



ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
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WASHINGTON, D.C. 20036

MEMORANDUM

TO: Interagency Working Group Search Term Heads (Mr. Harold Gracey, Dr. D.A. Henderson, Dr. Harry Holloway, Mr. John Pereira, Dr. Gordon Soper, Dr. Tara O'Toole, Mr. T. J. Glauthier, Ms. Eva Plaza)

CC: Dr. Wendy Baldwin, Mr. Pat Glynn, Dr. Janis Stoklosa

FROM: Dan Guttman
Anna Mastroianni

DATE: October 19, 1994

RE: Draft of Body of Advisory Committee Interim Report

We enclose a draft of the body of the interim report. (We have previously transmitted the agency-specific appendices to each agency for review and comment.)

We would appreciate your review of the report for any factual errors that bear on your agency that you feel require correction. In general, most of the agency-specific materials are contained in the appendices, which have, as noted, previously been transmitted. In the body of the text, agency-specific materials appear primarily in Parts I, II and V. If there are specific factual errors regarding your agency, we would appreciate your provision of alternative language, by fax (202/254-9827) or phone (202/254-9795), by 3 PM on Thursday October 20, 1994. The report is to be issued on October 21.

We understand that the time is rushed. As you know, the Committee's work in general is being conducted on an expedited basis. We have previously received each agency's comments on the agency-specific appendices, which we have sought to be responsive to, as appropriate.

Thank you.



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INTERIM REPORT

DRAFT DATE - October 19, 1994

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EXECUTIVE SUMMARY

The Advisory Committee on Human Radiation Experiments was created by President Clinton to advise 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 to its Charge

The Committee is charged with answering three fundamental questions: (1) What is the Federal Government's role in wrongs or harms done as a result of human radiation experiments? (2) What are the criteria for determining the remedies are due those wronged or harmed? (3) 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 public comment sessions 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 retell, the story unless it seeks out all who can aid its understanding, and works to bridge the cultural and linguistic gaps among them.

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1 The Committee is also convinced that an important determinant of its success will be its
2 ability to understand the present just as well as, if not better than, it understands the past.
3 Therefore, it has undertaken the burden of sampling the ethical practices and standards governing
4 human radiation research today, evaluating them, and deciding whether change is needed.

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

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

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

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

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

28 *The Committee Begins Its Work*

29 The Committee was created in tandem with a Presidential directive that the Executive
30 Branch be open to searching inquiry. When it began its work in April 1994, there were few
31 records in hand; the Committee was embarking on a daunting journey into the past and present
32 with neither stars nor compass to chart its course. For example:
33

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

- 4 • What codes of conduct, if any, existed before 1975 to govern federally
5 sponsored experiments? There was no readily identifiable body of ethics
6 policies; indeed, the prevailing assumption was that until the mid-1960s
7 Federal agencies, by and large, did not even possess such policies.

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

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

14 **Phase I.** The Phase I strategy has three components: (1) the development of a framework for all
15 the information the Committee hoped to collect, the "big picture" into which pieces of the puzzle
16 could be fit; (2) the development of a strategy to mine all available information sources; and
17 (3) the development of an information infrastructure to house and organize all the data. The
18 components of the "big picture" framework include:

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

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

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

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

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

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1 The working solution, therefore, is a strategy that seeks to address the basic questions of
2 concern to the Committee and the public by an overlapping set of case studies and samples. First,
3 the Committee is focusing on five groups of biomedical experiments, with each group anchored
4 in one or more specific experiments that have attained public attention. Second, the Committee is
5 simultaneously focusing on institutions that conducted the experiments, in order to examine the
6 decisionmaking process and determine responsibility. Third, the Committee's inquiry into
7 intentional releases will focus on determining (1) whether (at this late date) the public can learn
8 who planned the releases, why, and what precautions if any were taken; and (2) whether
9 intentional releases, which were often shrouded in secrecy, could take place today in the absence
10 of meaningful public notice.

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

14 **Phase III.** While Phase I continues, and Phase II has just begun, the Committee is
15 simultaneously turning to Phase III--the task of evaluating past and present experiments and
16 recommending policy changes and criteria for determining remedies due to those wronged or
17 harmed, as appropriate.

18 *Taking Stock: Some Accomplishment and Challenges*

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

33 **Piecing Together the Secret and Public Worlds of Experiments:** The Committee's
34 experiment database presently contains about 400 biomedical experiments conducted before
35 1975. The Committee possesses at least fragmentary indications of over 1,000 further
36 experiments. In addition to the 13 intentional releases identified in the Charter, the Committee is

1 now aware of hundreds of additional intentional releases.

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

7 **Piecing Together the Hidden History of Federal Ethics Policy and Practice:**

8 Documents delivered by the agencies, and others located by the Committee, have revealed that
9 there was discussion at the highest reaches of government--and often in secret--about the need
10 for human experimentation and for policies to govern it. Committee and agency staff have
11 placed the highest priority on tracking down the twists and turns in these discussions and in the
12 policies and practices that flowed from them.

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

- 17 • At mid-century, ethics policies were discussed and put on paper. A key
18 question then, as today, is the relation between policy and practice.
- 19 • Even as policies were put on paper, it was not always clear what they
20 covered. Did they cover sick patients as well as healthy volunteers? In
21 cases involving soldiers and workers, for example, what was understood
22 by responsible decisionmakers to be the difference between
23 experimentation with healthy volunteers and occupational safety
24 monitoring? Then, as today, the boundaries of experimentation may not
25 have been fixed.
- 26 • Even with the benefits of openness, basic information on some
27 experiments (notably the intentional releases) remains secret. Could these
28 releases be conducted today without basic public disclosure?

