the Food and Drug Administration (FDA), and the Health Services and Mental Health Administration--reported to the Assistant Secretary for Health and Scientific Affairs. Since 1973, HHS components relevant to the Committee's work have included the Office of the Assistant Secretary for Health (OASH), the Centers for Disease Control and Prevention (CDC), the FDA, the Indian Health Service (IHS), and NIH. The two historically significant agencies for radiation research within PHS are BSS and NIH.

BSS, historically responsible for industrial and occupational health within PHS, began to study the biological effects of radiation as part of research on worker and public health. The studies were conducted by a component of BSS, the Bureau of Radiological Health (BRH), which also served as liaison to AEC and Department of Defense. BRH sponsored extramural research related to radiation and its public health hazards. BRH ran regional sampling and research labs, including the national monitoring network for radioactive fallout from the atmospheric testing of nuclear bombs, sampling and research laboratories in Nevada and Alabama, the bone strontium sampling program, and the national milk testing network.

NIH has been the major Federal sponsor of biomedical research since the end of World War II and the dissolution of the War Department's Committee on Medical Research (CMR), which had previously sponsored such work. During the Korean War, representatives of PHS participated in interagency working groups that planned biomedical research of military relevance, including the Joint Panel on Medical Aspects of Atomic Warfare. Today NIH is one of the primary Federal sponsors for extramural biomedical radiation research. Most of the significant applications to NIH for radiation research funding were reviewed by the Radiobiology (later Radiation) Study Section of NIH.

NIH's intramural research is conducted by various institutes. Those of interest to the Committee include the National Cancer Institute (NCI), which funded and conducted radiation research related to cancer; the National Heart Institute (now Heart, Lung, and Blood), and the National Institute of Arthritic and Metabolic Diseases (since reorganized into two separate Institutes). Moreover, in 1953 NIH created an intramural research hospital, the NIH Clinical Center, and centralized its intramural radiation research. The Clinical Center had a radiation wing, in which radiation research was conducted.

Committee or evidence interagency radiation research with other federal agencies; this search is ongoing. During a reorganization in 1971, FDA received BRH's program and records related to its radiological public health responsibilities. FDA reports that it has not conducted or sponsored human radiation experiments, but FDA made approximately 26 boxes of BRH records available to the Committee.

NIH currently is refining a list of all awards in which grant applications were reviewed by the Radiology Study Section and its successors. Experiments involving ionizing radiation and human subjects that were reviewed by other study sections before 1966 will not be included in this list.

For those experiments conducted by NIH scientists, the Medical Records Department of the Clinical Center has records for the 245,000 patients admitted to the Clinical Center since it opened in 1953. Much of the Clinical Center's work is experimental, and this experimental work includes diagnostic/therapeutic procedures involving radiation. NIH staff reviewed the Medical Board minutes and the Radiation Safety Committee minutes from the Clinical Center. NIH staff is developing a database of human radiation experiments conducted in the NIH intramural program that will contain the protocols, titles, investigators, radiation usage, and so forth. This database will be provided to the Committee when it is complete.

Although the history of ethics policy development at NIH was relatively well documented before the work of the Committee, HHS has recently found documents concerning the evolution of consent policy at the Clinical Center. These materials show the varying perspectives of legal counsel and the medical board in the 1950s concerning the need for formal consent documents for all patients admitted to the Clinical Center.

In conjunction with the Committee's contemporary Research Proposal Review Project, Committee staff has been working with HHS staff to search the online CRISP (Computer Retrieval of Information on Scientific Projects) database for abstracts of extramural studies involving human subjects that were approved and funded in fiscal year 1993. From this search, HHS generated a preliminary printout of all fiscal year 1993 studies involving ionizing radiation and a sample of nonradiation studies. In addition, staff has received Request for Protocol Approval forms (including abstracts) for fiscal year 1993 intramural CDC human research studies, which are not available on CRISP. Abstracts of intramural human subjects research from other HHS entities (NIH, Agency for Health Care Policy and Research, and FDA) are currently "in process."

Remaining Tasks

NIH will continue to search and review its materials from the National Archives and the Federal Records Center. Various DOD documents from the 1950s indicate that the military consulted PHS on the health and biological effects of ionizing radiation (the contact points with the uniformed services appear to have been their respective Surgeons General offices); Committee staff will work with HHS to obtain memoranda and other correspondence between

PHS and defense organizations that would clarify the nature of this consulting relationship.

NIH and Committee staff will refine the Radiation Study Section and other experiment lists for both extramural and Clinical Center research and will explore search strategies to obtain the most useful, retrievable information on selected sets of experiments from the refined lists.

