THE WHITE HOUSE

WASHINGTON

March 11, 1998

MEMORANDUM FOR RECORDS MANAGEMENT

FROM: PHIL CAPLAN

The attached three boxes contain the following material relating to the Human Radiation investigation:

Box 1: Agendas, Search Group Meetings, Summary; ACHRE: First Meeting and Startup; Indemnification of Contractors; Marshall Islanders; GAO Letter; University of Rochester; Presidential Memo- Establishment of Advisory Committee; Working Groups/ Committees; Committee Vacancy; Committee Vacancy Letters; Atomic Vets; Presidential Memorandum: Human Subject Review; Resumes; Patient Interview Study; Compensation; FOIA Requests; Phone Numbers and Sign-ins; Conference Call Summaries; Nasopharyngeal Radiation; Green Run- DOD; Early Talking Points; ACHRE Minutes; Anything Congressional; Markey Report/ CIA Report; Records Retrieval/ Hotline/ Directives to Agencies

Box 2: Clips; Interim Reports- ACHRE; Stakeholder Workshop Parts I and II; Report on Human Radiation Experiments Associated with the Department of Energy; Final Report of the Radiation Exposure Compensation Act Committee; Interim Report of the ACHRE; Final Report of the ACHRE

Box 3: Working Documents: Compensation Subcommittee of Legal Issues Working Group (1/10/94); Victims Task Force; Research; October 3, 1995 Event; Administration's Response to ACHRE Report; Claud Bailey; Governor Leavitt (UT)/ Dugway Proving Ground; NBAC; Journal Issues Contributed by Dr. Faden to ACHRE; Clips; Dr. Saenger/ Cincinnati; Performance of Staff Committee Members; Miscellaneous; Briefing Book Number 2; Briefing Book Volume 15

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ENCLOSURES FILED OVERSIZE ATTACHMENTS

3 folders filed 3/13/98 PT

AGENDA
December 2, 1994

I. Vacancy

II. Designated Federal Official

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
1726 M Street, N.W., Suite 600
Washington, D.C. 20036
202-254-9795 (Phone)
202-254-9827 (Fax)

FAX TRANSMITTAL

NUMBER OF PAGES (including cover): 2

TO: Phil Coyle (202) 456-6704

FROM: Steve Klaidman

DATE: 11/28/94

RE: [redacted] Meeting

If there are any problems with the transmission of this fax, please call 202-254-9795.

MESSAGE:

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
1726 M STREET, N.W., SUITE 600
WASHINGTON, D.C. 20036

MEETING LOCATIONS

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

November 14-15, 1994
Renaissance Hotel
999 9th Street, N.W.
Washington, D.C. 20001-9000
202/898-9000

December 15-16, 1994
Omni Shoreham Hotel
2500 Calvert Street, N.W.
Washington, D.C. 20008
202/234-0700

January 19-20, 1995
Omni Shoreham Hotel
2500 Calvert Street, N.W.
Washington, D.C. 20008
202/234-0700

February 16-17, 1995
Washington, D.C.

March 16-17, 1995
Washington, D.C.

April 10-11, 1995
Washington, D.C.

- *A Public Comment period is scheduled for each meeting.*

SMALL PANEL DISCUSSION LOCATIONS

November 21, 1994 ✓
West Coast Ridpath Hotel
515 West Sprague Avenue
Spokane, WA 99204-0367
509/838-2711

Late Feb or Early March
Nashville

January 30,1995
Albuquerque, New Mexico
Santa Fe

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EXECUTIVE SUMMARY
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
MEETING OF 15-16 DECEMBER 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments (ACHRE) conducted its ninth meeting at the Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, D.C. The meeting's agenda is included as Attachment 1. Although the agenda order was not strictly followed and the Committee strategy and direction was incorporated into other discussions, the only content change was the replacement of the Spokane Small Panel Meeting Report by a report on the meeting with Dr. Gordon Soper, Principal Deputy to the Assistant Secretary of Defense (Atomic Energy) (ATSD (AE)). Tabs referenced in the following Executive Summary are from the ACHRE Meeting Briefing Book, Volume 9, which is available for reference in the Department of Defense (DoD) Radiation Experiments Command Center (RECC) library.

2.0 SUMMARY OF THE 15 DECEMBER 1994 MEETING

Mr. Phil Caplan, the Special Assistant to the President for Cabinet Affairs, opened the meeting. The Committee Chair, Dr. Ruth Faden, stated that this meeting would be different in character from the others. She explained that there would be no Subcommittee reports or Agency updates, but acknowledged that search efforts by Committee Staff and Agencies had resulted in a continuous flow of documents. Agency updates would be provided outside the meeting to anyone who inquired. Dr. Faden also explained that the objective of the meeting was to begin integrating retrospective moral judgment, remedies, and historical ethics policies. This integration involved debate on the issue of Government culpability. The meeting's discussion would also enable the Committee to provide the Staff with guidance on the Final Report. After approving the minutes to the previous meeting with one editorial change, the Committee began the discussion.

3.0 COMMITTEE DISCUSSION: RETROSPECTIVE MORAL JUDGMENT - CRITERIA FOR EVALUATING THE ETHICS OF EXPERIMENTS

The Committee discussed Briefing Book Tab F: Memoranda on Retrospective Moral Judgment, which was comprised of "Ethical Relativism and Retrospective Moral Judgment," by Committee Staff consultant Allen Buchanan, and "A Framework for Making Retrospective Ethical Judgments," by Committee ethicist Dr. Ruth Macklin. The authors provided overviews of the tab before the Committee engaged in discussion.

3.1 The first issue raised was the magnitude of wrongs. Committee radiologist Dr. Henry Royal expressed concern that Mr. Buchanan's essay described an ethical ideal but did not provide a sense that no one measures up to this ideal or a sense of different magnitudes of wrongs and culpability. The latter was of particular concern to him as the essay seemed to group slavery,

Nazi experiments, and human radiation experiments together. Committee ethicist Dr. Jay Katz was of the opinion that the Nazis' deliberate brutality was the only difference. Mr. Buchanan responded that his intent was to show that remedies may be provided even when the role of individual culpability is diminished.

3.2 The next issue involved making retrospective moral judgments when evidentiary information was missing. Dr. Katz felt that this was an impossible assignment and the Committee should not attempt it. Dr. Royal pointed out that another difficulty was that fifty years have passed since the events and many of the agents and subjects are deceased. However, Dr. Macklin responded that it was possible to make retrospective moral judgments about acts without being specific about agent culpability. She also emphasized that before the Committee recommends remedies, it must first be determined whether people's rights were violated and harms were done.

3.3 The debate then focused on whether the Committee should actively identify moral wrongs or let them emerge from the presentation of the story. Dr. Macklin upheld that the Committee could demonstrate that authorities had failed in their moral duties without identifying specific individuals. Mr. Buchanan recommended that the Committee actively make a judgment in order to send a clear message to authorities who fail in their institutional roles. In addition, he noted that it is possible to determine a human rights violation occurred even without knowing the consent status. Dr. Katz reminded the Committee that actions now considered deplorable may have been acceptable cultural behavior during the Cold War. Dr. Royal maintained that the Committee should not force the issue without sufficient evidence to find Agencies or individuals culpable, adding that it is impossible for institutions like the Government to function perfectly.

3.4 The issue of national security and secrecy was also raised. Committee radiation oncologist Dr. Eli Glatstein was of the opinion that continued classification of documents over forty years old was due to a bureaucratic desire to protect Agencies from culpability.

3.5 During the discussion, the Wilson Memo was frequently cited as an example of a failure in the institutional hierarchy to implement a regulation. Although Dr. Katz felt that Secretary Wilson should be held responsible because it was his memo, Dr. Macklin pointed out that as the origin of the memo's Top Secret status is unknown, the Committee can only draw the conclusion that an authority failed in his institutional role. The wrong therefore is an error of omission.

3.6 The role of informed consent standards in retrospective moral judgments was also a matter of debate, especially in terms of merging the ethics and realities of informed consent. Dr. Royal, who expressed doubts that contemporary standards promote ideal consent conditions, inquired as to what level of consent would be morally acceptable. He added that this issue made a subjective assessment necessary. Mr. Buchanan presented another aspect of the issue: The nuances of consent standards during the 1940s and 1950s make it necessary for the Committee to review each experiment by class to determine if (1) the consent procedures of the institution responsible were adequate and in keeping with the institution's standards, and (2) someone in a position of authority failed to exercise adequate oversight or fulfill his institutional role.

3.7 The discussion progressed to the issue of culpability. The Committee referenced that morning's *Washington Post* and *New York Times* articles which dealt with Agency concerns regarding lawsuits or adverse public opinion that might result from human radiation experiments. These articles are included as Attachment 2.

3.7.1 Committee member and military medicine specialist Dr. Philip Russell proposed that the Committee recommend Government conduct standards and remedies rather than ascribe individual culpability. He stated that the Committee must take into account the difficulties of managing a large organization, noting that "terrible things" can result even when people with good intentions are operating with incorrect or incomplete information. Furthermore, there would be many different concerns in an organization as large and new as DoD was in 1953. Dr. Russell theorized that the Wilson Memo was given Top Secret status under a regulation already in effect at the time, and therefore the author of the regulation could hardly have foreseen its impact on research. Other Committee members also expressed reluctance to ascribe culpability when necessary evidence was missing.

3.7.2 The Committee then discussed institutional culpability, particularly in terms of formulating remedies based on an organization's behavior. For example, DoD could be held culpable for harms done to its experiment subjects. Committee attorney Dr. Ken Feinberg questioned whether the Committee had the evidence to back up this case. Drs. Macklin and Faden supported the view that where wrongs, harms, or rights violations were committed, human agents of DoD were still culpable - even when these individuals cannot be identified.

3.7.3 Referencing supporting documents (Briefing Book Tab I), the Committee debated basing institutional culpability on Agency officials' awareness of the need for consent policies and discussion of the need for secrecy to prevent legal liability and adverse public opinion. Dr. Royal objected; he found that the terse language of the memos leaves them open to interpretation. Furthermore, in some plutonium injection cases, it was known that the patient was given some information. Dr. Royal also commented that had the doctors believed that their actions were wrong, they would not have proceeded to publish articles on the experiments in medical journals.

3.8 Dr. Faden summarized the discussion. There was some degree of consensus that it will be possible to make moral appraisals or judgments about actions, but the issue of culpability remained. The latter issue also involves determining (1) if the evidentiary base is sufficient to make judgments about culpability at any level, and (2) who or what is culpable. The Committee planned to continue the debate during the discussions on historical ethics policies.

4.0 COMMITTEE DISCUSSION: REMEDIES

Referencing Briefing Book Tab G, Dr. Ken Feinberg outlined the proposed blueprint to guide policymakers and Congress for providing remedies, as well as nine guidelines to assist the Committee in making remedies recommendations.

4.1 Dr. Feinberg summarized the Committee guidelines as follows:

(1) The Committee must stick to its charter.

(2) Remedies could include information, health and/or life insurance, medical evaluation, medical monitoring, monetary compensation, and an official apology.

(3) Remedies must be based on an analysis of Government culpability and the nature of individual harm, both of which relate to the issue of causation.

(4) Government culpability may range from none to a willful violation of ethical standards and include recklessness, negligence, and strict liability. Remedies will still be involved if there was no culpability, yet harm was done.

(5) The degree of harms range from none to death. The problem will be whether there is enough evidence to determine if the Government's role resulted in the harm(s).

(6) Causation needs to be considered, and in cases involving mass exposures, presumptive causation requirements may be necessary to guide Congress in determining remedies.

(7) For Government-sponsored work, the Committee needs to consider whether "one Government" is responsible or whether the contractor should be held culpable.

(8) Except for cases involving economic loss or premature death, remedies for injuries do not pass on to relatives or the estate.

(9) Measures must be taken to ensure that claims are evaluated in a fair, unbiased, efficient manner and that remedies are implemented in a proper and equitable way.

4.2 Dr. Feinberg concluded that before remedies guidelines are proposed, the Committee will need to discuss what minimum exposure and what minimum epidemiological connection should result in a remedy.

5.0 COMMITTEE DISCUSSION: INTEGRATION OF RETROSPECTIVE MORAL JUDGMENT AND REMEDIES

The Committee discussed the integration of retrospective moral judgment and remedies. Briefing Book Tabs G and H were referenced.

5.1 Committee epidemiologist Dr. Duncan Thomas proposed two Committee actions: (1) recommend to the Government procedures for investigating individual culpability and (2) pass judgment on whether mass population symptoms are the result of a particular event or exposure.

5.2 Committee ethicist Dr. Patricia King commented that the proposed culpability scale was derived from the criminal code, not civil compensation regulations. After expressing concern that Committee debate might be leading to a retrospective moral judgment based on hindsight, Dr. King reminded the Committee that people could still be compensated for their injuries no matter who was culpable. Dr. Faden also questioned whether culpability judgments were critical to establishing remedies schemes.

5.3 Dr. Faden recommended that remedies apply to heirs if the experiment subject was blocked from seeking redress or information during his/her lifetime. She summed up the Committee's four alternates in terms of Government culpability: (1) strict liability, (2) culpability based on individuals' actions, (3) reduced remedy possibilities due to inability to draw inferences about culpability, and (4) prospective remedies only.