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

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1 document collection databases should soon be available to the public on Internet.
2

3 **Challenges:** The primary challenge to the Committee now, as at the onset, is the
4 overwhelming nature of its tasks. Agency and Committee document and information searches are
5 progressing and should result in substantial new information about known experiments, policies,
6 and practices, and perhaps discovery of heretofore unknown experiments, policies, and practices.
7 However; (1) search efforts are necessarily time consuming and uncertain; (2) data on many
8 experiments will likely continue to remain fragmentary; (3) it appears that many important
9 collections have been long since lost or destroyed; (4) a great number of relevant collections
10 contain classified data; the declassification process may be a substantial bottleneck.

11 *Work To Be Done*

12 In the next six months the Committee will continue with the tasks of data gathering and
13 organizing. The focus of the work, however, will be the criteria for judging historical and
14 contemporary experiments, policies, and procedures, as well as criteria for determining remedies
15 due to those harmed or wronged. Based on what the Committee has learned, it will make
16 specific recommendations regarding policies for the future.

1 INTRODUCTION

2 CHARGE AND MANDATE

3 The Advisory Committee on Human Radiation Experiments was created by President
4 Clinton to advise the Interagency Working Group¹ on the ethical and scientific criteria
5 applicable to human radiation experiments carried out or sponsored by the U.S. Government.
6 (See Appendices A and B for Executive Order and Charter.) The Committee is composed of 14
7 members, including a citizen representative and 13 nationally recognized experts in bioethics,
8 radiation oncology and biology, history of science and medicine, epidemiology, nuclear
9 medicine, and law. (A list of Committee members is attached as Appendix C.)

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

- 11 "(1) experiments on individuals involving intentional exposure to
12 ionizing radiation. This category does not include common and
13 routine clinical practices
14 (2) experiments involving intentional environmental releases of
15 radiation that (A) were designed to test human health effects of
16 ionizing radiation; or (B) were designed to test the extent of human
17 exposure to ionizing radiation."²

18 The Committee is mandated to review experiments conducted between 1944 and May
19 1974, the date the Department of Health, Education, and Welfare issued regulations for the
20 protection of human subjects. Experiments done after May 30, 1974, may be sampled to
21 determine if further inquiry into experiments is warranted.

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

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.

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

5 **HOW THE COMMITTEE FUNCTIONS**

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

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

21
22 The Committee has been extremely fortunate to assemble a multidisciplinary staff of
23 substantial talent. The staff currently includes 34 full- and part-time members, supplemented by
24 several expert consultants. The staff includes individuals with backgrounds in internal medicine,
25 nuclear medicine, bioethics, physics, epidemiology, molecular biology, history (e.g., radiation
26 science, human experimentation, the Cold War), law, health policy, communications, archival
27 creation and management, and information systems development. The staff works at the
28 direction of the Committee, and subcommittees have been formed to oversee staff work between
29 meetings. The staff also consults with experts in dose reconstruction and other relevant technical
30 areas.

31 As discussed in Part III of this report, outreach is an essential component of the
32 Committee's activities. Staff routinely meets with individuals and groups who are interested in
33 learning about the Committee and from whom the Committee can learn. A public reading room

³ Charter, section 4.a, Appendix B.

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

1 at the Committee's offices contains basic Committee materials (such as Committee meeting
2 briefing books and transcripts) and key collections of historical documents assembled by the
3 Committee. The Committee expects that indices to document collections and its experiment
4 database will shortly be available on Internet.

5 THE COMMITTEE'S APPROACH TO ITS CHARGE

6
7 The Committee is charged with answering three fundamental questions: (1) What is the
8 Federal Government's role in human radiation experiments it sponsored or conducted that
9 resulted in wrongs or harms? (2) What are the criteria for determining the remedies due to those
10 wronged or harmed? (3) What lessons learned from studying research standards and practices in
11 the past and present should be applied to the future?

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

18
19 Created in tandem with a Presidential directive that the executive branch be open to
20 searching inquiry, the Committee got under way with few records, a huge task, and a short time
21 frame. The work began with an examination of a largely untold part of the history of the Cold
22 War. The examination entails digging into warehouses full of public and private records and
23 probing the memories of numerous individuals.

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

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

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1 progress.³ Together with the documentary evidence that the staff has unearthed and is continuing
2 to gather, the Committee is drawing on these disparate voices to articulate the vital themes that
3 will give structure and substance to its final report. To date the Committee has identified nine
4 such themes, italicized in the paragraphs that follow, but other themes may come to light as the
5 work shifts to analysis and normative judgment.

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

13 Similarly, it was clear that the Committee would have to make *assessments of the*
14 *potential harms and benefits* of the experiments it is charged with studying. It is in the nature of
15 most research that subjects may be exposed to risks in order to obtain desired information. It is
16 therefore important to understand (to the extent possible) the level of risk to which subjects were
17 exposed, as well as researchers' perceptions of the risk. It is also important to assess whether the
18 potential benefits to the subject or to society were sufficient to justify the risk to which subjects
19 were exposed. The Committee is aware that, within and without the scientific community, there
20 is study and debate regarding the effects of low doses of radiation. The Committee must be
21 sensitive to all viewpoints. At the same time, the Committee and the public must understand the
22 relation between this discussion and the Committee's charge. For example, the doses in
23 historical experiments evaluated by the Committee may not differ from those in use today in
24 routine and accepted diagnostic procedures. It is not the Committee's charge to go beyond
25 presently accepted radiation standards. By the same token, it is not the Committee's view that
26 contemporaneously accepted practices are risk free, and can have no health effects; accepted
27 practices often may well involve risks. It is the Committee's charge to assess whether the risk,
28 however low, was justified. Were subjects informed of the risk and the purpose(s) for its being
29 undertaken? Was their consent obtained? Where consent was obtained, were some populations
30 (e.g., indigent persons) chosen as subjects to the exclusion of others?