With respect to contemporary human subjects research conducted or supported by HHS, Committee staff will work with HHS to review records of intramural research and facilitate review of records of extramural research funded by HHS.

History and Organization of the Department of Veterans Affairs

The Veterans Administration (VA) was established in 1930 through consolidation of the Veterans' Bureau, the Bureau of Pensions (under the Department of the Interior), and the National Homes for Disabled Volunteer Soldiers. In the immediate post-World War II era, VA's second Administrator, General Omar Bradley, launched a major expansion and reorganization of VA's medical services; this expansion included establishing the Department of Medicine & Surgery in 1946. At that time the director of medical programs, Major General Paul Hawley, instituted residency programs and teaching fellowships in VA hospitals and established the policy of locating VA hospitals adjacent to, and affiliating them with, leading medical schools. Hospital-based research began, increasing in scope during the next decade. In 1988 legislation was enacted to elevate VA to cabinet status; the Department of Veterans Affairs (also referred to as VA) was established on March 15, 1989.

Today VA operates both nationwide health care and assistance programs for veterans and their families (e.g., pensions, disability compensation, vocational rehabilitation, education payments, and life insurance) and 113 national cemeteries. VA is divided into three main divisions: (1) the Veterans Health Administration (the linear successor to the Department of Medicine & Surgery); (2) the Veterans Benefits Administration; and (3) the National Cemetery System.

The framework of VA's radioisotope/radiation research was developed in the fall of 1947 with the establishment of a five-member Central Advisory Committee on Radioisotopes that reported to General Hawley. At its first meeting, this advisory body recommended (1) the establishment of an Atomic Medicine Division within the Department of Medicine & Surgery, (2) the establishment of a Radioisotope Section within that Division, and (3) the designation of the Atomic Medicine Division as "confidential," directing attention instead to the existence of a radioisotope program within the Radioisotope Section. Following the adoption of these recommendations, the first radioisotope unit opened in Van Nuys, California in February 1948. Seven additional labs in Framingham, Massachusetts; Cleveland, Ohio; Minneapolis, Minnesota; Bronx, New York; Hines, Illinois; Dallas, Texas; and Los Angeles, California opened by year's end. That number grew to 14 by 1951, to 33 by the end of 1953, and to 48 by 1958. From the outset, VA used radioisotopes for diagnosis, treatment, and research.

Experiments

Based on information from VA and other sources (e.g., documents received from other agencies) and based on the Committee staff's independent research, staff thus far has identified approximately 60 VA human radiation experiments during the period from 1946 to 1974. In late September 1994, VA sent a list of approximately 3,500 potential human radiation experiments conducted by its researchers between 1956 and 1973; information on most of these potential experiments is limited to title, year, location, and (in some instances) name of investigator. In the absence of additional information, it is unclear how many of these 3,500 experiments actually

are instances of human radiation research. (The list appears to include duplications, as well as some research involving animals.)

VA experiments were conducted in several areas. Based on brief descriptions in the annual *Medical Research in the Veterans Administration*, much of VA's radioisotope research involving humans appears to have consisted of tracer studies (e.g., with Iodine-131). Documents received from HHS and reference materials on the history of nuclear medicine indicate that fallout research with cesium and strontium was conducted in Hines, Illinois, and (as part of Operation Sunshine) in Salt Lake City, Utah. AEC materials indicate that total body irradiation occurred at five VA sites.[1]

As to the conduct of classified experiments, VA lacks original classification authority and VA staff has stated that it knows of no pertinent classified documents. However, VA apparently had such authority between 1951 and 1972 and could therefore have independently sponsored or conducted such research in the past. The West Los Angeles VA Medical Center was and still is affiliated with the University of California at Los Angeles' medical school, which has operated an Atomic Energy Project (now known as the Laboratory of Biomedical and Environmental Sciences) in conjunction with AEC/ERDA/DOE since 1947. The Committee has located documents that indicate that the Atomic Energy Project was engaged in some classified activities in the late 1940s and early 1950s; at present, it is unclear whether these activities included human radiation experimentation and to what extent (if any) VA may have participated in such activities.

In addition to the above information about specific experiments, the Committee has lists of several hundred journal articles published by VA radioisotope/radiation researchers concerning research projects that may be characterized as human radiation experiments; these publications must be located and reviewed.

Records Search

VA records are maintained at VA medical centers throughout the country, at regional offices, at its headquarters (Central Office), and at Federal Records Centers and National Archives.