5.4 Dr. Macklin objected to prospective remedies on the grounds that terrible wrongs, such as injecting someone with an unknown substance, should result in a remedy. Her statements elicited comments on informed consent and the information that was disclosed to patients.

5.4.1 The discussion addressed information doctors did not disclose to patients in the 1940s and 1950s. Dr. Royal proposed that an injection might not be a "terrible wrong" if the "unknown substance" was saline. On the other hand, Dr. Katz noted, it was considered cruel to tell patients that they were being injected with plutonium as it would have frightened them. Dr. Glatstein added that patients who developed cancer often were not informed of their condition.

5.4.2 Contemporary consent regulations were also criticized. Dr. Katz felt that they were neither protective nor effective. Dr. Thomas stated that today's standards are helpful for gauging whether a terrible wrong was committed, but not for determining culpability. Dr. King reiterated her reluctance to judge the past by today's moral standards.

5.4.3 Dr. Russell suggested that the Committee make judgments about physicians in cases where the patients were not volunteers and the research was not in the patient's best interests. However, Dr. Katz stated that in 1945, doctors decided what was in the patient's best interests. Informed consent was not a part of medical education at that time.

5.4.4 Dr. Russell also suggested that the Committee discover if informed consent policies were different for research on infectious diseases.

5.5 Dr. Royal questioned who would have the burden of proof and how it would be factored into the remedies picture. He also questioned how much evidence would be necessary for a remedies decision to be made, especially as the evidence was incomplete. The Committee decided that this was an issue which would require further debate.

6.0 COMMITTEE DISCUSSION: HISTORICAL ETHICS POLICIES

The discussion of historical ethics policies focused on DoD policies, particularly the 1953 Wilson Memo. Dr. Faden instructed the Committee to consider whether evidence that the memo was not implemented was sufficient to determine DoD culpability. Prior to the discussion, Staff policy and research analyst Jonathan Moreno provided an overview on DoD's policies.

6.1 Mr. Moreno explained that DoD underwent two policy stages. During the first stage, DoD codified practices in reaction to the events of 1945-1946. The second stage (1951-54) occurred in the wake of the Nuclear Energy Propulsion for Airplanes (NEPA) discussions and DoD reorganization. The reorganization meant that there was a need for Agency research policies, including human subject use, safe exposures, and injuries.

6.2 Mr. Moreno outlined two scenarios that might have resulted in the Wilson Memo. The Committee then discussed the ramifications of these scenarios on possible DoD culpability.

6.2.1 The first scenario is that the memo was a case of articulated but not widely understood or accepted standards. The Nuremberg Code was an American code, so presumably it was applicable to Americans as well as the Germans. However, the Nuremberg Code involved written and witnessed consent, a policy that was not welcomed by the Pentagon.

6.2.2 In the second scenario, the standards were not widely disseminated. Secretary of Defense Wilson signed the memo shortly after his appointment. Efforts were made in the services to implement the memo's policies, but secrecy issues (including national security, legal liability, adverse public opinion) resulted in the memo's classification and thereby its lack of dissemination.

6.2.3 Mr. Moreno stated both scenarios still resulted in instances of institutional failure. Dr. Russell argued that this was due to a structural failure rather than a moral shortcoming per se.

6.2.4 The Committee discussed measuring each experiment against the standards that were in place at the time, including the medical community's standards for infectious disease experiments. One applicable and significant standard was the condition that the experiment results should not be compromised by informed consent. However, Mr. Moreno argued that there was a pattern of risky experimentation without informed consent, as well as a pattern of using patients in experiments disguised as therapeutic procedures.

7.0 COMMITTEE DISCUSSION: INTEGRATION OF HISTORICAL ETHICS POLICIES, RETROSPECTIVE MORAL JUDGMENTS, AND REMEDIES

The discussion of historical ethics policies continued in the context of retrospective moral judgments and remedies. The Committee recognized the need to review the relevant documents for each experiment and determine if Government or researcher conduct departed from the

appropriate conduct or standards in areas where the Wilson Memo applied. In those cases, the Government was potentially culpable.

7.1 Dr. Faden stated that the Government should be held accountable for occasions when the Government has a policy but fails to implement it. Mr. Moreno cited a case where a flash-blindness study officer who had heard a rumor of a policy (the Wilson Memo) governing experiment procedures, but did not know what the policy entailed.

7.2 Dr. Faden raised another issue: Government-sponsored or -funded experiments that were not done at a DoD facility, but through a contractor (such as a university). Dr. Thomas felt that the Wilson Memo extended to contractors and that the Government would still be culpable for any inappropriate behavior unless the contractor deliberately misled the Government. Dr. Faden agreed. Dr. Thomas added that in future situations, the Government should not be held liable if it was deliberately misled by a contractor, unless institutional review board (IRB) reports indicated that something was wrong. For the January meeting, the Staff will provide documentation of both Government and contractor violations of the Wilson Memo in areas where it applied.

7.3 At Dr. Faden's request, Mr. Moreno explained that the memo only refers to "human volunteers" and does not distinguish between healthy volunteers and patients. The issue is therefore whether it is ethical to experiment on a patient in order to discover information on atomic defense rather than a new therapeutic modality. Dr. Faden questioned how Committee judgments or conclusions would alter in cases where the research had dual purposes.

7.4 The Committee debated whether the policy writer's intentions were a factor in determining culpability. Dr. Russell argued that if the Wilson Memo was indeed inspired by the Nuremberg Code (which was based on Andrew Ivey's codified ethics) and the contemporaneous civilian biomedical code, then the biomedical community - including university programs - shared culpability. However, Dr. Macklin pointed out that universities did not share the same type of authoritative or structural relationship with the American Medical Association (AMA) as DoD did with its services. The Committee decided that for the January meeting, the Oral History Project Staff would present biomedical community standards contemporaneous to the Wilson Memo.

7.5 The Committee discussed the role of doctors in Government-sponsored research in a civilian biomedical setting.

7.5.1 Dr. King expressed concern that doctors - such as Dr. Saenger - might have been inclined to perform experiments on patients in order to receive a Government-sponsored grant.

7.5.2 The Committee Executive Director of Staff, Dan Guttman, noted that during the Staff's interviews, civilian doctors suggested that consent had been mentioned; however, documents indicate no clear implementation of consent.

7.5.3 Committee Staff consultant Jon Harkness quoted Dr. Saenger as saying that he had neither seen a memo from DoD nor received any training instructions. Dr. Saenger did not have a Top Secret clearance.

7.5.4 Dr. Faden inquired if DoD should have applied the Wilson Memo to dual-purpose research and if DoD would be culpable in cases where the memo was not implemented. The Committee decided that the context would determine if DoD was culpable.

7.5.5 Mr. Guttman expressed concern about areas where code words were used (e.g., "nutritional study" for "fallout study") and how this would affect Government and biomedical researcher culpability.

7.6 The Army IG-75 report, which was commended by the Committee as clear and well-written, was cited as a turning point in ethics policies. Dr. Royal asked how this report resulted in remedies. Dr. Russell responded that the Office of the Army Surgeon General had the jurisdiction, power, and responsibility to oversee all Army research involving human volunteers.

7.7 Dr. Faden summed up the Committee's tentative position: The Government should be held accountable in arenas where it had a policy that was not followed. The discussion would continue the following day in the context of Department of Energy (DOE) and Atomic Energy Commission (AEC) policies.

8.0 SUMMARY OF THE 16 DECEMBER 1994 MEETING

Committee Chair Dr. Ruth Faden began the meeting with an explanation of the day's agenda, which included a two-hour public comment session; continued discussion of retrospective moral judgments, remedies, and historical ethics policies (particularly those of DOE and the AEC); discussion of the Final Report and Appendices; and a report on the meeting with Dr. Soper, Principal Deputy to the ATSD (AE), to view and discuss the classified portions of the Green Run document. Discussion of the Final Report also involved debate over an extension; the Committee decided to apply for one but proceed as though it would not be granted. Committee members Reed Tuckson and Ken Feinberg were not present for the entire meeting.

9.0 PUBLIC COMMENT SESSION

Dr. Faden explained the rules for the public comment session. The list of scheduled speakers is included as Attachment 3. Another speaker was added after Mr. Fred Boyce.

9.1 Ms. Doris Baker of Cincinnati, Ohio, was introduced by Dr. Gwendon Plair, Chairman for Concerned Relatives of Cancer Study Patients. Ms. Baker, who also testified at the Cincinnati meeting, expressed her outrage that her great-grandmother, Gertrude Newell, and other patients had been used in Dr. Saenger's total body irradiation (TBI) experiments without their knowledge or consent.

9.2 Ms. Vina Colley of McDermott, Ohio, is a member of Portsmouth/Piketon Residents for Environmental Safety and Security (PRESS). Citing the experiences of herself and former co-workers, Ms. Colley asserted that uranium plant workers received neither information on nor protection from their hazardous work conditions, and that a 1947 Government memo excluded contractor employees from these safety measures for reasons of national security. She stated that her occupational exposures resulted in health problems such as uranium in her lungs and multiple myeloma, and that she had been a victim of "tissue-snatching." She requested that someone stand trial for the Government's crimes and that all relevant DoD and DOE documents be declassified.

9.3 Ms. Diana Salisbury of Sardinia, Ohio, is also a member of PRESS. She voiced concerns about the effects - particularly on the Appalachian population - of occupational exposures and intentional releases of uranium hexafluoride by uranium plant facilities (including Paducah and Oak Ridge). She stated that workers believed they were subjects in an experiment to prove the safety of radiation, an experiment in which the medical test results were manipulated. In addition, she criticized the Agencies for putting the burden of proof on claimants, then withholding information in order to reject the claims on the grounds of insufficient evidence.

9.4 Ms. Lenore Fenn of Lexington, Massachusetts, provided extensive written testimony to the Committee about human radiation experiments that she had witnessed in 1955 when she was a medical student working at Massachusetts General Hospital. She described one experiment, which Dr. Sweet conducted late at night. Ms. Fenn detailed the semicomatose, brain tumor patient's suffering as he was injected with radioisotopes on several occasions. The experiment stopped after she and another medical student reported it to the hospital administration. Like other medical students, she was offered financial incentives to participate in ionizing radiation experiments; however, she did not participate because a fellow student warned her that they were dangerous. Ms. Fenn did not know who ran the Nuclear Laboratory at the time.

9.5 Mr. Peter Lewis of Uniontown, Pennsylvania, stated that he had been an experiment subject at Walter Reed Army Hospital, but declined to comment further as his attorney had advised him against it. The Committee told him that he could testify on a later occasion.

9.6 Mr. Robert Proctor, a Science History Professor at Pennsylvania State University and a Holocaust Museum Science staff member, explained how the attribution of blame was an important symbolic act for victims. While describing the history of the uranium miners' health problems, Mr. Proctor cited examples where the U.S. Government and the AEC had failed to warn miners of hazards, barred epidemiological studies on the issue, and taken a reactive approach rather than preventative measures. He requested that the Committee take a strong moral stand by sending a message to those who perform experiments but do not follow through.

9.7 Mr. William T. Jackling of Honeye Falls (near Rochester), New York, had taught radiological defense classes for the Army. He spoke of his shame at his role in exposing people to Cobalt-60 and in giving injections under the guise of therapy. He described the case of plutonium injection subject Fred Sours. In conclusion to his concerns about remedies and the protection of

victims' rights in court, Mr. Jackling maintained that civilian medical standards should have applied to experiments regardless of whether the Government had official standards. In response to his request for a Small Meeting in Rochester, the Committee assured Mr. Jackling that they would still conduct interviews even if the meeting was not arranged.

9.8 Mr. Fred Boyce of Norwell, Massachusetts, was an experiment subject at the Fernald School. He spoke of the mental and physical abuse of the children, who were treated like criminals and coerced into participation through verbal abuse and offers of special privileges. Mr. Boyce stated that Quaker Oats had been one of the sponsors of the experiment. After requesting that the Committee correct the injustices done to experiment subjects, Mr. Boyce made available to the Committee Dr. Bender's papers, which he had purchased at an estate auction.

9.9 Accompanying Mr. Boyce was Ms. Marlow, the Fernald librarian. She testified that her father, an Air Force Colonel who had been at Desert Rock in 1955, had been denied information from the Agencies. She described U.S. human experimentation as Kafkaesque and requested that the Committee investigate (1) documents at universities and psychiatric institutions, (2) the use of radiation in pharmaceuticals, and (3) the use of radiation in conjunction with chemical or biological warfare.

9.10 Mrs. Pat Broudy, who has testified before the Committee at other meetings, argued that atomic exposures to servicemen fall under the Committee's charter. She enumerated the roadblocks that face radiation victims trying to obtain their records: records are often destroyed, classified, the result of flawed or biased studies, or incomplete.

10.0 COMMITTEE DISCUSSION: HISTORICAL ETHICS POLICIES (CONTINUED)

The Committee continued the discussion of the previous day by examining the policies of the AEC and DOE. Staff members Jonathan Moreno and Valerie Hurt provided a briefing on the AEC's ethics policies. Mr. Guttman noted that the AEC's concerns covered a wide range: legal liability, public opinion, risk standards, healthy volunteer use, patient use, and national security. Briefing Book Tab H was referenced by the Committee.

10.1 The AEC had no counterpart to the Wilson Memo, which provided a definite demarcation in the policy structure of DoD.