31 Another theme the Committee noted early in its work concerns the *selection of research*
32 *subjects*. The ethics of research turn as much on considerations of justice in the selection of
33 subjects as they do on questions of consent or acceptable risk. The Committee deems it essential
34 that it examine whether particular populations were targeted for participation as research subjects

³ 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 report.

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1 because of their relative lack of economic, social, or political power. For instance, fetuses,
2 infants, children, prisoners, soldiers, minorities, the poor, the terminally ill, persons with
3 cognitive disabilities, and the institutionalized may have been chosen as subjects because of their
4 relative powerlessness.

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

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

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

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

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

1 Finally, the over-arching context for the Committee's retrospective judgments is that
2 during the historical period specified by its charter (1944-1974), the United States was not only
3 in the throes of the Cold War, but it was also living through the early stages of a profound
4 scientific and social revolution. It was the *dawn of the Atomic Age*. The power of the atom was
5 seen as a source of great promise--it would cure cancer and provide limitless cheap energy. But
6 it was also the source of the most destructive force ever created by humanity and unleashed on
7 the earth. A complete understanding of human radiation experiments must situate the research in
8 this complex cultural context.

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

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

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

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

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

- 28 • An experimental database, to provide a single locale for cataloguing
29 experiments as they are identified and storing basic information as it is
30 retrieved;
- 31 • An ethics timeline, to chart the evolution of Federal and private sector
32 policies and practices pertaining to research ethics;
- 33 • A scientific and medical standards timeline, to chart the evolution of these

1 standards; and

- 2 • Institutional maps, to plot the network of public and private institutions
3 that planned, funded, managed, and performed the experiments and used
4 the resulting data.

5 The second component of this phase was an effort to identify the world of potential
6 sources of information, and the most efficient methods to mine these sources below. As
7 discussed in Parts II - III below, for example, this strategy involved:

- 8 • Refocusing agency document searches on headquarter level
9 collections, in order to gain an overview of the forest in which
10 individual experiments were set and identify data trails that might
11 be followed;
- 12 • Surveying private archives and library sources;
- 13 • Initiating oral history, interview, and outreach projects to tap
14 individual memories; and
- 15 • Planning several research projects to assess and evaluate human
16 experimentation that is ongoing today.

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

21 **Phase II: Information Organization - Gathering in the Threads; Focusing on**
22 **Experiments**

23 While Phase I is still in progress, the Committee's brief tenure requires that it
24 simultaneously focus on particular experiments (or groups of them) in order to begin the
25 evaluative process. But on which experiments should energies be focused? The elements of the
26 strategic problem include the following: (1) the number of pre-1975 experiments and intentional
27 releases may well be in the thousands, and the number of post-1975 experiments even larger; (2)
28 data gathering will remain incomplete even as evaluation begins; and (3) the Committee may be
29 able to collect only fragments of data about many (probably most) experiments.

30 The need, therefore, was for a strategy that (1) made use of available data; (2) was likely
31 to address particular experiments and releases of clear public concern; (3) would not neglect

1 experiments and releases simply because applicable data were not readily available; (4)
2 addressed experiments and releases that involved basic issues of concern to the public and the
3 Committee; and (5) was sufficiently flexible so as not to be derailed by information roadblocks.

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

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

- 16 1. a review of a sample of recently funded research proposals (including
17 radiation and non-radiation treatments), with the ethical evaluation
18 focusing upon the processes of subject selection, harm/benefit, and
19 disclosure of information and informed consent;
- 20 2. interviews with subjects of current research, attempting to assess their
21 attitudes and beliefs related to research participation; and
- 22 3. collection of current agency policies related to the oversight of research on
23 human subjects.

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

26 **Phase III: Information Analysis - Evaluation and Recommendations**

27 While Phase I continues, and Phase II has just begun, the Committee must
28 simultaneously turn to the Phase III task of evaluating past and present experiments and
29 recommending policy changes and criteria for determining the remedies due to those wronged or
30 harmed, as appropriate. The development of a strategy for this effort is the immediate priority of
31 the Committee as the first six months of its tenure come to an end. Specifically, the Committee
32 currently is focusing on the development of ethical standards for judging past and present
33 experiments and releases, as well as on criteria for determining the remedies due to those

1 wronged or harmed. In Part V of this interim report, the Committee takes stock of where it has
2 been; in Part VI the Committee summarizes the work to be done in the next six months.

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

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

15 **A. THE PROBLEM: WIDELY DISPERSED AND FRAGMENTARY**
16 **INFORMATION**

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

21 The Committee could begin with documents that were assembled during the 1980s and
22 that underlay the "Markey report."⁶ There were significant collections regarding the plutonium
23 injections and some other well-publicized experiments. But review of the materials available for
24 the Markey report confirmed that, even for that relatively well-known group of experiments,
25 basic information was lacking. The Department of Health and Human Services (HHS) reported
26 that its data on mid-century research grants was limited to capsule descriptions that often did not
27 permit distinction of work performed on humans from that performed on other forms of life.
28 Components of Department of Defense (DOD) and other agencies did provide lists of human
29 experiments; in many cases, however, even when reports on the research were available they
30 often lacked data on basic questions of concern (for example, who the subjects were and what

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).

1 they were told about the risks of the experiment).