VA's search for documentation of human radiation experiments began in early 1994 with a review of records then housed at the Central Office. Due to the paucity of responsive documentation at that site, the search was expanded to the field. A series of directives to the approximately 170 field locations requested (1) the completion of several surveys about radioisotope/radiation research and radiotherapy and (2) the location and retrieval of all pertinent records. The surveys did not expressly ask the field sites to identify and/or quantify their human

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[1] Those sites were Long Beach, California; Denver, Colorado; New Orleans, Louisiana; Houston, Texas; and Wood, Wisconsin.

radiation experiments; as a result, some responses merely included lists of radioisotopes employed, some appended lists of pertinent publications, and some attached descriptions of potentially relevant activities. Based on information contained in these survey responses and other sources, Committee staff identified an initial subset of field sites from which all records were requested.

In August 1994, VA began to review approximately 1,800 boxes containing potentially relevant Central Office files that had been transferred to the Federal Records Center; it expects to complete its review of these materials no later than mid-November 1994. As of September 28, 1994, VA had transferred to Committee staff approximately 13.5 cubic feet of records. On October 7, 1994, VA's Chief of Staff requested the assistance of the Inspector General in the search for pertinent records.

VA has produced little documentation regarding specific experiments. VA has produced policy manuals and annual reports dating back to the early 1950s, but it has provided little contemporary correspondence (e.g., to or from the Administrator or General Hawley) or other early materials that might provide context or information about actual implementation of policy. Additionally, VA's decentralization makes the location and retrieval of responsive documents difficult; many potentially responsive documents likely would be held in the field rather than in the Central Office, but retention policies suggest that such materials may long since have been destroyed. Records retention practices, however, may have varied among field sites, and some investigators may have retained some records.

Remaining Tasks

As discussed with VA, VA will follow several paths. First, VA will complete its review of potentially relevant Central Office materials now held at the Federal Records Center. Second, VA will continue to seek additional information about and locate documentation regarding its "confidential" Atomic Medicine Division, so that the nature and purpose of that entity can be understood. Third, based on an initial assessment by VA and Committee staff, VA will be asked to seek more detailed information about human radiation experimentation conducted at a selected subset of VA medical centers. Fourth, VA will locate documentation of its early ethics policies and practices regarding human subjects research in general, and human radiation experiments in particular.

The Committee will continue to work with VA to quantify the universe of VA human radiation experiments. Further, Committee staff will continue its archival research to learn more about VA's work during the early years.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

History and Organization of the National Aeronautics and Space Administration

The National Aeronautics and Space Administration (NASA) was founded in 1958 as a civilian space agency, incorporating the older National Advisory Committee on Aeronautics (NACA) and some facilities and programs of the Department of Defense (DOD). NASA inherited no significant life science programs, and developed a centralized Office of Life Science Programs that operated briefly from 1960 to 1961.

In 1962, NASA was reorganized along programmatic lines, and life sciences programs were divided among three main programs: the Office of Manned Space Flight, the Office of Space Science and Applications, and the Office of Advanced Research and Technology. The Office of Manned Space Flight was responsible for astronaut selection and training, including medical screening, and for biomedical studies on the effects of space flight on astronauts, primarily through the Manned Spacecraft Center in Houston, Texas (now the Johnson Space Center or JSC). The Office of Advanced Research and Technology included studies of astronaut life support systems. These life science studies were conducted mainly through the Ames Research Center (ARC) at Moffett Field, California.

In many cases, particularly in its early years when it had limited intramural capabilities, NASA funded biomedical research through contracts and grants. NASA also funded research on radiobiology jointly with AEC and Air Force and, with some pressure from Congress, developed a coordinated program in space medicine with the Air Force.

A reorganization in the early 1970s led to some consolidation of life science programs in the Life Sciences Programs Division of the Office of Manned Space Flight. These programs are now fully consolidated in the Office of Life and Microgravity Sciences and Applications, which is responsible for NASA's current review of records on human radiation research.

Experiments

NASA's initial document search identified 189 publications and reports describing human radiation experiments. From this list and from personal contacts, NASA has identified six human radiation studies--specific experiments or series of related experiments--undertaken before 1974, and three broad categories of research that it is now analyzing to identify individual experiments. A complete list or accounting of NASA-sponsored studies is not yet available.

NASA was involved in two types of human radiation research: (1) studies to understand the effects of radiation in space on astronauts, and (2) studies of other effects of spaceflight that used radiation and radioisotope tracers as diagnostics. In the first category, NASA and AEC developed a joint research agenda on radiobiology, which included NASA support for total body irradiation studies at Oak Ridge as well as several studies that did not involve humans. NASA has also sponsored research on the effect of radiation on the human eye and collaborated with DOD in the study of space radiation hazards.