10.2 In 1947, shortly before the end of the plutonium injection experiments, the AEC was concerned about possible legal problems and adverse public reaction.

10.3 In their correspondence, General Manager Carroll Wilson of the AEC and Dr. Stafford Warren of the University of California Los Angeles Medical School reached the following conclusions about clinical testing: (1) treatment which may involve clinical research must have therapeutic involvement; (2) doctors will make the decision to go beyond therapeusis to

experimental procedures; and (3) written consent was not required, but two other doctors must certify as to the patient's understanding and state of mind.

10.4 In situations where radioisotopes were used, a local committee of three physicians was to take full responsibility for the conduct of the experiment, subject consent was to be obtained, and there was to be no damage manifested by the isotopes.

10.5 The Committee debated whether the AEC had placed physicians in a conflict of interest situation, but Mr. Moreno stated that the physicians seemed to have been concerned that the Government would rein in their research, not coerce them into it.

10.6 The Committee also questioned how the policies were tied in with particular cases. One point of focus was a document in which the doctor requested approval to use Iodine-131 on diseased patients. Some Committee members were of the opinion that the radioisotope use was not for therapeutic reasons. However, Committee radiation oncologist Dr. Mary Ann Stevenson stated that large doses of Iodine-131 would be appropriate for thyroid diseases, although the planned doses and the reason for the treatment were not apparent from the document.

10.7 Mr. Moreno noted that the language in the historical documents was not always consistent. "Clinical testing" and "clinical research" were often used interchangeably.

10.8 Dr. Faden queried whether the subjects were strictly a patient population. Dr. Royal replied that diagnostic testing requires knowing what the normal values are, so healthy volunteers should have been used at some point.

10.9 The AEC's clinical research standards were analyzed. The Committee had two main concerns: (1) whether the AEC, which was then a new organization, officially adopted standards for consent and appropriate use, and if so, (2) whether the AEC followed its own guidelines.

10.9.1 One point of debate was the fact that some of the documents were letters rather than memos. Dr. Faden asserted that a memo is intended for distribution, but a letter would not be. Dr. Macklin agreed that a letter should not be considered a policy intended for dissemination.

10.9.2 Dr. Russell felt that DoD had a clearer need for much stronger policies than DOE because DoD had to coordinate the services, which generally preferred to remain independent.

10.9.3 Mr. Moreno added that he did not recall any references to the Nuremberg Code in AEC documents.

10.9.4 The ambiguity of language in the documents makes interpretation problematic. Dr. Royal questioned how, given the general language of the proposed standards, it would be possible to determine if the AEC met its own standards. Dr. Faden pointed out that even the basics of the standards would have to be met. Dr. King observed that although some of the documents were

written in medical and legal language, they nevertheless expressed value concerns. It was agreed that for bureaucratic purposes, such language would forward value concerns more expeditiously than moral language.

10.9.5 Dr. Macklin stated that the meaning of "informed consent" has changed over time, and that in some respects, the then-proposed AEC standards are higher than today's standards. For example, today's standards do not require a certification of the patient's understanding.

10.9.6 Committee historian Dr. Susan Lederer questioned whether the standards were sufficient for AEC's responsibility toward human subjects. She also wanted further elaboration on the AEC's fears concerning public relations.

10.9.7 Dr. Faden stated that it is important to distinguish whether the standards reflected the AEC or just the academic and medical communities.

10.10 Dr. Faden requested that the Staff do the following before the January meeting:

- Examine AEC documents to reconstruct (1) what AEC's position was on standards (particularly concerning consent) and the experiments to which they applied; (2) how, based on standards, acceptable risk and dose levels were determined; and (3) how subjects were selected.

- Find examples of dual-purpose experiments and see if there are any connections between AEC and DoD standards.

- Write their findings in language that could be used in the Final Report.

11.0 COMMITTEE DISCUSSION ON THE DEPARTMENT OF VETERANS AFFAIRS (VA): INTEGRATION OF RETROSPECTIVE MORAL JUDGMENT AND HISTORICAL ETHICS POLICIES (CONTINUED)

The Committee discussion continued in the context of the Department of Veterans Affairs (VA) standards. Committee Staff research analysts Jonathan Moreno and Denise Holmes briefed the Committee on VA documents.

11.1 Ms. Holmes said that the earliest document available was a 1950s General Counsel opinion apparently drafted in response to questions on two specific projects. The only policy document that has been located is a 1967 circular that superseded a 1964 policy. It is thought that standards were previously handled by local communities or offices.

11.2 The number of studies has been placed at 3500, but some of the studies may have been listed more than once and others may not have involved radiation or human subjects. Most of the experiments probably took place before the 1964 policy went into effect.

11.3 The Investigative Inspector General is involved in the search. However, the reconstruction of VA standards will probably result in only a sketchy overview. Dr. Faden stated that if no VA standards could be identified, then the Committee could consider the VA experiments in terms of the standards the VA should have had; an Agency with no articulated standards is not necessarily less culpable. Mr. Guttman noted that community standards could have played a role in VA experiments and that Dr. Sweet's experiments, which were described in Ms. Fenn's testimony, may have involved the VA and DOE. Dr. Macklin pointed out that the VA might actually be more culpable if they were exposed to interagency ideas and yet did not create their own standards.

11.4 Ms. Holmes felt that more information would be forthcoming by January, so further debate on the issue was postponed until then.

12.0 COMMITTEE DISCUSSION: INTEGRATION OF RETROSPECTIVE MORAL JUDGMENT, REMEDIES, AND HISTORICAL ETHICS POLICIES (CONTINUED)

The Committee continued with a discussion focused around Remedies Guideline 3, which states that remedies must be based on an analysis of Government culpability and the harm to the individual.

12.1 Dr. Thomas questioned how the Committee would decide when there was adequate evidence to determine culpability, especially as evidence of both standards and violation of standards was necessary. He also felt that it would be necessary to apply the guidelines to each experiment as the language of the guidelines was so abstract.

12.2 Dr. Katz pointed out that while DoD could be held culpable if it did not implement its own standards, the standards of the Nuremberg Code are more stringent than today's standards. Dr. Macklin directed the Committee to consider what areas of today's standards need improvement. If the Committee holds the Government culpable for past practices, then the Committee also needs to ensure that mechanisms are in place to prevent future wrongs or harms. She also supported holding DoD culpable in specific cases where violations of standards were found.

12.3 Dr. Faden suggested that the Committee may ultimately determine Government culpability in some structure or category other than by Agency, although the policies of other agencies will be discussed in January. The culpability debate will also continue.

13.0 FINAL REPORT AND APPENDICES

The Committee discussion of the Final Report and Appendices included concerns regarding technical presentation (i.e., organization, layout, and tone), content and theme, and the possibility of an extension. Mr. Guttman presented the Committee with a preliminary draft which was mainly the thematic conception.

13.1 Dr. Glatstein expressed his concern that the Final Report reflect the big picture and take into account the positive side of human experimentation.

13.2 Dr. Thomas maintained that a Final Report discussion of ethical standards needs to include the ethical criteria that were applied by the Committee.

13.3 Mr. Guttman explained that in terms of the theme, there were four ways to improve the world: balance (such as between national security and openness), ethical codes, institutional checks and balances, and imparting the story so that the public understands it. The latter is especially important in the context of the public's fear of radiation and the notion that health experts cannot make decisions on matters affecting victims.

13.4 Dr. Faden described the Final Report first draft as being produced by Staff and flowing from detailed studies extracted from Staff and Subcommittee reports. She estimated that the report would be approximately 300 pages and have four companion volumes (the Appendices).

13.5 One dilemma stemmed from the Committee's desire to present the information in an engaging manner. Dr. Macklin recommended that the introduction draw the reader in with a case study or witness example, and that the report should state what has been found and what can be learned in terms of ethics policies and standards. Dr. Faden also informed the Committee that they would have to resolve the tension between the desire to write a volume that people would want to read and communicating the work of the Committee. Dr. Russell felt that the emphasis should be on writing as honest and procedurally accurate account as possible, and that the Committee's evolution of thought should also be presented.

13.6 Public accessibility was another concern, as the intended audiences are the President, Congress, the Interagency Working Group (IWG), and the public. The Appendices, however, could focus on more technical detail, evidence, and discussion. Also, the avenues of publication (such as a private press or Government press) will need to be explored and discussed.

13.7 The possibility of an extension was a matter of debate. Although the Committee agreed that additional time would be beneficial for turning out a quality product, some members felt that the Committee should proceed on the assumption an extension would not be granted, especially given the current political situation. Although Dr. Faden agreed the Committee should apply for an extension, she emphasized the need for the Committee to begin reviewing sections of the Final Report and otherwise proceed with the intent of completing the work on time.

14.0 BRIEFING ON THE PENTAGON MEETING

Dr. Duncan Thomas and Committee radiation biologist Dr. Nancy Oleinick provided a summary of their meeting with Dr. Gordon Soper, Principal Deputy to ATSD (AE), at the Pentagon. The purpose of the meeting was for these Committee members to review the classified portions of the Green Run document.

14.1 Dr. Thomas described the classified portions as (1) being a total of approximately one-and-a-half pages, (2) containing no major bombshells, (3) containing names of the individuals and the military unit involved, and (4) containing no technical information of relevance to Committee concerns. He added that while the classified portions did not answer the questions of who ordered the test and why, those questions have been addressed by information from other sources.

14.2 The Committee planned to dedicate a portion of the January meeting to discussing intentional releases, particularly in terms of whether such releases could happen today despite institutional oversight mechanisms.

14.3 On the latter issue, Dr. Oleinick stated that Dr. Soper was of the opinion that such releases could not happen today, but he nevertheless planned to review relevant documentation and regulations to answer this question. Dr. Oleinick mentioned that Dr. Soper asked another gentleman, whom she presumed to be from the ATSD office, if there was other documentation involved. He replied that he did not know of any such documents.

14.4 The Committee instructed the Staff to follow up on this matter and to investigate whether the Government could change current policies in order to conduct an intentional release.

15.0 CLOSING DISCUSSION

The discussion of intentional releases produced other concerns about the Final Report and the Committee's January meeting.

15.1 Dr. Stevenson was concerned about the conceptual overview, stating that certain technical details (e.g., the mechanisms of certain drug actions) must be included so that the public is not left with a perception of omniscient scientists doling out large doses of radiation. The debate of low-dose radiation is still ongoing today and must be acknowledged.

15.2 Dr. Lederer and Mr. Guttman felt that the final report should address the risk-benefit equation, which includes the process of how scientific knowledge is generated.

15.3 Dr. Faden announced that the Committee would do the following at the January meeting: (1) continue discussion of retrospective moral judgment, remedies, and historical ethics policies; (2) include only presentations relevant to this discussion; (3) include a brief status update on various projects; and (4) keep the extended hours.

15.4 The Executive Director of Staff, Mr. Dan Guttman, adjourned the meeting.

Shelley Mennella
RECC Research Staff

ATTACHMENT 1

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

15-16 DECEMBER 1994 MEETING AGENDA

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

DECEMBER 15-16

Omni Shoreham Hotel ✣ Empire Room ✣ 2500 Calvert Street NW ✣ Washington, DC

FINAL AGENDA

Thursday, December 15, 1994

9:00 AM	Call to Order
9:05	Opening Remarks *Ruth Faden, Chair*
9:10	Approval of Minutes of November 14-15 Meeting *Ruth Faden*
9:15	Committee Discussion: Retrospective Moral Judgment - Criteria for Evaluating the Ethics of Experiments [TAB F]
10:30	Break
10:45	Committee Discussion: Remedies [TAB G]
12:15 PM	Lunch
1:30	Committee Discussion: Integration of Retrospective Moral Judgment and Remedies [TAB H]
2:30	Committee Discussion: Historical Ethics Policies [SUPPLEMENT]
3:00	Break
3:15	Committee Discussion: Historical Ethics Policies (continued)
	Committee Discussion: Integration of Retrospective Moral Judgment, Remedies, and Historical Ethics Policies [TAB H]
5:00	Meeting Adjourned

Friday, December 16, 1994

8:00 AM	Opening Remarks *Ruth Faden*
8:05	Public Comment Period
10:00	Break
10:15	Committee Discussion: Integration of Retrospective Moral Judgment, Remedies, and Historical Ethics Policies (continued) [TAB H]
11:45	Lunch
1:15 PM	Committee Discussion: Integration of Retrospective Moral Judgment, Remedies, and Historical Ethics Policies (continued) [TAB H]
	Committee Strategy and Direction
2:45	Break
3:00	Report on Spokane Small Panel Meeting [TAB E] *Reed Tuckson*
	Final Report & Appendices *Ruth Faden*
5:00	Meeting Adjourned

ATTACHMENT 2

WASHINGTON POST AND *NEW YORK TIMES* ARTICLES ON HUMAN RADIATION EXPERIMENTS

New Reasons Revealed for Radiation Test Secrecy

Concern About Lawsuits, Public Reaction Fueled Government Policy After World War II

By Gary Lee
Washington Post Staff Writer

In the aftermath of World War II, when federal researchers began conducting human radiation experiments on a large scale, government officials deliberately withheld information about the tests from individuals participating in them and from the general public in order to avoid lawsuits and negative public reaction, newly uncovered government documents have revealed.