2 What codes of conduct, if any, existed to govern federally sponsored experiments? Who
3 developed them? How were they put into effect? There was no readily identifiable body of
4 ethics policies that governed human experimentation in the pre-1974 period. Indeed, the
5 prevailing assumption was that until the mid-1960s Federal agencies, by and large, did not even
6 possess such policies for their extramural research programs.⁷ In order to evaluate experiments it
7 also is necessary to understand the scientific or medical standards in effect during the period of
8 their performance. What were they? How were they made known and put into effect?

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

12 Finally, when the facts and standards are assembled, by what factors is the past to be
13 judged? What precedent is there for providing remedies where wrongs are found, and by what
14 criteria are wrongs to be assessed?

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

19 **B. BIOMEDICAL EXPERIMENTS: 1944-1974**

20 **1. Phase I: Mapping of Experiments and the World In Which They**
21 **Were Set**

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

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 as well.

1 a. *Experiment Database*

2 The aim of this activity is to provide a living electronic document that will serve as a
3 central record on the identity of many (but by no means all) Government-sponsored human
4 radiation experiments, with basic information on each experiment and keys to permit further
5 research. To this end, the Committee created a form to collect standard information regarding
6 each biomedical experiment of which it became aware.⁸ As of mid-October, the database
7 comprised about 400 experiments that were conducted prior to 1975. In addition to the
8 experiments in the database, the Committee has at least fragmentary data that may involve 1,000
9 or more further experiments⁹.

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

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

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 (1) 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.

⁹As 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.

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

7
8 b. *Ethics Policies and Practices*

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

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

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

- 25 • The extent to which the Secretary's policy, which was stamped "Top
26 Secret", was known throughout DOD and by civilian researchers funded
27 by DOD;
- 28 • Whether and how the Armed Services implemented the Secretary's policy;

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.

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- 1 • The extent to which implementing directives were actually applied to
2 particular experiments; and
- 3 • How the 1953 policy was interpreted: What research activities were
4 considered to be covered by the directive and which were not? For
5 example, how was research distinguished from training maneuvers? Were
6 activities conducted by DOD contractors, as well as DOD employees,
7 covered?; and
- 8 • The meaning of "human volunteers" in the context of military activities.

9 ii. Central Intelligence Agency (CIA). The Committee is
10 seeking information on the relation between early ethics policies in DOD, HHS, and AEC, and
11 experiments conducted by the CIA. In the 1970s, public and congressional attention focused on
12 MKULTRA, a program of CIA experiments on mind control (most famously involving LSD)
13 conducted without evident regard for consent requirements. Documents show that CIA
14 representatives who were involved in the predecessors to MKULTRA also participated in the
15 DOD groups at which, as discussed above, the Nuremberg Code policy was debated and
16 formulated.

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

21 iv. Department of Health and Human Services (HHS). The
22 initial HHS policy appears to have been that applied to the National Institutes of Health (NIH)
23 Clinical Center, which opened in 1953. The Committee has been researching the development
24 and application of that policy. Policies governing extramural research were initiated during the
25 1960s.

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

31 vi. Department of Veterans Affairs (VA). The recovery of
32 policies related to experiments sponsored by the then-Veterans Administration has been limited.
33 However, it appears that work done under VA auspices was often performed in coordination with
34 other agencies or by investigators who also worked under DOD, AEC, or HHS (predecessor)
35

1 funding. The relation between the policies and practices of VA and those found elsewhere
2 should be of interest.

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

7 c. *Institutional Mapping.*

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

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

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

35 Mid-century debates and sponsorship of human experimentation often involved

1 participation by multiple agencies. It is therefore necessary to understand relationships among
2 agencies, as well as within them. For example, AEC and DOD (and their consultants), engaged
3 in vigorous discussion over the need for human experimentation in connection with the nuclear-
4 powered airplane (which was never built). Civilian agencies or their representatives also were
5 involved in defense-related discussion and planning. Following World War II, the National
6 Institutes of Health (NIH) inherited many of the research grants and contracts of the World War
7 II Committee on Medical Research, the medical research and development component of the
8 military effort. During the Korean War period, representatives of the VA, NIH, and PHS, as well
9 as AEC and DOD, were involved in the discussions of the Joint Panel on the Medical Aspects of
10 Atomic Warfare. PHS played an important role in relation to bomb tests and fallout
11 measurement. When NASA was created in 1958, it was able to rely on a research heritage from
12 agencies such as the Air Force and AEC, and NASA established a joint research program in
13 radiobiology with the AEC in the early 1960s..

14 **d. *Scientific Standards Timeline.***

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

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

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

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

1 and Committee resources.

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

8 *a. Biomedical Experiments*

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

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

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

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

28 *v. Radioisotope Research.* This group, which includes
29 experiments at the Wrentham School, encompasses studies using radioisotopes that were
30 products of the nuclear age and also had major medical applications in both diagnosis and
31 therapy. Examples of these radioisotopes include iodine and iron. Unlike the biodistribution
32 group, this group allows a purposive sampling of cases that include research on medical
33 applications.
34

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

3 b. *Institutional Case Studies*

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

- 9 • Where higher-level policies existed, how were they supposed to flow
10 down from headquarters to research institutions and, ultimately, to
11 investigators and subjects?
- 12 • Where did responsibility lie for determining the formal and practical reach
13 of policies and the requirements for implementation?
- 14 • If policies were limited in coverage, or in their implementation, why was
15 that the case?
- 16 • Where did responsibility lie for failure to implement and/or enforce
17 policies and was a policy oversight process either in place or considered?

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

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

1 C. INTENTIONAL RELEASES

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

- 7 • The Charter included 8 radiation warfare experiments; the number is at
8 least 53.
- 9 • The Charter includes 4 Los Alamos, New Mexico, implosion tests
10 involving radiolanthanum. DOE reports that the number of such tests
11 approximates 250.
- 12 • The Charter includes one intentional release from a plutonium production
13 facility (Green Run). Examples of further releases from nuclear
14 production facilities have been found.