NASA was interested in other physiological effects of space flight, particularly the effects of weightlessness. NASA conducted its own studies and sponsored studies by others on the effects of bed rest, which simulated some aspects of weightlessness. NASA also funded studies to develop radiation techniques to diagnose bone loss due to weightlessness in space. In addition to its simulations, NASA conducted numerous studies using astronauts themselves as subjects in order to observe the actual effects of space flight.

In the area of intentional releases, NASA sponsored joint research with AEC on nuclear-powered rockets -- i.e., the Rover and NERVA projects. AEC conducted the Kiwi series of ground tests of nuclear-powered rockets, with some human exposures to the radioactivity released in these tests. It remains unclear which NASA offices were responsible for the nuclear rocket programs and what role, if any, NASA had in these field tests and associated human radiation exposures.

Records Search

NASA maintains records in a variety of forms. NASA's paper records may be located in any of its program offices and field installations, in internal records storage facilities, at Federal Records Centers (FRCs), or may have been transferred to the National Archives and Records Administration (NARA). NASA maintains comprehensive indexes of records transferred by any NASA installation to internal storage facilities, FRCs, and NARA, but not for documents that remain in NASA program offices. NASA has provided the Committee with complete listings of accessions to NARA. NASA plans to search its indexes of all stored and transferred records, identify potentially relevant records, and review those records by the end of November 1994.

NASA has instructed officials throughout its organization to locate all records related to human radiation experiments and has requested employees, contractors, and grantees to do the same. NASA has also searched those offices for specific files (e.g., files relating to the Oak Ridge studies), and has identified and begun to search three specific collections: (1) a Space Life Sciences Archive in Houston, (2) a collection within NASA's History Office, and (3) a collection of files of the former chief radiation safety officer at the JSC.

NASA's initial search included interviews, document searches, and electronic literature searches of several databases, including the RECON aerospace research database, the ARIN and NTIS databases of NASA documents, and other public databases. The database searches led NASA to identify more than 2,000 publications, from which 189 that were selected as relevant have provided the most valuable documentary source of information on NASA's human radiation experiments. Reviews of NASA records and interviews with over 20 current and former NASA employees have supplemented the literature search and provided additional leads on human radiation research. Further leads have come from responses to a letter sent to all current and former NASA employees, contractors, and grantees requesting information on possible human radiation experiments.

NASA has provided summaries of the specific human radiation studies it identified, along with supporting documentation for some of those studies. This documentation includes reports and some correspondence regarding the Oak Ridge total body irradiation studies, supplemented by some contract and financial information provided by the Department of Energy. NASA reports that it destroyed most documents pertaining to the Oak Ridge studies in 1980, in accordance with standard records retention schedules.

NASA has provided the Committee with secondary and some primary documents on its organization and history. These documents include one overall history of NASA, summary reviews and/or histories of NASA's life science programs and of the biomedical research programs for Projects Mercury, Gemini, Apollo, and Skylab. Primary documents include early plans and recommendations for NASA's life sciences program, several reports and reviews of those programs, and organizational charts.

The earliest records received on NASA's ethics policies on the use of human subjects in research are from 1969. These records document the formation in 1969 of the Medical Isotopes Subcommittee of the Radiation Safety Committee at the Manned Spacecraft Center and the revision in 1969 of the Ames Management Manual for the operation of the Human Research Experiments Review Board. NASA has also provided some indications of earlier policies and practices, including references to consent procedures and radioisotope licenses at the Ames Research Center.

In 1972, NASA established an overall policy on the use of human subjects in research conducted by NASA that established approval and oversight procedures and required written informed consent. This policy was revised and extended to grantees and contractors in 1986. NASA has provided some documents and other information that describes policies and practices involving the use of human subjects prior to the establishment of these official policies, and is attempting to reconstruct this information for each of the experiments it identifies.

Remaining Tasks

The Committee has asked NASA to complete its identification of individual experiments and provide a complete list with supporting documentation. The Committee also has requested additional information on biomedical studies involving astronauts as subjects and the rules that governed those studies, beyond what NASA has already provided.