During the Cold War, officials of the Atomic Energy Commission (AEC)—the forerunner of the Energy Department—and of the Defense Department, the Agency for Veterans Affairs and other federal agencies overseeing radiation research on humans took the position that details of such experiments must be kept secret on the grounds of maintaining national security.

Behind the scenes, however, particularly during the late 1940s and early 1950s, officials argued vigorously that files on human radiation experiments and on occupational radiation exposure in government workers must be classified to prevent litigation, bad publicity and adverse labor relations, according to the documents.

"It is desired that no document be released which refers to experiments with humans and might have an adverse effect on public opinion or result in legal suits," O.G. Haywood, a colonel in the Atomic Energy Commission's Corps of Engineers, wrote in a 1947 letter included in the documents. "Documents covering such work field should be classified 'secret.' "

The documents were provided to The Washington Post and other publications by the Committee on Human Radiation Experiments, a 14-member panel appointed by the White House to investigate the radiation experiments. The committee is holding a public meeting here to review the documents today and tomorrow.

"Clearly, in the immediate post-war period, there was a conscious attempt to keep information from affected individuals and from the public for reasons that don't seem as if they were very important," said Ruth Faden, a prominent ethicist from Johns Hopkins University and chairman of the panel. "On the face of it, that is very disturbing."

The government's position led to the classification of files on a wide range of experiments conducted during the late 1940s and early 1950s, including a project involving the injection of plutonium into sick persons to measure how much of the radioactive substance was excreted from the body. The plutonium experiments were the subject of a 1993 series in the Albuquerque Tribune that received a Pulitzer Prize.

Editors of scientific journals and other publications also maintained secrecy about the experiments, panel members said. The official history of the Manhattan Project also was vetted before publication for references to human experimentation, the documents revealed.

The policy of maintaining secrecy apparently extended beyond the participants in radiation research to include keeping information on exposure from workers in plants where atomic weapons were produced and from personnel in military facilities where weapons were tested.

In one case in the mid-1940s, an employee under medical observation at a chemical facility developed nephritis, an acute kidney disease, after prolonged exposure to radioisotopes at the workplace.

"Claims and litigation will necessarily flow from the circumstances outlined," warned one file describing the case. Officials apparently withheld information from the employee about her illness.

Panel members, originally prepared to believe that secrecy surrounding the experiments was largely a result of national security considerations, were stunned by the findings, Faden said. Exploring the extent to which a policy of secrecy prevailed concerning the experiments will become a major focus of the panel, she added.

An exchange of letters about the plutonium injection experiments clearly illustrates the thinking about the radiation studies among researchers and senior federal officials during the late 1940s. Reports about some of the experiments, originally classified, were declassified in January 1947, apparently at the suggestion of researchers involved.

The next month, however, C.L. Marshall, an AEC deputy declassification officer, wrote, "This document appears to be the most dangerous since it describes experiments performed on human subjects, including the actual injection of the metal, plutonium, into the body. . . .

"Unless, of course, the legal aspects were covered by the necessary documents, the experimenters and the employing agencies, including the U.S., have been laid open to a devastating lawsuit which would . . . have far reaching results."

In March, the report was reclassified "secret."

Researchers who conducted experiments occasionally fought for declassification of reports, the documents show. But such arguments apparently were routinely outweighed by warnings from public relations and insurance officials, who vetted the documents and argued for classification.

The documents show that on occasion, a final decision was referred to Shields Warren, then director of the AEC's division of biology and medicine, who seemed to favor classification of reports about the experiments.

Some of the reports were declassified in the late 1950s and 1960s, suggesting that attitudes within the federal government about the secrecy of the tests evolved over time.

While intense behind-the-scenes debates about classifying reports about the experiments took place, federal officials argued publicly for openness. In May 1947, AEC chairman David Lilienthal convened a group of senior researchers to develop recommendations on the new agency's policies on medical research.

"Secrecy in research is distasteful," the group declared in a June 1947 report, "and in the long run is contrary to the best interests of scientific progress."

15 December 1994

Inquiry Links Test Secrecy To a Cover-up

A Fear of Publicity Is Seen as a Motive

By PHILIP J. HILTS
Special to The New York Times

WASHINGTON, Dec. 14 — Military and nuclear energy officials were motivated by fear of lawsuits and unfavorable publicity in their decision to keep secret many experiments using radiation on humans, Federal investigators have found.

The President's Advisory Committee on Human Radiation Experiments, the panel charged with unearthing the history of all government-sponsored experiments in which radiation was used on humans, has found new documents showing that as early as 1947 public relations and legal considerations, not security concerns, were principal motives in the decision of Federal officials to cover up radiation experiments.

In the past six months, the panel has searched out and logged hundreds of thousands of papers on experiments with humans, beginning in 1945 at the dawn of the atomic age.

Until the panel began its work, the experiments were thought to have been scattered incidents, but the documents show that they were part of a plan that was debated and approved at high levels. It was also previously thought that there were only a handful of such experiments, but the panel has found hundreds, from the deliberate release of radiation into the air to the injection of people with radioactive plutonium.

The most recent documents unearthed at the Oak Ridge National Laboratory in Tennessee show that officials of the military and the Atomic Energy Commission at first sought to declassify reports of experiments on humans, in accordance with public statements that scientific reports should not be secret.

For example, Dr. Alan Gregg, the chairman of one of the committees that oversaw the human experiments, wrote in May 1947: "A policy of secrecy in science is neither personally courageous nor politically wise. As Lord Acton said, 'Power corrupts, and absolute power corrupts absolutely.' "

But at the same time, C. L. Marshall, a declassification officer with the Atomic Energy Commission, wrote in February 1947 that a scientific paper outlining experiments in which two people were injected with plutonium should not be declassified.

"This document appears to be most dangerous since it describes experiments performed on human subjects, including the actual injection of the metal, plutonium, into the

He noted that there was no statement in the paper about whether the patients experimented on had given their consent, and concluded: "The experimenters and the employing agencies, including the U.S., have been laid open to a devastating lawsuit, which would, through its attendant publicity, have far-reaching results."

It has long been suspected that legal and public relations concerns helped drive the ethical debate over the experiments on humans, and the advisory committee in recent weeks has found many memorandums substantiating that.

On Oct. 3, 1947, J. C. Franklin, the manager of operations of Oak Ridge, wrote to Carroll L. Wilson, general manager of the atomic agency, "There are a large number of papers which do not violate security but do cause considerable concern to the Atomic Energy Commission insurance branch, and may well compromise the public prestige and best interests of the commission."

He added: "Papers referring to levels of soil and water contamination surrounding Atomic Energy Commission installations, idle speculation on the future genetic effects of radiation and papers dealing with potential process hazards to employees are definitely prejudicial to the best interests of the Government. Every such release is reflected in an increase in insurance claims, increased difficulty in labor relations and adverse public sentiment."

He ordered that any such documents be edited or kept secret.

The advisory committee investigators said that documents so far found that an official as highly placed as Dr. Shields Warren, head of the medical division in Washington, had classified human experiments because of public relations or legal implications.

The investigators said the classification on that basis may have been illegal, but have not yet determined which laws would have governed the classifications carried out in the 1940's.

The advisory committee staff also found documents in which military officials at the Oak Ridge laboratory discussed what to do about workers at the Tennessee-Eastman factory who were experiencing kidney disease and tuberculosis at a higher-than-usual rate.

A memorandum from an engineering officer on July 25, 1945, noted that a kidney disease victim "is unaware of her condition, which now shows up on routine physical check and urinalysis."

New York Times

15 December 1994
A-26

New York Times

ATTACHMENT 3

PUBLIC COMMENT SCHEDULE

15-16 DECEMBER 1994 MEETING

Advisory Committee on Human Radiation Experiments

Public Comment Section

December 16, 1994 8:05 a.m. to 10:00 a.m.

1. Mrs. Doris J. Baker, Cincinnati, Ohio
2. Ms. Vina Colley, Portsmouth/Piketon Residents for Environmental Safety; McDermott, Ohio
3. Ms. Diana Salisbury, Sardinia, Ohio
4. Ms. Lenore Fenn, Lexington, MA
5. Mr. Peter Lewis, Uniontown, Pennsylvania
6. Professor Robert Proctor, Pennsylvania State University
7. Mr. William T. Jackling, Honeye Falls, New York
8. Mr. Fred Boyce, Norwell, Massachusetts
9. Mrs. Pat Broudy, National Legislative Director, National Association of Atomic Veterans accompanied by Dr. Oscar Rosen, National Commander, National Association of Atomic Veterans

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
Rm 3E1074 (703) 697-5561
3050 Defense Pentagon

January 10, 1995

MEMO FOR: Mr. Phil Caplan

SUBJECT: Executive Summary of the 15-16 Dec Advisory Committee Meeting

Phil:

Attached you'll find Executive Summary as above. The DoD Radiation Experiments Command Center personnel prepared this summary for me. If you have any questions, please let me know. I'll continue to send you these reports as they are generated.

Best.

Gordon

Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, DC 20036
202/254-9802
Fax: 202/254-9827

FAX TRANSMISSION COVER SHEET

Date: *January 17, 1995*

To: *Phil Caplan*

Fax: *202/456-6704*

Re: *Tentative Agenda for January Meeting*

Sender: *Anna Mastroianni*

YOU SHOULD RECEIVE 3 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.

TAB A-1

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

JANUARY 19-20, 1995

Omni Shoreham Hotel ✣ Empire Room ✣ 2500 Calvert Street NW ✣ Washington, DC

TENTATIVE AGENDA (Revised 1/10/95)

Thursday, January 19, 1995

9:00 AM	Call to Order
9:05	Opening Remarks *Ruth Faden, Chair*
9:10	Approval of Minutes of December 15-16 Meeting *Ruth Faden*
9:15	Update on Subject Interview Study *Jeremy Sugarman and Nancy Kass*
9:30	Update on Research Proposal Review Project *Sara Chandros and Gail Geller*
9:45	Committee Discussion: Government Standards and Government Culpability (TAB F)
10:45	Break
11:00	Committee Discussion: Government Standards and Government Culpability (TAB F) (continued)
12:15 PM	Lunch
1:30	Research Practices: Report on Ethics Oral History Project (TAB G) *Susan Lederer*
	Committee Discussion

3:00	Break
3:15	Committee Discussion: Individual and Professional Culpability (TAB E)
5:00	Meeting Adjourned

Friday, January 20, 1995

8:00 AM	Opening Remarks *Ruth Faden*
8:05	Public Comment Period
10:00	Break
10:15	Contemporary Agency Oversight (TAB H) *Wilhelmine Miller*
	Committee Discussion
11:45	Lunch
1:15 PM	Committee Discussion: Total Body Irradiation
2:15	Committee Discussion: Final Report Planning
3:15	Break
3:30	Committee Discussion: Final Report Planning (continued)
4:30	Meeting Adjourned

OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

FAX #:
COML:

Date: 2/23/95

TO: Phil Caplan
W.H.

FAX NO: 202-456-6704

VERIFY NO. 202-456-2572

FROM: Lisa Chrisos

PHONE NO. 202-586-5289

PAGES 3
(Including Cover Sheet)

REMARKS: Advisory Committee on Human Radiation Experiments February stg.

CC Bob Nordhaus
Phil Caplan - w
Pat Glynn - DoJ

To: Tara O'Toole
Assistant Secretary for Environment, Safety and Health

Lisa Schiavo, Esq.
Office of General Counsel

From: Ellyn R. Weiss

Date: February 22, 1995

Re: Advisory Committee on Human Radiation Experiments
February Meeting

Remedies

As of their meeting last week, the Committee is divided on how to deal with the remedies issue. Ruth Faden drafted the chapter on remedies that was the basis of the discussion, but she was relatively quiet during the discussion. The chapter was not distributed.

Ken Feinberg wants to point to the grid that the Committee has fitfully discussed, which has as one axis the degree of government "culpability" and as the other axis the degree of harm to persons, as a way of conceptualizing the remedies issue, feels that they can fit certain experiments into spots on the grid, but feels that the committee does not know enough to recommend specific remedies for specific classes of experiments and questions whether that is part of its mandate. Feinberg advocated identifying a menu of remedies which might or might not be associated with particular points on the grid.

Duncan Thomas is also unclear as to whether recommendation of remedies is within their charter and questions whether they have sufficient facts to place specific experiments on the culpabilty/harm grid. Thomas suggests that specific remedies could be recommended for hypothetical grid-points -- e.g. death with government culpability warrants compensation.

Phil Russell ,suggests that an effort to classify experiments on the grid would so bog the committee down as to threaten its ability to bring in its report. Henry Royal seems to be essentially in the same place.

The strongest position in favor of recommending specific redress was Ruth Macklin, who voiced the view that that there will be less chance of justice if these decisions are left to policymakers, that ethics should be the basis of judgments.

Jay Katz seemed persuaded that the committee would not be able to fit experiments into the boxes and argued against being too prescriptive and specific. He also expressed discomfort with the basic grid methodology and wanted to see alternatives. Pat King suggested that the only way to see if the impasse can be broached is to try and work the

facts of some particular case. She manifested a certain degree of impatience with the committee's lack of progress and the degree to which they are still dealing in abstractions and generalities.

No resolution was reached and it appears that this issue is up for grabs. Note, however, that there seems to be general agreement that the Committee will find that the current compensation scheme for atomic veterans and uranium miners is flawed and will recommend unspecified changes.