15 In addition to the types of releases identified in the Charter, additional intentional releases
16 include:

- 17 • Releases related to the development of nuclear rocket and nuclear aircraft
18 technology;
- 19 • One-point safety tests of fission warheads at the Nevada test site that were
20 performed to determine whether the accidental detonation of the high
21 explosive at one point in a warhead would produce a nuclear yield;
- 22 • Radioecology tests, in which radioactive material was introduced into the
23 environment to test for retention or transmission through the environment;
24 and
- 25 • Tests of reactor safety and simulated accidents, such as reported by DOE's
26 Idaho National Engineering Laboratory.

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

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

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

- 6 • What was the purpose of the release (e.g., bomb testing, reactor testing,
7 long-range detection, environmental study)?
- 8 • How much radioactivity was released and in what form?
- 9 • Was radiation monitored on and off site? Who was responsible for the
10 monitoring?
- 11 • Were there human biomedical studies in connection with the releases?
- 12 • Were participants and bystanders notified in advance of potential hazards?
- 13 • What measures were recommended or taken to minimize risks to
14 participants and bystanders?
- 15 • What rules govern intentional releases today (for example, environmental
16 impact regulations)?
- 17 • How would the historical releases be conducted today? For example,
18 would environmental impact statements be required? Would there be
19 public notice? Could all or portions of the review process be kept secret?
- 20 • What kind of releases are being conducted today, and what rules are being
21 followed?

22 **D. A NOTE ON SCOPE**

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

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

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

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

- 21 • Documents related to the biomedical panels (or offices, committees, etc.)
22 that planned the biomedical components of atomic bomb tests;
- 23 • Documents related to human subject data-gathering activities that,
24 according to available documentation, may have been experiments
25 (including, for example, flash-blindness testing, psychological observation
26 or testing, the measurement of radioisotopes in body fluids, and the
27 measurement of radiation in ground or aircrews, all in connection with
28 weapon tests); and
- 29 • Documents related to DOD's ethics policies (particularly the 1953
30 Secretary of Defense Directive) to atomic bomb test activities.

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

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

9 E. THE CONTEMPORARY STORY

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

25 1. Subject Interview Study

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

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

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

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

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

- 15 • Beliefs about being a research participant, such as whether the subject is
16 currently receiving any treatments or drugs considered to be experimental,
17 or participating in any research studies or proposals.
- 18 • Voluntariness (to be asked of those who believe they are currently
19 participants in research), such as whether he/she believes there was a
20 choice about whether to participate in research or experimental therapies,
21 and why or why not.
- 22 • Reasons for participating, e.g., to receive state-of-the-art treatment; to help
23 advance science; to receive compensation; because someone
24 recommended they should, etc.
- 25 • Understanding of what it means to participate in research, such as whether
26 the subject understands what it means for radiation therapy to be
27 experimental, the difference from regular medical care, whether everyone
28 in their research proposal is getting the same therapy or treatment.
29

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

8 **2. Research Proposal Review Project**

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

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

- 21 • All human subject research proposals involving ionizing radiation that
22 were newly approved and funded or renewed by the agency in fiscal years
23 1990-1993.
- 24 • Human subject research proposals not-involving ionizing radiation that
25 were newly approved and funded or renewed during the same period as the
26 ionizing radiation proposals, for the purpose of creating a comparison
27 group.

28 Both intramural and extramural proposals in each category will be considered for review.
29 Grantee institutions and the agencies will be asked to provide relevant documents for a sample of
30 the radiation research proposals as well as a parallel sample of non-radiation research. A subset

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

1 of Committee members and staff will review and evaluate the proposal materials based on
2 evaluation criteria developed by Committee and staff. This team of evaluators will include
3 persons with technical radiation risk and medical expertise, knowledge of the appropriate
4 standards for informed consent and selection of human subjects, and any additional expertise
5 necessary to address the objectives listed above.

6 **3. Agency Oversight Review**

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

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

21 **A. THE AGENCY SEARCH PROCESS**

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

27 The Interagency Working Group has, collectively, devoted considerable time to these
28 search efforts, which are ongoing. Numerous records collections, encompassing thousands of
29 boxes of potentially relevant files in Federal Records Centers throughout the country, have been
30 identified. Even where relevant collections are identified, however, the search process has been
31 arduous; dozens of boxes may yield only a handful of relevant documents, yet these documents
32 may be of great value. Overall, the level of effort expended by the agencies has been admirable
33 and the yield significant.

1 **1. Initial Reports**

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

- 4 • The CIA stated that its search had failed to retrieve a single document that
5 either showed CIA sponsorship or funding of human radiation experiments
6 or bore relevance to experiments conducted by others.

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

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

- 18 • HHS reported that data on the many thousands of grants for earlier years
19 were limited to capsule grant descriptions, which did not always make
20 clear whether research involved human subjects. HHS is currently
21 working on targeted approaches to locate data on specific experiments or
22 groups of experiments.

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

- 26 • VA's initial search focused on a survey of 172 medical centers throughout
27 the country and a review of reports at the central office. There was no
28 formal effort to identify and list experiments. VA told the Committee it
29 would search for further information on its confidential Atomic Medicine

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.

1 Division, which was created in 1947.

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

5 **2. Committee Assessment**

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

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

28 **3. Committee Work with Agencies on Search Strategy**

29 The initial agency searches provided a start in identifying experiments and an
30 appreciation for the difficulty in retrieving substantial data about the experiments. With this data
31

1 and experience in hand, the Committee sought to determine how to assist agencies in directing
2 the searches. The particulars of these activities are discussed in more detail in Appendix E and in
3 staff memoranda and related Committee discussion concerning each agency.