Once NASA completes its review of records indexes, it will begin to search selected paper records. This search will focus on the following four areas:

(1) records pertaining to the cooperative agreement between NASA and AEC on radiobiology research, including the total body irradiation studies carried out at Oak Ridge;

(2) records pertaining to joint research activities between NASA and Air Force on aerospace medicine;

(3) records describing NASA's role with AEC in the Rover and NERVA nuclear-powered rocket programs, including any NASA participation in the Kiwi field test series; and

(4) additional documents describing NASA's policies and practices for the use of human subjects in research. These would include documents describing policies in place at ARC and JSC prior to 1969, policies in place at other NASA field installations, any discussions of human use policies at NASA headquarters prior to the first agency-wide policy in 1972, and NASA licenses with AEC for the use of radioisotopes.

APPENDIX F

INFORMATION MANAGEMENT

INFORMATION MANAGEMENT: STAFF AND PUBLIC ACCESS NOW, ARCHIVAL ACCESS LATER

The Committee's work requires the rapid assimilation of large quantities of information assembled from disparate sources, and received in various formats and in widely differing states of organization. A central focus of staff effort has been creating the infrastructure (human and electronic) needed to organize this information not only for immediate Committee use and near-term public use, but also, upon the Committee's termination, for future use by citizens and scholars.

Information Technology

The Committee has a computer network consisting of Novell and Lotus Notes servers connecting 38 workstations. The network provides access to Lotus Notes (used for electronic mail and database applications, described below), shared word processing and graphics programs,, and the Internet. CD-ROM access is available at several workstations, and an optical character reader is also available.

Electronic Information Services

In addition to the standard mail and help databases, Committee staff members now have access to the following databases:

- *Document Collection* contains lists and descriptions of all documents received by the Committee staff. It can be manipulated to show subsets of the collection of particular interest to the user.

- *Publications Collection* serves as a catalog of published research materials held or used by the Committee.

- *ACHRE Indexes* contains standard information sets developed by Committee staff (e.g., isotope formulas, acronyms, and other general information).

- *Experiment Index* contains information in a standard format for each experiment indentified as of interest to the Committee, classified according to the agreed themes and emphases in the Committee's research.

Additional databases include *Timeline* (a single chronology for items of research interest); *Congressional Hearings Review* (an index and commentary on congressional hearings and reports of research interest); *News Clippings* (abstracts of new items from all media of research interest, retrospective and current); *Agency Data Requests Tracking* (self-explanatory); *ACBM Minutes Index* (a complete set of the minutes of this important AEC component); and various discussion databases used by staff.

Records and Records Services

The archival collection now contains approximately 182 cubic feet of records in 370 separate collections. All records are to be reviewed at the collection level to determine the value of document-by-document review. The structure and handling of the Committee's own records has been addressed through the issuance of guidelines for records retention and the identification of lead staff members who are responsible for seeing that specific categories of records are preserved and organized. The staff also plans to create a comprehensive collection of electronic versions of important Committee documents, to provide better access for both staff and the public.

Public Access

Public access to some Committee information is now available in the Committee offices. Plans are being developed to provide electronic access.

Public Records Area: The Committee offices (1726 M Street, N.W., Washington, D.C.) now contain a public reading area that has copies of agenda and minutes for all Committee meetings, including supporting documentation developed for or used by members of the Committee for those meetings; assembled collections of documents, such as agency histories or the minutes of meetings of agency committees; and descriptions of the collections of records deposited by the agencies, together with lists of significant documents identified in those collections. A staff member is available to assist the public with the use of Committee information, in both hard copy and electronic formats.

Internet: Plans for external electronic access to Committee information currently include the following facilities:

- *E-mail.* When the Committee's Internet gateway is in place, members of the public will be able to contact individual staff members directly. A procedure is already in place for handling these requests when they are received by mail or telephone, and that same procedure will be used for E-mail.

- *Gopher.* A gopher server is an electronic repository of information that is accessible through the Internet. Individuals access the server using standard communications protocols and, using a series of hierarchical menus (or performing a text search), can identify the information they want and download an electronic copy to their own computer. The information available would include electronic copies of Committee meeting materials; important memoranda; text copies of records from several Committee databases, including the Document Collection, Publications Collection, and Experiment databases; and possibly some agency correspondence.

- *Newsgroup.* This is a discussion list on the Internet that would be open to anyone for sending and receiving messages. The list would be moderated by Committee staff to provide information in response to requests, and to assure that the discussions remained pertinent and included no inappropriate messages.