Scope Issues

The committee staff have drafted a chapter on "Experiments of Opportunity", including the Marshallese and the uranium miners and a chapter on "Human Experiments in Connection with the Atomic Bomb Tests". These have not been given to the agencies, but were discussed in general terms at the meeting. Since we have not seen these, only general observations from the discussion can be made: the committee staff intend to replow this ground in some detail - enough to conclude that current compensation schemes are in some sense inadequate.

The committee itself has yet to grapple with the difficult questions in these areas, either factual or political, and considering how long it is taking them to come to some consensus on the biomedical experiments (indeed, their lack of consensus at the moment), the risk of their getting this part of the story wrong is quite serious. E.g. Ruth Macklin takes the position that there is no difference between occupational monitoring and experimentation in the context of the pilots who flew atomic cloud testing missions, implying that if you wore a film badge you were part of an "experiment." Duncan Thomas does understand these issues and questioned whether the bomb tests are within the scope, opining that the chapter should focus on the meaning of consent in the context of the military.

Current Studies Research

As of the time of the meeting, about half of the 19 IRB approvals had been received for the committee's interviews with current patients. I believe that data gathering has now begun. I am told that the NIH IRB was quite unhappy but will very likely approve some version of the proposal so as to prevent being painted as uncooperative.

The committee is also reviewing about 170 current research protocols and needs to finish 30 a week to get done on time. I think it prudent to plan under the assumption that they will find problems both with some number of protocols and with the degree to which current informed consent practices actually "inform" patients.

3/25

Radiation

- brachy -- current subjects - what about those not performing well
- remedies brachy -- when to do?
- Hill outreach - which GOP to speak with
- ~~George - scheduling request - Melanne memo - George~~

Rural Conference

- ~~Tuesday meeting -- Hoyt, Goldstein + others~~
- ~~dates for VP + FLOTUS~~
- ~~tentative agenda - participants~~
- ~~arrange site visit - Harken~~
- ~~Kitty - contacting w/ Hoyt~~ - Cynthia Metzler (Tom Delaney)
- ~~check out 2 Ag appointees~~ Asst Sec for Admin + Mgmt 219-9086

~~Social Memo for Tues breakfast~~
- ~~Olympic Memo → Mack~~
- ~~John Kristmer - soccer~~
- ~~Harold talking points - NEA~~

- policy list of things that don't work
- ~~Nat'l vol week - call Allison Osborne~~

~~Tentative agenda - Atlanta~~

- Tom O'Donnell
- Bill Rogers (Non-Ded)

MK
- Miles
- Leg → Delor. Minky

MSF
Jay Kriegel
Valenti
Rahm - Minky

TO DO
12/23

RADIATION:
-Schedule compensation meeting with T.J, Bruce, Ruth, Steve, Joel, Nordhause, Emily Pelton ....then briefing by Feinberg?
-compensation letter to committee...read Nordhaus draft
-read Feinberg tab insert
-"life of the Committee" meeting...timing and release of report...1st part of May
-Note to Steve Neuwirth...what to do for me as DFO
-Draft response letter to Cooper Brown...circulate to Tara, MRC, Neuwirth, Nordhaus/Schiavo, Bruce
-follow-up with Dan re: CIA
-check with Bruce re: FACA lawsuit..are we doing the right thing by not meeting and turning over docs

Has this gone away? Is letter not necessary?

OTHER:
-correspondence
~~-National Park Week~~
-memo to George on Human Radiation
~~-Dan Goldin - blue pass (standard is 3 times/week).~~
-Brian Burke - Steve Curran (length, start date, hours/week, fulltime?)
~~-Peter Yu - WH Conf on Small Business.~~
-OTC Memo to Harold - CNN Headline News Transcript on OTC 12:40 pm 12/30

COMPUTERS:
-schedule OMB demo
-MOU - where is it?...when does transfer to GSA occur?
-update meeting with Jerry, Debbie, Chris (status of records)

MISC.
-Peter Scher
-Tony Coelho
-Harold

Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, DC 20036
202/254-9817
Fax: 202/254-9827

FAX TRANSMISSION COVER SHEET

Date: *May 4, 1995*

To: *Philip Caplan*

Fax: *202/456-6704*

Re: *Tentative Agenda for May 8-10 Meeting*

Sender: *Anna Mastroianni*

YOU SHOULD RECEIVE 3 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

MAY 8-10, 1995

The Doubletree Hotel ✣ Ballroom ✣ 1515 Rhode Island Avenue, NW ✣ Washington, DC

TENTATIVE AGENDA

Monday, May 8, 1995

9:00 AM	Call to Order
	Opening Remarks *Ruth Faden, Chair*
	Approval of Minutes of April 10-12, 1995 Meeting
9:10	Public Comment
10:15	Break
10:30	Discussion of Overall Report Organization and Structure
11:45	Lunch & Reading Time
1:30	Discussion: Part I of Draft Final Report
	(1:30) Chapter 2: Government Standards for Human Exper.--the 1940s and the 1950s
	(2:10) Chapter 5: Conclusions--Ethics Standards in Retrospect
	(2:50) Remaining Chapters of Part I
3:30	Break
3:40	Discussion of Part II of Draft Final Report
	(3:40) Chapter 1: Biodistribution
	(4:20) Chapter 2: Radioisotopes
5:00	Meeting Adjourned

Tuesday, May 9, 1995

9:00 AM	Discussion of Part II of Draft Final Report (continued)
	(9:00) Chapter 3: Children and Pregnant Women
	(9:45) Chapter 8: Observational Studies
10:30	Break
10:45	Discussion of Part II of Draft Final Report (continued)
	(10:45) Chapter 9: Secrecy, Openness and Human Radiation Experiments
	(11:30) General Discussion of Remaining Part II Chapters
12:15 PM	Lunch & Reading Time
1:45	Discussion of Part III of Draft Final Report
	(1:45) Chapter 2: Research Proposal Review Project
	(2:45) Chapter 3: Subject Interview Study
	(3:45) Chapter 1: Agency Oversight
	(4:00) General Discussion of Part III
4:20	Stretch Break
4:30	Discussion: Committee Strategy & Direction
5:00	Meeting Adjourned

Wednesday, May 10, 1995

8:30 AM	Discussion of Part IV of Draft Final Report: Findings
10:00	Break & Reading Time
10:30	Discussion of Part IV of Draft Final Report: Recommendations: Looking Backward
12:00 PM	Lunch
1:15	Discussion of Part IV of Draft Final Report (continued)
	(1:15) Recommendations: Looking Backward [Notification & Epidemiological Studies]
	(2:15) Recommendations: Looking Forward
3:20	Stretch Break
3:30	Discussion: Committee Strategy and Direction
4:00	Meeting Adjourned

May 1, 1995

MEMO TO: **PHIL CAPLAN**
WHITE HOUSE CABINET AFFAIRS

FROM: **LORI AZIM, 586-5319**
DEPARTMENT OF ENERGY

SUBJECT: **ADVISORY COMMITTEE TIMETABLE**

I have attached a letter from Steven Galson submitting DOE's comments on their draft timetable and draft letter transmitting the timetable to the Interagency Working Group.

Steven would like your blessing on our letter. Please call me and let me know what you think. We would like to send this letter as soon as possible.

If you have questions, please give me a call. Thanks!

Attachment

cc: **S. Galson**

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ► 2

To Phil Caplan	From Lori Azim, DOE
Dept./Agency WH Cabinet Affairs	Phone # 586-5319
Fax # 456-6704	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

OK
5/2/95

May 1, 1995

Ruth Faden
Chair
Advisory Committee on
Human Radiation Experiments
1726 M Street, NW #600
Washington, DC 20036

Dear Ruth:

Thank you for an advance review of both the Advisory Committee's timetable for completion and letter transmitting the timetable to the Interagency Working Group.

The timetable indicates that the Advisory Committee still intends to compile "companion volumes" in addition to the final report, yet the agencies will not see even a draft of these volumes until August 7, 1995 and as yet have no clear idea of the topics these volumes will cover. We believe that the Advisory Committee should specify the topics covered by these"companion volumes" as soon as possible. Additionally, we would like to suggest that the agencies receive early drafts for review well before August 7.

The Department also needs to know the Advisory Committee's specific plans for staffing through the end of the period. Please inform beyond "reduced staff."

Thank you again.

Sincerely,

Steven Galson, M.D., M.P.H.
Chief Medical Officer

cc: T. O'Toole
E. Weiss
D. Guttman

Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, DC 20036
202/254-9795
Fax: 202/254-9827

FAX TRANSMISSION COVER SHEET

Date: *April 28, 1995*

To: *Phil Caplan*
Steven Galson

Fax: *456-6704*
586-0956

Re: *Draft Workplan*

Sender: *Anna Mastroianni*

YOU SHOULD RECEIVE 2 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.

As per April 27 fax, I have attached the draft workplan referenced in the draft letter to the Interagency Working Group. Again, please call Dan or me with comments. Or, if you wish to speak with Ruth directly, please call Melissa at the Advisory Committee offices to arrange a time. Thank you.

cc: Ruth Faden
DanGuttman
Jeffrey Kahn
Stephen Klaidman

April 28, 1995

Tentative Work Plan for Final Report Release between September 8-15

AC=Advisory Committee Members
IAWG=Human Radiation Interagency Working Group designees

Week 1 [May 1]	Mailing of Part III and IV of final report to AC and IAWG; Drafting and finalizing of companion volumes continues through August 31
Week 2 [May 8]	**Meeting**
Week 3 [May 15]	Revise drafts based on AC comments; Mailing of revised Part I draft chapters to AC and IAWG (staggered mailings)
Week 4 [May 22]	Revise drafts based on AC comments; Mailing of revised Part II draft chapters to AC and IAWG
Week 5 [May 29]	Revise drafts based on AC comments; Mailing of revised Part III draft chapters to AC and IAWG
Week 6 [June 5]	Mailing of revised Part IV draft chapters to AC and IAWG
Week 7 [June 12]	Mailing of draft executive summary to AC and IAWG
Week 8 [June 19]	**[Meeting--2 or 3 day, June 21-23, depending on AC decision at May 8-10 meeting]**
Week 9 [June 26]	Revise draft chapters and executive summary based on AC comments at meeting; Mailing revised Part I draft chapters to AC
Week 10 [July 3]	Mailing of revised Part II and III draft chapters to AC
Week 11 [July 10]	Mailing of revised Part IV draft chapters and revised executive summary to AC; Mailing of draft Final Report to IAWG; Copy edit begins
Week 12 [July 17]	**[Meeting--2 or 3 day, July 17-19, depending on AC decision at May 8-10 meeting]**: AC sign off on Executive Summary and Final Report as much as possible
Week 13 [July 24]	IAWG final comments due (per request for 7 working days from delivery); Revision of draft and delivery to AC for final sign off
Week 14 [July 31]	Final sign off of Executive Summary and Final Report by AC
Week 15 [Aug 7]	Delivery of Companion Volumes to IAWG and AC; Editing of Companion Volumes
Week 17 [Aug 14]	Final Production & Delivery of Executive Summary and Final Report to GPO/Publisher; Editing of Companion Volumes
Week 18 [Aug 21]	Editing of Companion Volumes
Week 19 [Aug 28]	Delivery of Companion Volumes to GPO
Week 20 [Sept 4]	Preparation for Public Release of Final Report and Executive Summary

Executive Summary and Final Report Public Release between September 8 and 15

-Thank you

-Intros

-Christine Varney is now the former Cabinet Secretary...and I am now the primary contact here in the White House for this Committee...whether that is good or bad, I am now left holding the baby...AND IT IS A VERY VERY GOOD BEAUTIFUL BABY

-this committee and the people around this table, so a little more than others, have lived this issue for many months

-there is so much good that has come out of this for this Adminsitration and for the country...evidence the front page of the NYT a week ago...this is about openess in govt, accountability

-we have had, it appears, a misunderstanding, over a part of this effort...and that is over the issue of remedies, responses, righting wrongs, etc.

-I understand from lengthy conversations with Ruth and her staff that they have gone down a path publicly, with public statements, presentations and briefing papers for the Committee Members that talks about "remedies"...the word has some specific legal connotations which is why we have so many lawyers today sitting around this table

-we must get this report out the door tomorrow at 1:00 PM and to the printers several ours beforehand...that is the context

-if you turn to page iii of this report, you will read....

-I think what many people around this table would like to hear, and what I would like to hear, is an accurate preview, as best you can, what that means.

-we want to make sure it gives the right impression to the press, the public and, frankly, to subjects of experiments...we do not want to raise expectations nor do we want to blow the federal budget

-Ruth...can you give the meaning

POLICYMAKERS

10/20/94

URGENT

DATE: 7-21

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C. 20585

95 JUL 21 AM 9:09

OFFICE: (202) 586-6151 FAX: (202) 586-0956

TO: Phil Caplan

FROM: Ellyn Weiss

NO. OF PAGES TO FOLLOW: 456-2715 1 PAGES

___For your information

___Please call upon receipt

___As requested

___For review and comment

___Original copy to follow via mail

COMMENTS/MESSAGES:

FOR 1 PM MTG

TO: TARA O'TOOLE
FROM: ELLYN WEISS

RE: ADVISORY COMMITTEE BRIEFING OF INTERAGENCY GROUP
JULY 21, 1995

The general goals of this meeting should be, I think, to advance the process of achieving agency buy-in of the committee's product, to discuss and decide on the overall themes of the administration's response, and to develop a 6-week plan to 1) brief the appropriate internal and external groups (e.g. selected congressional staff, AAMC, AMA, university associations); 2) develop options for actions/decisions the President can announce when the report is officially released. There may also be a brief window of opportunity to influence the committee's deliberations on outstanding issues.