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

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

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

20 a. *CIA.*

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

28 b. *DOD.*

29 The Committee proposed that DOD agencies ¹⁶ look for headquarters-level planning,
30 programming, and budgeting documentation. The headquarters-level ethics and policy

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

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1 documentation located as a result of this effort did reveal important documentary trails. For
2 example, the records of the Joint Panel on the Medical Aspects of Atomic Warfare include
3 debate on the need for human experimentation, plans for experimentation, and digests of
4 experiments. Similarly, the Armed Forces Medical Policy Council initiated discussions in 1951
5 that led to both the Secretary of Defense's February 1953 issuance of the top secret version of the
6 Nuremberg Code for human experimentation and to the Joint Panel's consideration of
7 experimentation in connection with atomic bomb tests.

8
9 DOD will continue to search at least for the location and retrieval of the records of
10 relevant headquarters-level groups (through at least 1974), and the location of documents relating
11 to the development and implementation of its 1953 Nuremberg Code policy. It is also refocusing
12 field-level searches in light of the new understanding that has been gained.

13 c. *DOE.*

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

20 The Committee's initial review of DOE efforts led to specific Committee requests that
21 DOE (1) locate the files of the AEC Intelligence Division, which may have contained data on
22 work performed for other agencies and on intentional releases; (2) locate the collection of 250
23 documents that underlay DOE's 1974 reports on the plutonium injection experiments; and (3)
24 arrange for the retrieval of documents from the three universities involved in the plutonium
25 injections (University of Chicago, University of Rochester, and University of California at San
26 Francisco). DOE is currently retrieving materials from the universities, but it reported that the
27 files of the AEC's Intelligence Division had been destroyed and that the collection associated
28 with the 1974 report could not be located. As discussed in Appendix E, the volume of
29 documents that remain to be examined is quite large. On an ongoing basis, DOE and Committee
30 staff are working to identify headquarters and field collections for priority retrieval.

31 d. *HHS.*

32
33 Initial review by HHS produced a computer-generated list of experiments which
34 apparently involved both ionizing radiation and human subjects, but only for research initiated in
35 and after 1962. Although components of the agency and its predecessor conducted or funded
36 numerous human radiation experiments before 1962, a complete review of potentially relevant
37 records was determined not to be feasible given current time and resource constraints, in

1 considerable part because the extant records of earlier research are fragmentary. Accordingly,
2 once a partial listing of experiments reviewed by the NIH Radiation Study Section was produced,
3 the systematic search for early experiments was suspended, pending archival research into
4 organizational and policy-related evidence. More recently, the Committee and HHS have
5 decided to further develop data bearing on the Radiation Study Section list as a reasonable proxy
6 for a comprehensive search of pre-1962 experiments. This approach is reasonable because many,
7 if not most, of the experiments of interest likely were reviewed by this study section. This
8 approach will be complemented by review of a more complete listing (up to 1974) of intramural
9 human radiation research conducted at the NIH Clinical Center.

10 e. *NASA.*

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

16 f. *VA.*

17 VA's initial effort focused on a survey of field locations, in response to which some data
18 were provided. There was only limited review of headquarters-related documents and no
19 provision for the systematic identification of experiments conducted or sponsored by VA.
20 Following review of the responses to the survey, the Committee and VA agreed to search
21 headquarters records and, as that search proceeded, focus on a sample of field sites. In July, VA
22 committed to a search of the approximately 1,800 Washington, DC-area record boxes that may
23 contain relevant information. VA initially agreed to complete this search in 90 days; the present
24 estimate is that the review will be completed by mid-November. The Committee simultaneously
25 identified a number of field offices from which additional information was requested.

26 As noted previously, VA intends to find the purpose of its Atomic Medicine Division,
27 which apparently included confidential activities. In October, VA asked the Inspector General,
28 because of its expertise in records examination and search, to assist in the research for
29 information on the Atomic Medicine Division.

30
31 4. Classified Documents

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

1 In the cases of DOD, DOE, and the CIA, significant collections of relevant material are
2 still classified.¹⁷ The Committee sought, and received, written assurance that reasonably discrete
3 requests for declassification would be acted upon within three weeks. Where large classified
4 collections of documents remain to be searched, Committee and staff may review the collections
5 to identify priorities for declassification requests. This process has been impeded because of
6 delays in the receipt of security clearances. By mid-October, only the Chairperson and six
7 staffers had received interim clearance.

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

- 12 • DOD has stated that information related to the planning and purpose of the
13 Green Run intentional release must still remain classified;
- 14 • DOE has stated that the majority of documents related to the 250
15 radioactive lanthanum intentional releases conducted at Los Alamos must
16 remain classified.

17 B. ADDITIONAL METHODS OF INQUIRY

18 In addition to documentation available from the agencies, the Committee seeks to locate
19 information from all feasible sources and is conducting an interview and oral history program
20 towards that end.
21

22 1. Documentary Search

23 This search for information includes:

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

¹⁷ HHS initially stated that it did not have classified documents. This turned out not to be the case. HHS 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 authority; VA lost this authority in 1972, apparently due to non-use.

¹⁸ The Committee will explore the further possibilities for declassification.

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

- 3 • *Congressional materials.* Staff has compiled a chronology of
4 congressional hearings related to human research involving radiation
5 going back to 1948, and the hearing materials have proven to be a valuable
6 research tool.