Permanent Records

Under the Federal Advisory Committee Act (FACA), the Committee is obligated not only to provide in-office public access to its information, but also to ensure that its permanent records are appropriately preserved and deposited with the National Archives and Records Administration (NARA). Guidelines for this process provided by NARA are explicit as to which records are permanent and which are not. The management of Committee document, publication, and office records collection has been structured to conform to these requirements and to ease the depository process. The body of deposited records will include the following:

(1) the research document collection and its supporting electronic records management tools and indices;

(2) those parts of the publication collection that are not owned by others (e.g., the DOE library), together with the supporting electronic management tools and indices;

(3) all Committee records in whatever media that meet the permanency requirements of the NARA guidelines, including both electronic and print copies (when appropriate) of database records, database design documents and other metadata, and electronic mail and other records of communication, together with copies of the appropriate software and hardware specifications or, if feasible, the actual hardware and software required to use the information; and

(4) other records or access facilities required to manage or preserve external electronic environments created by the Committee.

Interest has also been expressed in the secondary deposit of copies of some Committee documents in other Governmental repositories. The appropriateness and feasibility of secondary deposits will be explored with NARA.

TERMS AND ACRONYMS

TERMS AND ACRONYMS

ABCC	Atomic Bomb Casualty Commission (established in 1946 to study effects of atomic bombs dropped on Japan; disbanded in 1975; see RERF)
ACBM	AEC Advisory Committee on Biology and Medicine (established in 1947 to review medical and biological research and to asssist AEC in developing policy in these areas; the principal advisory committee to DBM; dissolved in 1974)
ACXRP	Advisory Committee on X-ray and Radium Protection (1929-1946 independent committee under the auspices of the National Bureau of Standards; recommended dose limits; predecessor of NCRP)
AEC	Atomic Energy Commission (1947 MED successor and ERDA predecessor)
AFB	Air Force Base
AFMPC	Armed Forces Medical Policy Council (late 1940s/early 1950s medical advisory group to OSD)
AFRRI	Armed Forces Radiobiology Research Institute (part of DASA and later of DNA, 1962-1993)
AFSWP	Armed Forces Special Weapons Project (DOD successor, with AEC, to MED; predecessor to DASA, 1947-1958, and present Defense Nuclear Agency)
AHCPR	Agency for Health Care Policy and Research (one of eight components of PHS)
ALARA	as low as reasonably achievable (standard for acceptable occupational exposure to radiation)
ANL	Argonne National Laboratory (AEC facility for nuclear research, established near Chicago in 1946; now operated by the University of Chicago for DOE)
ANP	Aircraft Nuclear Propulsion program (see NEPA)
ARC	Ames Research Center (established in 1941 near Palo Alto, now part of NASA; conducts life sciences and aerospace technological research)
ARS	acute radiation syndrome (disease produced by exposure to excessive dosage of radiation; term coined by Dr. Robert Stone in 1949)

ATSDR	Agency for Toxic Substance and Disease Registry (established in 1983, one of eight components of PHS)
BNL	Brookhaven National Laboratory (AEC clinical research facility established in 1947 on Long Island, now operated by Associated Universities and funded by DOE; a key site of biomedical research with radionuclides)
BRH	Bureau of Radiological Health (part of PHS)
BUMED	Bureau of Medicine and Surgery (part of Navy)
CDC	Centers for Disease Control and Prevention (successor to 1942 Malaria Control in War Program; established in 1946 as the Communicable Disease Centers, now one of eight components of PHS; based in Atlanta; responds to public health emergencies, including radiation emergencies, and seeks to prevent and control infectious and chronic diseases)
CDRH	Center for Devices and Radiological Health (FDA predecessor)
CHR	Center for Human Radiobiology (created within Argonne National Laboratory in the late 1960's)
CIA	Central Intelligence Agency (established in 1947 to replace the wartime Office of Strategic Services; Federal agency charged with coordinating intelligence activities and carrying out clandestine activities abroad)
CIC	Coordination and Information Center (contractor that acts as a repository for DOE documents)
CMR	Committee on Medical Research (WWII funder of medical research as part of OSRD; contracts folded into NIH)
CRS	Congressional Research Service (part of Library of Congress; prepares reports on any topic at the request of a Member of Congress)
DASA	Defense Atomic Support Agency (1958 AFSWP successor, within DOD; responsible for coordinating production and study of nuclear weapons, weapons effects, and nuclear weapons testing programs)
DBM	AEC Division of Biology and Medicine (established in 1948 to direct and coordinate AEC biomedical research activities; became the Biological and Environmental Research Division in 1974)