I suggest that we have Ruth brief us, convey whatever messages we wish and then send her home with our thanks, reserving at least the last hour for discussion among the interagency group

Status of Committee Deliberations

The final meeting of the committee concluded yesterday with much left yet to be decided. This much is clear:

-- Compensation will be recommended for a relatively small number of people, basically the WWII-era plutonium injections, on the grounds that the government kept it secretfrom the subjects;

-- They will state that there were only a small number of cases where the radiation dose was high enough to potentially cause physical harm and will identify several in this category, but will say they don't know whether harm was actually caused in any of these cases.

--They will state that the great majority of the work was done to advance science and medicine;

-- Substantial problems will be found in current research practices, primarily related to the failure of consent forms to

communicate risks well.

-- In light of the above, they will recommend steps to enhance ethical education; to strengthen sanctions for violations and to survey "outcomes" periodically (e.g.. to measure the subjects actual understanding of the research and risks);

-- They will criticize the administration of RECA and failure to update the epidemiological tables;

-- They will ask the President, perhaps in their transmittal letter, to express deep regret to persons who were mistreated and to reflect on the historical context of these events.

-- A number of innocuous recommendations will be made to improve public access to information, enhance openness, etc.

Among the major issues that the committee did not appear to have resolved are:

-- Are there are any subjects who should be notified so that they can take some action to mitigate a health risk?

-- Will they recommend specific amendments to the Radiation Exposure Compensation Act?

-- Will they recommend apologies to persons not physically harmed where consent was either actually or presumptively inadequate?

-- What will they recommend for the Marshall Islanders?

-- Will they recommend a new federal entity to interpret ethical rules, oversee federal research, etc?

Ruth should have insight into the probable resolution of these issues.

Messages to the Committee

The overall message should clearly be positive; they are very near the finish line and have done a great service. I suggest the following in addition:

-- On the issues squarely within the charter, push to reach decision. The evidence is always incomplete, but weigh it and make your best call, e.g. on the notification issue.

-- In the areas tangential to the charter (Marshall Islanders, atomic vets, etc.), the committee has a high risk of error in making findings and recommendations since they heard from only one side and did not have the expertise to evaluate the issues or investigate the facts fully. Particular caution is warranted.

-- The media WILL screw this up (see Phil Hilts' article in yesterday's Times re :the "thousands" of unwitting subjects. And he is probably the best we'll get). The more complicated the findings and recommendations, the more they will be screwed up.

N.B. The committee has hired a public relations firm . It is very important that we get Ruth's committment to coordinate their work with the interagency group and the White House.

Minefields

I suspect that the most adverse reaction will be from the scientific/research communities, which will construe the report as finding that things were terrible 50 years ago and they are still bad. This is exacerbated by the fact that the committee finds that, if anything, ethical practices are now more strict for radiation-related work than for other research. Hence, the indictment extends to all biomedical research. It would be very helpful if a respected academic or scientific group would endorse the recommendation for better education in ethics, e.g. at the time the report is released, that would be

In addition, there are groups whose expectations that the committee would make stronger findings will be disappointed -- the veterans, certain experiment subjects (the Cinncinnati group is well organized), the Task Force on Radiation and Human Rights, the Marshallese. I have kept in fairly close touch with the Task Force; they are again pushing the proposal for a post-report conference of "victims" funded by DOE.

Suggested General Themes for Response

-- This has been a remarkable achievement for openness in

government and we will not stop now.

-- Connect to the worldwide effort to come to terms with the legacy of WWII and express regret for those mistreated;

-- Emphasize the achievements of American medical science;

Six - Week Plan

One possibility is to form subcommittees of the interagency group. Possible areas are:

--Analysis of recommendations and implementation options - (could be further subdivided into recommendations re:past and those re:current research);

--Outreach to science and academia;

--Outreach to Congress;

--Contact with stakeholder groups

- started Dec 93 - interagency working group immediately formed - crisis management in Jan-Mar - committee appointed, first meeting in April 94 - a lot of work in a little time - six month report in November

- report initially due in April - we extended Committee's life until September 15

- final report due in September - very, very likely that President will personally participate in release of the final report - release date is scheduled for September 27 -- tell your bosses

- thus the PURPOSE of today's meeting -- we, the Administration, must have our collective act together in order to accept this report and then be able to respond to some of its recommendations

- Dr. Ruth Faden - brief us on the findings and recommendations

- I should emphasize that this is not a gripe session for those of us who have been involved for so long now and don't like some of the things the report says... Committee is essentially done with its work...independent...we appointed, but we said long ago that the Committee had license to hold our feet to the fire

- Ruth is here with some of her staff, but we can and shouldn't say to her, please change your conclusion about Finding X or Recommendation Y

- We can make some suggested language changes or correct erroneous facts (and I know a lot of you have been doing that right along) but the purpose of this meeting is to be briefed by Ruth so that we can determine how the President and the Administration should respond

- One point -- there are a lot of legal implications to the report, a lot of lawyers here, recovering lawyers, near lawyers and practicing lawyers -- but this is not a legal meeting per se -- we can touch upon some of those issues but the real, nitty gritty of compensation, Fedl Torts Claims Act and other pending litigation we should do in another meeting

- gameplan - introductions around the room, hear from Ruth (30 minutes) interject with Q if you must, but might be more efficient to hold them (although if there is something you really don't understand, I'm not going to hold you back) then Q&A, then Ruth can leave if she wants, and we can do a few minutes of planning

95 JUL 13 PM 5:06

Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, DC 20036
202/254-9795
Fax: 202/254-9827

FAX TRANSMISSION COVER SHEET

Date: July 13, 1995

To: Phil Caplan

Fax: 202/456-2215

Re: Tentative Agenda for July 17-19 Meeting

Sender: Anna Mastroianni

YOU SHOULD RECEIVE 3 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

JULY 17-19, 1995

Madison Hotel ✦ Executive Chambers ✦ 15th & M Street, N.W. ✦ Washington, DC

TENTATIVE AGENDA

Monday, July 17, 1995

9:00 AM	Call to Order
	Opening Remarks *Ruth Faden, Chair*
9:10	Public Comment
10:15	Break
10:30	Committee Discussion: [Part I and II chapters to be determined by the Committee]
12:00	Lunch
1:15	Committee Discussion: [Part I and II chapters to be determined by the Committee]
2:15	Committee Discussion: Findings (1944-74) [Part IV, Chapter 18]
4:00	Break
4:30	Committee Discussion: Recommendations for Remedies for Former Subjects [Part IV, Chapter 19]
6:00	Meeting Adjourned

Tuesday, July 18, 1995

9:00 AM	Committee Discussion: Recommendations for the Remedies of Former Subjects [Part IV, Chapter 19]
10:45	Break
11:00	Committee Discussion: Research Proposal Review Project [Part III, Chapter 15]
11:45	Committee Discussion: Subject Interview Study [Part III, Chapter 16]
12:30 PM	Lunch

1:45	Committee Discussion: Contemporary Projects–An Ethical Analysis [Part III, Chapter 17] Findings for the Contemporary Period [Part IV, Chapter 19]
3:30	Committee Discussion: Recommendations for the Protection of the Rights and Interests of Human Subjects [Part IV, Chapter 19]
4:00	Break
4:30	Committee Discussion: Recommendations for the Protection of the Rights and Interests of Human Subjects [Part IV, Chapter 19] (continued)
6:00	Meeting Adjourned

Wednesday, July 19, 1995

8:30 AM	Approval of Minutes of June 21-23, 1995 Meeting
8:35	Committee Discussion: Strategy and Direction and Sign off of Final Report
9:30	Committee Discussion: Findings–Contemporary Intentional Releases [Part IV, Chapter 18]
	Committee Discussion: Recommendations for Balancing National Security Interests and the Rights of the Public [Part IV, Chapter 19]
10:45	Break
11:00	Committee Discussion: Recommendations on Openness [Part IV, Chapter 19]
12:15 PM	Lunch
1:30	Committee Discussion: Executive Summary
3:30	Meeting Adjourned

AGENDA

Briefing - Advisory Committee on Human Radiation Experiments

Friday, July 21, 1995
1:00 PM
472 OEOB

I.	INTRODUCTION	Phil Caplan
II.	BRIEFING	Dr. Ruth Faden, Chair Advisory Committee on Human Radiation
	A. Findings (1944-1974) Findings (contemporary)	
	B. Recommendations	
III.	Q&A	
IV.	NEXT STEPS - preparation for release of final report	

o Current Subjects - Currently Letter

Problem

o

AGENDA

Interagency Working Group Meeting
Wednesday, August 16, 1995
10:00 AM

I. September 22

II. Subcommittee 1

Recommendations 1 - 7

III. Subcommittee 2

Recommendations 8 - 13

IV. Subcommittee 3

Recommendations 14 - 17

Needs to
be meeting of IAWG heads
to arrive at conclusions -- happen
before report? -- or
to happen in recess report

AGENDA

Friday, August 11, 1995
1:00 pm

Planning Meeting - Human Radiation Report

I. Background - Advisory Committee

II. September 22

III. Government Response to Committee's Recommendations

-POTUS response
-Interagency Working Group Committee Structure
-August 16 meeting

IV. Communications/Press Strategy

- Aug 16 - set of responses
- split out Gov't staff + craft event
- OSTP : Plan to work on community

AGENDA
INTERAGENCY WORKING GROUP
January 18, 1994

I. Introductions and Overview

II. Report on Principals Meeting

III. Presidential Memorandum on Human Subject Guidelines Review

IV. Working Group Subcommittee Updates

Public Information and Communications
- -800 number
- -Intergovernmental

Record Retrieval
- -FOIA
- -Report from each agency

Ethics and Science Standards
- -Status of names
- -Ruth Faden announcement

Legal Issues
- -Compensation Meeting with Budget Committees

V. Congressional Hearings
Glenn hearing - today
upcoming

VI. Next meeting

AGENDA
INTERAGENCY WORKING GROUP
January 18, 1994

I. Introductions and Overview

II. Executive Order

III. Working Group Subcommittee Updates

Public Information and Communications
-800 number
Record Retrieval
-status of memo
Ethics and Science Standards
-status of names

IV. Congressional Hearings
Fernald School
Sharp hearing - today
Glenn hearing - Thursday, Jan 20

V. Principals Meeting - Friday, Jan 21 (tentative)

VI. Next meeting

ETHICAL AND SCIENTIFIC STANDARDS WORKING GROUP

AGENCY COORDINATING GROUP ON RADIATION EXPERIMENTS

3-4:30 p.m. Wednesday, January 5, 1994
OEOB, Room 422

MEMBERS:

John H. Gibbons, EOP (Chair)
M.R.C. Greenwood, OSTP
Paul Freedman, DOJ
Jamie Gorelick, DOD
D.A. Henderson, DHHS
Harry C. Holloway, NASA
Susan Mather, VA
Tara O'Toole, DOE

AGENDA

I.	Introduction and Statement of Mission	John H. Gibbons
II.	Review of Agency Activities to Date	Members
III.	Discussion of Group Goals	
IV.	Definition of Next Steps	
V.	Guidance to Retrieval and Review of Records Working Group	

AGENDA

LEGAL ISSUES WORKING GROUP

January 5, 1993
5:15 p.m.

I. WELCOME

II. BACKGROUND

A. The Working Groups

B. Short-term timetable

III. DEFINING THE LEGAL ISSUES GROUP MISSION

A. Determine applicable legal standards for investigating radiation experiments

B. Advise other working groups

C. Compensation

1. Address issues relating to compensation and assistance for victims

2. Review and assess past and existing compensation schemes, including statutory schemes

D. Notice issues

E. Assess and monitor pending litigations

F. Outside advisors

G. Other

IV. UPDATE ON PENDING LITIGATION

V. ASSIGNMENTS

A. Departmental assignments

B. Report to Agency Coordinating Group

January 4, 1993

TO: **Public Information/Communications Work Group**

FROM: **Mike Gauldin, DOE**

RE: **Thursday meeting**

Attached is a proposed agenda for tomorrow morning's meeting.

I doubt that we can cover all these subjects in an hour, but we need at least to resolve Hotline problems since that is currently the spearhead of our outreach program.