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

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

30 2. Ethics Oral History and Interview Projects

31
32 In addition to collecting documentation, the Committee has embarked upon an Ethics
33 Oral History Project in order to understand the evolution of ethical norms and research practices
34 in human experimentation from World War II onward. Oral histories are essential, since
35 information from other primary and secondary sources will be incomplete. Approximately ten to
36 25 senior research scientists active in both radiation and nonradiation research from 1944 to the
37 present are being interviewed by experienced interviewers from the Advisory Committee and its

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1 staff. Interviewees are being selected from two age groups: (a) clinical researchers who began
2 their careers in the 1940s or 1950s, and (b) those whose careers began in the early 1970s.
3

4 In developing this project, the Committee has consulted with independent experts
5 (ethicists and historians) concerning both whom to interview and how to conduct an oral history.
6 Because the project involves the collection of information from human subjects, and the
7 Committee seeks to draw generalizable conclusions from this information, the project was
8 submitted to an institutional review board (IRB) from Pennsylvania State University College of
9 Medicine (the home institution of the Committee member directing this effort). With IRB
10 approval granted September 26, 1994, the Advisory Committee began interviewing on
11 September 30, 1994, and will continue to conduct interviews at a rate of approximately one per
12 week. All interviews are being tape-recorded and transcribed; interviewees will be given a
13 chance to review transcripts before they are evaluated by the Advisory Committee.

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

23 **PART III. OUTREACH**

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

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

33 At the core of the Committee's efforts are those who participated (or participate now) in
34 human radiation experiments. This group includes all living human subjects of federally funded
35 experiments involving ionizing radiation, and family members (or other representatives) of
36 subjects who are no longer alive. It also includes biomedical scientists and policymakers who

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1 were or are involved in human radiation experiments. The Committee has sought to contact
2 these groups and individuals in a number of ways. Letters inviting participation in Committee
3 meetings and soliciting relevant documents and information were sent to more than 50 groups
4 representing subjects and families and to 15 professional societies.¹⁹

5 In addition to the public comment period that is a component of every Committee
6 meeting, the Committee will hold several meetings outside of Washington with the purpose of
7 hearing from the public. The October meeting of the full Committee was held in San Francisco
8 so that interested parties in the Western part of the United States could attend a meeting and
9 express their views directly to the Committee. The Committee also has scheduled three small-
10 panel meetings, in Cincinnati (October 21), Spokane (November 21), and Albuquerque or Santa
11 Fe (January 30, 1995). As time permits, the Committee may seek to use portions of its future full
12 Committee meetings to engage representatives of the various constituencies in discussions of
13 particularly knotty questions that the Committee must address.

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

20 Committee staff and Committee members meet regularly with individuals who contact
21 the Committee and respond to calls and letters. Where time and location permits, staff and
22 Committee members are available to speak at conventions or other meetings. The
23 is seeking to provide the public with the fruits of the documentary inquiry as soon as possible, in
24 hopes that members of the public will continue to provide analyses and reflections that the
25 Committee can draw upon. Finally, the Committee seeks to engage with Congress and the press.

26 Outreach efforts to date have yielded a substantial number of useful documents from
27 private collections, including those of families of atomic veterans and of researchers who played

¹⁹ Some responded by attending Committee meetings and addressing the Committee during the public comment period, some 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 gotten elsewhere.

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 sample 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.)

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1 important roles in the early days of radiation experimentation. Also as a result of the
2 Committee's outreach program, members have heard testimony from many persons with relevant
3 radiation-related experience. Through its interview project the Committee so far has collected
4 valuable information from researchers and others in their own voices. And Committee and staff
5 members have spoken at public meetings and met with stakeholder groups to explain the
6 Committee's work and report on its progress.

7 **PART IV. INFORMATION MANAGEMENT AND PUBLIC ACCESS**

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

- 13 • Well over 370 individual document accessions, ranging in size from 1 or 2
14 documents to several thousands, had been received or retrieved from a
15 wide variety of public and private sources.
- 16 • Data (often fragmentary, as noted) had been received on many hundreds of
17 experiments.
- 18 • Almost 2,000 journal articles, Congressional reports, and secondary
19 sources, that bear on experiments or experimentation have been
20 assembled.

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

- 26 • The Committee has an interactive network based on Lotus Notes, for use
27 by staff. The Committee expects to shortly connect with the public via the
28 Internet. The network should provide direct public access to the index of
29 document collections possessed by the Committee, and to the experiment
30 database.
- 31 • The Committee has established a public reading room. Basic committee
32 materials (e.g., transcripts and briefing books for each meeting) are
33 available. As they are assembled by staff, collections of historically

1 important material—e.g., minutes of important committees, histories of
2 relevant programs--are being organized and placed in the reading room .

3 **PART V. TAKING STOCK: SOME INITIAL OBSERVATIONS**

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

10 **A. OPENNESS**

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

- 20 • At the Committee's request, the Defense Nuclear Agency has declassified
21 the table of contents of its more than 500 histories, on the basis of which
22 declassification of portions of these histories is being requested. The
23 histories of this agency, that has been at the center of nuclear weapons
24 research and development, had previously been available only on a limited
25 basis.
- 26 • The Committee is organizing the minutes and related records of the AEC
27 Advisory Committee on Biology and Medicine and several DOD
28 committees that were central to biomedical research related to atomic
29 warfare.
- 30 • The Committee has located and is assembling documentation of the mid-
31 century relationship between the civilian health research agencies
32 (predecessors to the current HHS) and defense agencies.
- 33 • The Committee is assembling histories of military research organizations

1 and activities. (DOD, for example, has provided multivolume histories of
2 the Air Force's School of Aviation Medicine and the Naval Radiological
3 Defense Laboratory, and a history of the Atomic Cloud Sampling
4 Program.)