DCI	Director of Central Intelligence
DDP	Directorate of Plans (part of CIA; now the Directorate of Operations)
DDR&E	Department of Defense Director of Research & Engineering (1953 RDB successor)
DMA	Division of Military Application (part of AEC, concerned with nuclear weapons and some radiological health/safety issues)
DNA	Defense Nuclear Agency (1971 successor to DASA, within DOD)
DOD	Department of Defense (organized in 1949 to replace the War and Navy Departments)
DOE	Department of Energy (1977 ERDA successor; responsibilities include directing nuclear weapons research and development, and nuclear energy)
EOP	Executive Office of the President (U.S.)
ERDA	Energy Research and Development Agency (1974 AEC successor and DOE predecessor)
FACA	Federal Advisory Committee Act (federal statute governing procedures for Presidential advisory committees)
FDA	Food and Drug Administration (established in 1927 within Agriculture Department; transferred to FSA in 1940 and to HEW in 1953; part of PHS since 1968; oversees safety of food, drugs, cosmetics, and medical devices)
FOIA	Freedom of Information Act (1966 federal statute governing public release of government documents; nine categories of documents, including those relating to national security, are exempt)
FRC	Federal Records Center (repository of agency documents)
FSA	Federal Security Agency (1939 HEW predecessor)
GAO	General Accounting Office
GSA	General Services Administration (the Federal Government's office administrator)

GSFC	Goddard Space Flight Center (NASA division in Beltsville, MD; conducts research on the atmosphere and space environment; site of design and construction of satellites and spacecraft)
HASL	Health and Safety Laboratory (AEC facility that worked on industrial hygiene and fallout questions)
HEW	Department of Health, Education and Welfare (1953 HHS predecessor)
HHS	Department of Health and Human Services (1980 HEW successor; the principal Federal agency charged with advancing the health of Americans and providing essential human services)
HUMRRO	Human Resources Research Organization (affiliate of George Washington University; prepared reports on bomb tests)
ICRP	International Commission on Radiation Protection
IG	Inspector General
IHS	Indian Health Service (provides comprehensive health services for Native Americans and Alaska natives; successor to programs of Interior Department begun in 1849, part of PHS since 1955; elevated in 1988 to full agency status)
INEL	Idaho National Engineering Laboratory (DOE facility)
IRB	Institutional Review Board
JAEIC	Joint Atomic Energy Intelligence Committee (1948 JNEIC successor, chaired by the CIA; monitored Soviet nuclear weapons program)
JCAE	Joint Committee on Atomic Energy (1947-1974 Congressional body charged with oversight of AEC)
JNEIC	Joint Nuclear Energy Intelligence Committee (1947-1948 interagency group providing foreign atomic energy program estimates)
JRDB	Joint Research and Development Board (1946-1947 successor to OSRD; coordinated R&D between War and Navy Departments)
JSC	Johnson Space Center (NASA division in Houston, TX; conducts research on space medicine, responsible for astronaut selection and training, and handles mission control for space flights)

LANL	Los Alamos National Laboratory (AEC facility in New Mexico established in 1943 as the Atomic Research Laboratory; site of biomedical and other research; produced the first atomic and hydrogen bombs; now operated by the University of California with DOE funding)
LASL	Los Alamos Scientific Laboratory (prior name of LANL)
LBL	Lawrence Berkeley Laboratory (research center near San Francisco established in 1931; operated by the University of California, now funded by DOE; site of first cyclotron accelerators)
LETBI	low exposure total body irradiator
LLNL	Lawrence Livermore National Laboratory (established in Livermore, CA in 1952 as a separate institution from LBL; conducts nuclear research and underground nuclear explosion tests in Nevada)
MED	Manhattan Engineer District, also known as the Manhattan Project (AEC/AFSWP predecessor; established in 1942 under the U.S. Army to build the atomic bomb)
METlab	Metallurgical Laboratory (Chicago-based MED laboratory)
METBI	medium exposure total body irradiator
MGH	Massachusetts General Hospital (Boston site of radiation research)
MLC	Military Liaison Committee to AEC (DOD liaison to AEC; reports to OSD)
MOU	Memorandum of Understanding
MKULTRA	A domestic CIA program in the 1950s and 1960s involving human experimentation to investigate control of human behavior through the use of chemical, biological and other means (including drugs such as LSD, psychology, and possibly radiation)
NACA	National Advisory Committee on Aeronautics (NASA predecessor, established in 1915 to advance U.S. aviation technology)
NARA	National Archives and Records Administration
NARS	National Archives and Records Service (NARA predecessor, part of GSA before establishment as an independent agency)