PUBLIC INFORMATION/COMMUNICATIONS WORK GROUP

First meeting
10 a.m. Room 476 OEOB
Thursday, January 6, 1994

Proposed agenda

1. Hotine coordination — Heather Stockwell, DOE

   a. Options for coordinating agency Hotline efforts
   b. Standardizing information taken from callers
   c. Coordinating and standarizing follow-up to calls
   d. Confidentiality issues
   e. Publicizing Hotlines and their purpose

2. Other methods of outreach to locate experiment subjects or their families

3. Releasing records — Mike Gauldin, DOE

   a. When and how records can be made available to press and public
   b. Privacy issues

4. Press issues — Mike Gauldin, DOE

   a. Discussion of press needs and how to serve them
   b. Key messages to communicate

Executive Office of the President

OEOB Conference Rooms/White House Conference Center

Date of Meeting: Aug 16

Time: 10 To: 12

CONFIRMATION AND NOTIFICATION

Name of Individual Hosting Event: Phil Caplan	Office/Agency: Staff Secretary		
Staff Contact: "	Extension No.: 6-2702	Pager No.:	Room No.: GFC/WW

Type of Event:

☒ Meeting ☐ Reception ☐ Other _____

Name/Description of Event: Advisory Committee on Human Radiation Meeting

Number of Outside Guests: 25

Total Number of Attendees: _____

In Attendance:

☐ President ☐ First Lady ☐ Vice President ☐ Mrs. Gore

Room(s) Requested:

☐ Roosevelt Room ☐ Rm. 180 ☒ Rm. 472 ☐ Rm. 474 (Indian Treaty Room)

☐ Rm. 476 ☐ Rm. 450 ☐ Rm.459 ☐ Other: _____

White House Conference Rooms: ☐ Truman Room ☐ Wilson Room ☐ Eisenhower Room

☐ Jackson Room ☐ Lincoln Room

General Services:

☐ Elevator Service ☐ #4 ☐ #6 ☐ #7

Time Reserved: _____ Floors Reserved: _____ ☐ Podium ☐ Flags

Special Room Arrangements for the Indian Treaty/Truman Room:

☐ Conference Style ☐ Theatre Style ☐ Other _____

Number of Chairs: _____ Number of Table(s): _____

Entrance/Gate Preferred:

☐ 17th & G ☐ Pennsylvania Avenue ☐ Southwest Appointments Gate

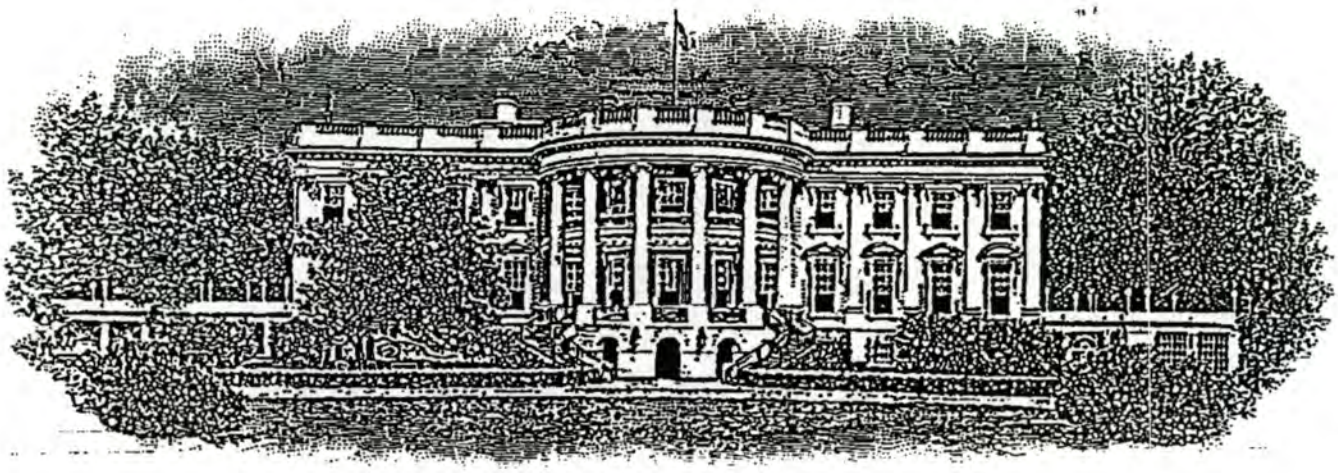
☐ Northwest Appointments Gate ☐ East Appointments Gate ☐ East Visitors Gate

Additional Requirements or Requests:

Forms Must be Returned to Room 1, OEOB, **48 Hours Prior to Event**

The White House

96 JUL 16 A8:05



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Phil Caplan

FAX NUMBER: 202-456-2215

TELEPHONE NUMBER: 202-456-2702

FROM: Diane Regas, Domestic Policy Council

TELEPHONE NUMBER: 202-456-2216

PAGES (INCLUDING COVER): 3

COMMENTS: Please circulate to all on the interagency working groups.

THE WHITE HOUSE
WASHINGTON

July 15, 1996

MEMORANDUM FOR **THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS**

FROM: **Elizabeth Drye**
Diane Regas Diane Regas

SUBJECT: **Summary of Meeting (July 9)**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on July 9. We discussed issues related to Atomic Veterans and to waiver of informed consent in classified research. Please review the summary below for accuracy and any information that your agency needs to provide.

We will meet next on July 16 at 10:30, to conclude the discussion of waiver of informed consent; to discuss notification (led by DOE) and IRBs (led by HHS); and to identify other outstanding issues. The meeting will be held in the Eisenhower Room, White House Conference Center. (You do not need to be cleared into the White House complex for this meeting.) Based on the discussion at the last meeting, we expect to meet again, tentatively scheduled for July 23 at 10:30 A.M.

SUMMARY OF MEETING

I. Administrative Issues: DPC staff reiterated the expectation that attendees are representing the views of their Departmental Secretaries at the IAWG meetings; the ACHRE follow-up will be mentioned at an upcoming discussion among the chiefs of staff. DPC staff requested that each agency review the summary memoranda to ensure their accuracy.

At the next meeting (July 16) we will identify what policy issues need further discussion, with the expectation that the IAWG will need at most one more decision meeting. After July 16, DPC staff will draft a proposed summary of the Administration responses to ACHRE. We will circulate the draft for review and, if necessary, schedule a meeting to discuss any issues that arise.

Atomic Veterans: The Department of Veterans Affairs (VA) presented background information on some of the efforts that are underway to update epidemiological tables, and on the available processes to consider whether it would be appropriate to expand the availability of benefits to atomic veterans.

The IAWG agreed as follows:

1. By August 15, VA will have in place a contract or an agreement in principle to update the epidemiological tables, including consideration of whether additional diseases should be considered to be radiogenic. The expected time to complete the work is 18 months after the contract is signed.
2. VA and HHS will work out an agreement on how to pay for the update of the epidemiological tables. If necessary DPC will request help from the Secretaries on this issue.
3. For the July 23 meeting VA will provide a proposed rationale for deciding whether the law should be amended to add classes of veterans who should be eligible to claim benefits under a presumption of service connection. The VA and other IAWG agencies will identify potential additional classes of veterans (in particular cleanup crews, and perhaps those exposed during plane crashes) and recommend whether they would fall within the proposed rationale.
4. For the July 23 meeting the VA will identify several options for an appropriate process to determine whether additional diseases should be eligible for a presumption of service connection (these could include relying on the current FACA process, as well as other options.)

Waiver of Consent in Classified Research: HHS proposed that there be no change in government-wide policy. HHS also proposed that this issue should remain outside the perview of the interagency working group on Human Radiation Experiments. This discussion will continue at the July 16th meeting.

U.S. DEPARTMENT OF ENERGY

1000 INDEPENDENCE AVE., SW, RM., 7A-075
WASHINGTON, D.C. 20585

96 JUL 15 PM 1:42

UNCLASSIFIED FACSIMILE MESSAGE
Office Fax: (202) 586-2268
Verify Fax: (202) 586-5680

DATE: 7/15/96

TO: IAWG MEMBERS

FROM: ELLY MELAMED / DOE
202 586-6857

No. Of Pages To Follow: 3

COMMENTS: ATTACHED IS MATERIAL FOR 7/16 MEETING: (1) NOTIFICATION BRIEFING PAPER (2) PROPOSED RESPONSE TO REC. 15. CALL IF QUESTIONS.

PLEASE TELEPHONE _____, AT THE NUMBER ABOVE TO VERIFY RECEIPT OF THIS FAX . . . . . .

THANK YOU

Briefing Paper on ACHRE Recommendation 4

ASSUMPTIONS:

-Agencies accept ACHRE recommendation 4 and will follow-up in accord with ACHRE criteria for notification - increased lifetime risk for development of a fatal radiation-induced malignancy and recognized medical benefit from early detection and treatment.

-An individual notification effort that goes beyond the ACHRE criteria - attempting to identify, locate, and contact all named individuals who may have been subjects of federally funded human radiation experiments - would be a high cost, low yield endeavor, may not satisfy the groups that are requesting it, and carries potential risks identified by the Advisory Committee as well as the possibility for invasion of privacy.

- in many cases names are not available or hard to extract; even with names the process of locating these individuals many years after the experiments will be very difficult.

- meaningful notification would require a contemporary dose analysis and presentation of risk, which is complicated, expensive and data is often inadequate.

- many stakeholders have indicated that their greatest concern is notification on the basis of records of private hospital and universities where confidentiality and privacy rules prohibit government access.

-Notification has been carried out by agencies in response to specific inquiries that came via the Helpline which was established at the beginning of this effort for those who thought they were potentially subjects of experiments.

-The process the Administration followed in uncovering human radiation experiments - document searches, the ACHRE hearings and report, and agency efforts to make documents publicly available through the National Archives and via the Internet - was predicated on openness and providing as much information to the public as possible and was itself a nationwide notification effort.

ACTIONS:

- In response to Helpline inquiries, DOE has sent over 20,000 replies including intensive research of approximately 3,000 cases; DOD had a caseload of 5,992 inquiries of which 997 are undergoing active research; VA has responded to over 1700 inquiries; and HHS has responded to 88 individuals.

-All Advisory Committee meetings were open; some were held outside of Washington; stakeholders were invited to participate at open forums.

-Agencies carried out an open, thorough and fully documented search for information; provided close to a thousand cubic feet of records to the Advisory Committee; and are in the process of making all documents located available on the World Wide Web as images and with full text searching capabilities.

OPTIONS:

1. Accept Advisory Committee recommendation 4 and frame an IAWG response that makes clear how much the Administration has done to honor the principles of openness throughout all human radiation experiment activities as well as the high costs, feasibility limits, and potential adverse impacts of a major individual notification effort.

There are two additional options:

2. Carry out an individual notification effort as requested by some stakeholders and potentially some members of Congress. This effort would require IAWG member agencies to pull together all reasonably available names of those who were subjects of identified experiments, locate current addresses using the IRS and other methods, develop appropriate information about dose and risk where data is available, and contact the individuals with this information.

3. In terms of meeting the stakeholder desire for medical care rather than medical follow-up, offer Medicare coverage to uncovered members of groups already recognized in law as subjects of government sponsored radiation exposure; these include the atomic veterans (ca. 200,000), Nevada downwinders (ca.19,000), and uranium miners (ca. 18,000).

3-8-21

SECRECY AND OPENNESS

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

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

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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

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

With regard to 15b, the IAWG staff endorses the current IRB system which already must include at least one member not affiliated with the institution. The IRBs can guarantee participation of non-government persons in reviewing classified research by establishing a dedicated panel for classified research review or by ensuring that all IRB members possess the necessary clearances.

96 JUL 8 P2:29

July 8, 1996

FAX TO:

Elly Melamed
William Frank
Phil Caplan
Susan Mather
Rachel Levinson
Eric Macris
Arnauld Nicogossian
Gary Ellis
Pat Glynn
Claud Bailey
John Pereira

FROM:
Diane Regas

NOTE: I am sending the attached 3 page memo to you as the lead contact for your Department. Please ensure that others in your Department get copies as needed.

Thank you.

Confirmation: If pages are missing please call 456-2216.

THE WHITE HOUSE

WASHINGTON

July 8, 1996

MEMORANDUM FOR **THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS**

FROM: **Elizabeth Drye**
Diane Regas

SUBJECT: **Summary of Meeting (June 28)**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 28. We had a very productive discussion on issues related to uranium miners, nasopharyngeal radiation and the Marshall Islanders. We expect to come very close to making policy decisions on all outstanding issues related to the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) recommendations by mid–July. Please review the summary below for accuracy and any information that your agency needs to provide.

At the close of the meeting, the IAWG developed agendas for the next two discussions. We will meet next on July, 9, at 10:30 a.m., in the Eisenhower Room, White House Conference Center. (You do not need to be cleared in to the White House complex for this meeting.) We will discuss the Atomic Veterans (led by VA) and the waivers of consent for classified information (led by HHS). We will meet again, tentatively on July 16 at 10:30 (note the change), to discuss notification (led by DOE) and IRBs (led by HHS).

SUMMARY OF MEETING

I. Public Involvement in follow–up to ACHRE

DPC reported that we have agreed on at least the following steps for public involvement in our ongoing process. When we are ready to propose legislation we will advise stakeholders and listen to any reactions that they may have to our proposals. When we are ready to propose regulations, each Agency will make an extra effort to notify and involve stakeholders in this process––recognizing that many do not regularly scan the Federal Register for notices of relevant changes in the rules. Lastly, when we are ready to announce other executive actions, the DPC staff will give stakeholders notice and a brief, informal opportunity to understand what actions we intend to take.