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

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

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

25 **C. HISTORICAL DISCOVERY**

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

29 **1. Government Ethics Debate and Policy**

30 While full evaluation must await the final report, it already is clear that the information
31 developed by the Committee should require a significant revision of our understanding of the
32 history of research ethics. (This information is detailed in staff memoranda.)
33

1 2. Government Rediscovery of its Past

2 The events that the Committee is studying often predate the working careers, even lives,
3 of those now staffing the agencies. The search process has involved the continued discovery of a
4 heritage that had been lost even to those to whom it had been bequeathed. Consequently, the
5 search has been an opportunity to rediscover this past. For example, there was limited
6 recollection of the extent to which the Cold War linked the activities of civilian and military
7 agencies. The reconstruction of the intertwined Cold War roots of civilian and defense agencies
8 requires the piecing together of documents and memories from many sources.

9 3. Discovery of the Present in the Past

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

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

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

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

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

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

16 D. PUBLIC ACCESS TO THE RECORDS OF OUR PAST

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

21 E. CHALLENGES TO RECONSTRUCTING THE PAST

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

26 1. Agency Searches Are Time Consuming

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

1 2. Data on Experiments are Fragmentary

2 In the case of many experiments, only fragmentary data are available from government
3 and public sources (e.g., journal articles). Data on key questions, such as consent practices and
4 subject selection, are often lacking. Additional information may be available from the
5 institutions that conducted the experiments, the investigators who conducted them, and the
6 subjects themselves. The Committee will seek to focus its efforts on cases where access to
7 additional information is more likely. However, the reconstruction of experiments will be time
8 consuming and its success uncertain. The problem of fragmentary data also applies to intentional
9 releases, where in some cases pertinent information remains classified.²¹

10 3. Loss or Destruction of Important Document Collections

11 Even when important document collections have been identified, they can rarely be rarely
12 be recovered *in toto*. In some cases they have been destroyed as a matter of routine, in accord
13 with record retention schedules. But in a few cases, significant collections appear to have been
14 lost or intentionally destroyed. The destruction often may have been in accord with standard
15 records destruction practices. For example:

- 16 • CIA acknowledged that the charter of its MKULTRA program of
17 experiments included radiation research; however, as CIA previously
18 reported, Director Helms ordered MKULTRA files destroyed a number of
19 years ago.
- 20 • Documents provided by DOD and DOE, and/or located by staff in the
21 National Archives (in the files of HHS predecessors) show that CIA
22 played a continued role in the mid-century DOD committees that debated
23 and planned for human experimentation. CIA, however, reports that it has
24 not yet been able to locate any materials related to these groups in its own
25 files.
- 26 • In issuing his Nuremberg Code directive in 1953, Secretary of Defense
27 Wilson required the advance approval of covered human experimentation
28 by the Service Secretaries. With limited exceptions, the files containing
29 such approvals have not been located.
- 30 • The Naval Radiological Defense Laboratory (NRDL) was established in

²¹ The Committee will likely not have time or resources to engage in independent dose reconstructions. However, it can seek to ensure that they will be performed where reasonably doable.

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1 1947 to study contamination problems posed by the use of the atomic
2 bomb. At the time of its "disestablishment" in 1969, its library of research
3 reports was evidently dispersed, and basic records were evidently
4 destroyed. However, the Navy continues to search for surviving NRDL
5 materials.

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

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

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

- 20 • At the outset, HHS reported that, save for capsule descriptions of grants, it
21 no longer possessed material on experiments for the years through the
22 early 1960s.

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

- 29 •
30 • At the time of the Committee's creation, VA announced its intent to learn
31 about the purpose of a confidential "Atomic Medicine Division," that,
32 according to a 1952 report, was created in 1947. VA has located only a
33 handful of additional relevant documents that might shed light on the
34 confidential division. However, as noted, VA has asked its Inspector
35 General to assist in the search.

1 4. Classification

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

9 **PART VI. THE NEXT SIX MONTHS**

10 A. **WORK TO BE DONE**

11 In the next six months, the Committee will continue with the tasks of data gathering and
12 organization. The focus of the Committee's work, however, will shift to (1) the criteria for
13 judging historical and contemporary experiments, policies, and procedures, and (2) the criteria
14 for determining remedies due to those wronged or harmed. Based on what the Committee has
15 learned about both past and present experiments, the Committee then will make specific
16 recommendations regarding policies for the future.

17 1. Continuation of Present Tasks

- 18 • Continuing Phase I of the inquiry: Identifying experiments and mapping
19 the world in which they were set (1944-1974).
- 20 • Implementing Phase II of the inquiry: Focus on specific experiments and
21 their context (1944-1974).
- 22 • Implementing the three projects designed to gather data about the current
23 state of human radiation research.
- 24 • Continuing the agency search process.
- 25 • Continuing other methods of inquiry, including documentary search
26 efforts from members of the public, published literature, congressional
27 materials, universities, and collections of personal papers.
- 28 • Continuing to interview individuals connected with particular experiments
29 and Government programs, and continuing with the oral history project.

- 1 • Continuing outreach efforts.
- 2 • Continuing to develop and make available public archives.
- 3 2. Identifying Relevant Ethical Criteria for Judging Past and Present
- 4 Experiments

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

13 3. Making Recommendations on Criteria for Determining Remedies for
14 Past Experiments

15 Based on an analysis of past experiments in light of the ethical criteria adopted by the
16 Committee, and on an analysis of the alternative forms of remedy that may be available, the
17 Committee will make recommendations on criteria for determining the remedies due to those
18 wronged or harmed.

19 4. Making Recommendations on Policies for Future Research

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

23 B. TIMING OF FINAL REPORT

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