NAS	National Academy of Sciences (private body of scientists and engineers chartered by Congress in 1863; goal is to further the use of science for the general welfare; acts as official Government advisor on science and technology issues)
NASA	National Aeronautics and Space Administration (established in 1958; agency responsible for the development of aviation and space technology and for space exploration)
NCI	National Cancer Institute (established in 1937, part of NIH)
NCRP	National Committee on Radiation Protection (1946 ACXRP successor, known after 1964 as National Council on Radiation Protection and Measurements; expanded ACXRP's interests to include ionizing radiation)
NDRC	National Defense Research Committee (with CMR, formed OSRD during WWII)
NEPA	Nuclear Energy Propulsion for Airplanes (1946-1961 Air Force program on nuclear-powered bomber; also known as ANP)
NHI	National Heart Institute (part of NIH)
NIAMD	National Institute for Arthritis and Metabolic Diseases (part of NIH)
NIH	National Institutes of Health (part of PHS; focuses on research on causes, prevention, and cure of diseases; begun as a one-room Laboratory of Hygiene in 1887, now the world's largest biomedical research facility; based in Bethesda, MD)
NIOSH	National Institute for Occupational Safety and Health (part of CDC)
NNES	National Nuclear Energy Series (series of 50 reports comprising the official history of the Manhattan Project)
NNMC	National Naval Medical Center (military medical facility in Bethesda, MD)
NRC	National Research Council (operating arm of NAS; established in 1916 to coordinate scientific and technological resources for national service)
NRC	Nuclear Regulatory Commission (with ERDA, successor to AEC; established in 1974 to run civilian nuclear power program, including regulatory and licensing authority, and assume radioisotope distribution)

NRDL	Naval Radiological Defense Laboratory (Navy radiation research lab; dissolved in 1969)
NSC	National Security Council (a seven-member body established in 1947 to advise the President on national security matters; directs policies of the CIA)
NTPR	Nuclear Test Personnel Review (DNA program, established in 1978)
NTS	Nevada Test Site (locus of 925 bomb tests between 1950 and 1992)
NWER	Nuclear Weapons Effects Research
OHRE	Office of Human Radiation Experiments (DOE headquarters component responsible for identifying human radiation experiments)
ONR	Office of Naval Research (part of Navy, established at the end of World War II)
OPRR	Office for Protection from Research Risk (established within NIH in 1966 to educate investigators and others about research ethics)
ORAU	Oak Ridge Affiliated Universities (1966 successor to ORINS; site of TBI)
ORD	Office of Research and Development (CIA and other agencies)
ORINS	Oak Ridge Institute of Nuclear Studies (site of biomedical research; later renamed ORAU)
ORNL	Oak Ridge National Laboratory (AEC research facility in Tennessee; established as Clinton Laboratories in 1943 as part of the MED; renamed in 1948)
ORO	Operations Research Organization (Johns Hopkins University affiliate; produced reports on bomb tests)
OSD	Office of the Secretary of Defense
OSG	Office of the Surgeon General (within PHS and other agencies)
OSI	Office of Scientific Intelligence (part of CIA's Directorate of Intelligence)
OSRD	Office of Scientific Research and Development (within EOP during World War II; composed of NDRC and CMR)

PHS	Public Health Service (the Federal Government's principal health agency; restructured three times since World War II, now one of five operating divisions of HHS)
PNL	Pacific Northwest Laboratory (DOE contractor: successor to Hanford Laboratory; part of Batelle/Memorial Laboratories, a private nonprofit organization)
R&D	research and development
RAC	Research Advisory Council (coordinated Navy's R&D from late 1940s to 1960s)
RDB	Research and Development Board (1947-1953 JRDB successor; within DOD)
RERF	Radiation Effects Research Foundation (1975 successor to ABCC)
RFA	Request For Applications
RFP	Request For Proposals
SAB	Scientific Advisory Board (coordinates Air Force R&D, established in 1947)
SAM	School of Aviation Medicine (Air Force component; conducted radiobiology research beginning in the late 1940s; coordinated efforts with AFSWP and ORNL)
SAP	Scientific Advisory Panel (coordinated Army's R&D from late 1940s to 1960s)
SWRHL	Southwestern Radiological Health Laboratory (PHS facility in Las Vegas, NV, that performed work for AEC)
TBI	total body irradiation
TSD	Technical Services Division (part of CIA's former Directorate of Plans; ran Project MKULTRA)
UCSF	University of California at San Francisco (key research site)
USAF	United States Air Force
USN	United States Navy
VA	Department of Veterans Affairs (successor to 1930-1989 Veterans Administration)

VACO	VA Central Office (VA headquarters)
VAMC	VA Medical Center (VA field site or facility)
VHA	Veterans Health Administration (VA division; successor to Department of Medicine and Surgery)
WNRC	Washington, D.C., National Records Center
WRAIR	Walter Reed Army Institute of Research
WRAMC	Walter Reed Army Medical Center