II. Uranium Miners (Recommendation 7) (DOJ):

a. *Criteria for compensation of lung cancer.* We agreed that new criteria for determining whether uranium miners' lung cancer was caused by exposure in the mines should be added to existing legislation. We agreed that miners who qualify under either set of criteria should be eligible for compensation. DOJ will draft the proposed legislation by the end of July with new criteria, using a 90% level of assurance. OMB will analyze whether new legislation,or other action, is needed to address funding issues.

b. *Non-malignant respiratory disease criteria.* The Radiation Exposure Compensation Act Committee, led by DOJ, will propose revised criteria for compensation of non-malignant diseases. The Committee will have a proposed criteria by the end of the summer, and will draft proposed legislation soon thereafter.

c. *Presumption that members of the Navajo Tribe are non-smokers.* We agreed that there should be a presumption that Navaho were non-smokers based on the information and research that has been developed to date. DOJ will notify the IAWG if it determines that there are equal protection concerns with this decision. DOJ plans to propose changes in the regulations by the end of this summer.

d. *B-readers.* DOJ will propose changes in the regulations to emphasize the use of high resolution CT scans in determining the presence of non-malignant respiratory disease. In addition, DOJ will propose changes to eliminate any appearance of bias in the operation of the B-reader program. Those people who have been denied compensation solely because of a negative chest radiograph will be notified of the new encouragement to use CT scans.

e. *Non-reservation mines.* The Administration will propose legislation that would expand eligibility for compensation under RECA to miners with non malignant respiratory diseases who worked in mines outside of the Reservations.

f. *Smoking cessation.* DOJ will propose to modify its regulations to define non-smokers to include lung cancer claimants who stopped smoking 15 years or more before the date of diagnosis.

g. *Accepting CT scans.* DOJ will propose to modify its regulations to accept high-resolution CT scans as proof of the presence of a compensable non-malignant respiratory disease.

h. *Accepting lung biopsies.* DOJ will propose to modify its regulations to allow lung biopsies to be used as proof of the presence of non-malignant respiratory disease, where there is a medical reason to conduct the biopsy.

i. *Ethno-specific pulmonary function tables.* DOJ will propose to modify its regulations to adopt scientifically supported, ethno-specific pulmonary function tables to be used in judging whether pulmonary function is impaired. DOJ will notify the IAWG if it determines that there are equal protection concerns with this decision.

j. *Definition of Impaired Pulmonary Function.* DOJ will propose to modify its definition of impaired pulmonary function to be consistent with the American Thoracic Society.

III. Nasopharyngeal Radiation Treatments (CDC – DOD):

a. *Military Nasopharyngeal Radiation Treatments*

DOD will continue its efforts to identify members of the military who were treated with nasopharyngeal radiation. Recent new information suggests that as many as one thousand individuals may be identifiable. This information raises the possibility that an epidemiological study of the effects of these treatments could be possible. Neither the feasibility nor the desirability of such a study will be decided upon before the end of the summer.

The appropriateness of notification of affected veterans will be decided in reference to the overall criteria for notification that the IAWG will discuss in a future meeting.

VA is drafting legislation to make veterans treated with nasopharyngeal radiation eligible to participate in the VA's Ionizing Radiation Registry Examination program as well as to have priority eligibility for treatment of radium-related conditions. This legislation will be available for interagency review soon.

b. *Military Experiments involving Nasopharyngeal Radiation and External X-ray treatments*

DOD has found information about 5 – 10 individuals who were the subject of experiments involving nasopharyngeal radiation and external X-rays. The appropriateness of notification of affected veterans will be decided in reference to the overall criteria for notification that the IAWG will discuss in a future meeting.

c. *Risks from Nasopharyngeal Radiation Treatment in the General Public (non-experimental):* The IAWG endorsed CDC's recommendation that efforts to address risks to the general public should focus on education of the medical community. CDC described several efforts underway to ensure that this education is adequate.

IV. Marshall Islanders (DOE):

The IAWG endorsed DOE's recommendation that the federal effort in the Marshall Islands needs to flow from a long-term planning process that supports full involvement of the Marshallese in decisions about how to spend available federal money; how to support improvements in the health care infrastructure; and how to ensure that medical surveillance, and any ongoing studies, reflect the needs of the community.

Fax Cover Sheet

96 JUN 20 A9:30

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Please Deliver to:

Phil Caplan

Fax #: 94562215
Company: WH

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 2

==========

Message:

******URGENT!!!******

I've attached the agenda for today's IAWG meeting at OEOB. Diane Regas submitted the agenda. Hope we will see you there. Call with questions 202-586-5319. Have a great morning!

Agenda
Interagency Working Group on Human Radiation Experiments
June 20, 1996, 2:30-4:00

I. National Bioethics Advisory Committee - Jon Foster

Status and content of announcement

ACHRE recommendations identified as possible referrals to NBAC:

* Recommendation 9: NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.
* Recommendation 10: NBAC's role in changing IRB's.
* Recommendation 11: Ongoing public forum needed to discuss ethical issues raised by human experimentation.
* Recommendation 13: NBAC's role in improving oversight, sanctions, and scope of human subjects protections.
* Recommendation 14: NBAC's role in future compensation for research injury.
* Recommendation 15: NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.

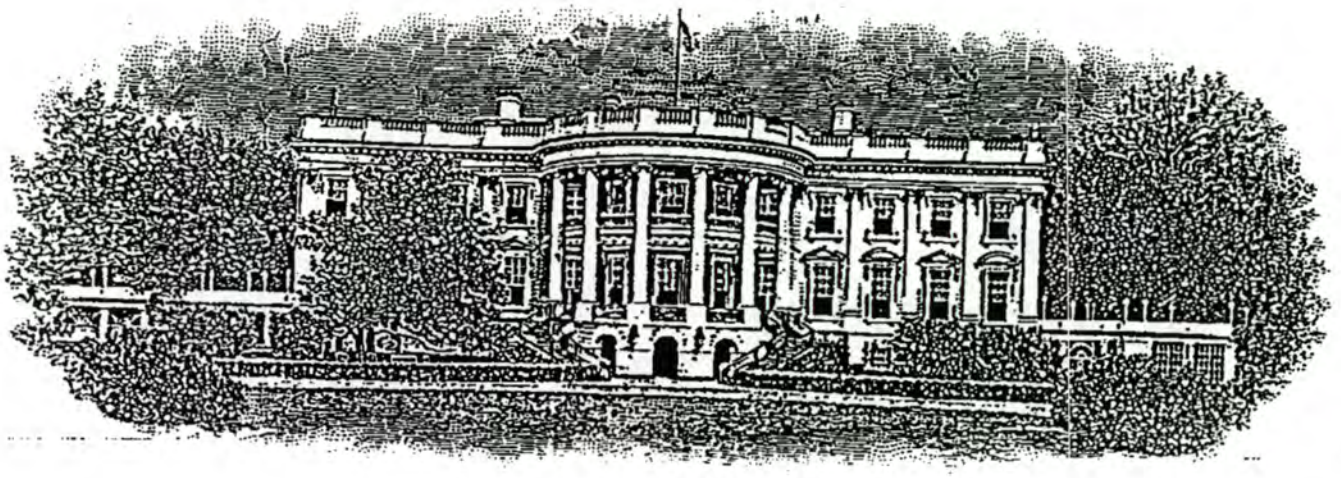
II. Uranium Miners (Recommendation 7) - Justice

III. Public Involvement in follow-up to ACHRE

IV. Next Steps

Next meeting schedule and agenda (proposed: Atomic Veterans; Marshall Islanders; nasopharyngeal radiation)

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: William Frank
Phil Caplan
Neil Otchin
Harold Gracey
Susan Mather
Rachel Levinson
TJ Glauthier
Eric Macris
Janis Stoklosa
Earl Ferguson
Arnauld Nicogossian
Wendy Baldwin
Gary Ellis
Eva Plaza
Pat Glynn
Tara O'Toole
Robert Nordhaus
Steve Galson
Lisa Blatt
Lori Azim
Elly Melamed
Gordon Sopher
Joan Ma Pierre
Claud Bailey
John Pereira

FROM: Diane Regas, DPC
(202) 456-5589

PAGES: 3

THE WHITE HOUSE

WASHINGTON

June 25, 1996

MEMORANDUM FOR THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: **DIANE REGAS**

SUBJECT: **SUMMARY OF MEETING (JUNE 20)**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 20. Our goals were to begin making policy decisions on outstanding issues related to the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) so that the Administration can respond publicly to ACHRE's recommendations by mid-July.

At the June 20 meeting we discussed issues related to the National Bioethics Advisory Commission and related to compensation for uranium miners. Below is a summary of our discussion, including decisions made and outstanding decisions and information that we need. Please read the summary carefully for material that your agency may need to provide. **Our next meeting will be on Friday, June 28 at 10:30-12:30 in OEOB Room 472**. At the meeting we will conclude our discussion on uranium miners (led by DOJ); decide on our course of action related to nasopharyngeal radiation treatments (led by DOD and CDC) and Marshall Islanders (led by DOE). DPC will also report on our discussions regarding public involvement. All materials for the meeting should be delivered to Elly Melamed at DOE by COB Wednesday June 26.

We will not meet during the week of July 1, however **we expect to meet twice during the second week of July (tentatively Tuesday and Friday)** and very frequently thereafter until we have IAWG recommendations on all the outstanding policy issues. We appreciate your dedication to solving the difficult challenges raised by Human Radiation Experiments, and look forward to your help in a strong push to resolve the remaining questions in the next few weeks.

SUMMARY OF MEETING

I. National Bioethics Advisory Commission: We discussed the six tentative issues for referral to NBAC, and made the following decisions (the "recommendation number" refers to the ACHRE report):

Recommendation 9 : (NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.) We decided it is appropriate to refer this to NBAC, but every agency also needs to explain the efforts underway now to respond. In addition, HHS agreed to work with DOD and VA to resolve the outstanding issue of money for research in this area.

Recommendation 10: (NBAC's role in changing IRB's.) We agreed that we need further discussion of the regulations that set guidelines for IRB's, to be led by HHS (probably July 12). In addition we agreed that we should be more specific in the questions that we ask NBAC on this issue (recognizing that NBAC will set its own priorities).

Recommendation 11 : (Ongoing public forum needed to discuss ethical issues raised by human experimentation.) We agreed that it is misleading to suggest that NBAC is the only ongoing federal public forum to discuss bioethical issues. All agencies need to provide information explaining the public fora that they make available to discuss such issues. We may need to revisit this discussion after we evaluate the agncies' information.

Recommendation 13 : (NBAC's role in improving oversight, sanctions, and scope of human subjects protections.) This referral is within the scope of NBAC. Action is needed to get the reports in response to the executive order from HUD, DOT, DOL, DOI. HHS agreed to follow up with these agencies, with help from DPC if necessary.

Recommendation 14: (NBAC's role in future compensation for research injury.) We agreed that this issue would not be referred to NBAC. Instead DOJ would take the lead in explaining the priniciples behind our belief that the current case-by-case approach is appropriate.

Recommendation 15: (NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.) We agreed that this issue would not be referred to NBAC. Instead, we may recommend that the criteria for waiver of consent in classified and non-classified research will be the same. To decide this issue HHS will outline the criteria and circumstances under which consent may be waived in non-classified research. We will discuss this at a future meeting (probably July 9).

II. Uranium Miners DOJ led a discussion of the technical report from the Radiation Exposure Compensation Act Committee on amending RECA. DOJ distributed material identifiying non-controversial recommendations and those that may need discussion. We plan to complete this discussion on June 28.

With regard to amendments to RECA to change the eligibility requirements for lung cancer compensation, we agreed to consider only those policy options that do not exclude either currently eligible miners or the additional miners that the report identified. DOJ agreed to provide options and lead another discussion on this issue.

We also agreed that the RECA committee should study and recommend changes to RECA to compensate miners who have non-malignant respiratory diseases. We still need to decide how to approach this issue in a public response to ACHRE given that the work of the Committee will not be completed before fall.

THE WHITE HOUSE

To: Phil Caplan

Date: 6-12-96

From: REGAS_D

Page 1 of 3

Please deliver the attached memo immediately. If you have any problems with the fax, call (202)456-2216 and leave a message for Diane Regas. Thank you.

June 11, 1996

MEMORANDUM FOR THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: **ELIZABETH DRYE**
DIANE REGAS

SUBJECT: **SUMMARY OF MEETING**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 6. Our goals were to identify what issues need further work before the Administration can respond publicly to each of the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE); to establish a process to resolve those issues; and to prepare to respond to ACHRE's recommendations by mid-July.

At the June 6 meeting we identified the major issues that may need work, described below, and agreed to some next steps towards resolving them. In particular a lead agency for each issue agreed to summarize outstanding decisions needed, and options by June 14, and deliver the material to Elly Melamed at DOE. Please send the material by noon on June 14 so that it can be distributed before the end of the day to the IAWG. **Our next meeting will be on June 20, at 2:30, in Room 472.**

- Compensation: The Department of Justice will review and edit the previous explanation of the Administration's policy on compensation, and determine whether there are outstanding issues that need to be resolved.
- Notification: The Department of Energy (DOE) will outline a response to ACHRE's recommendation. The response will highlight our agreements with the Committee; explain what is or soon will be available to the public; explain what will not be available and why; and explain ongoing efforts by the agencies to respond to inquiries and to find additional relevant information. We recognize that the Administration's ultimate statement on this issue needs to go further than responding to ACHRE.
- Expectations for the National Bioethics Advisory Committee (NBAC): The White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) will work together to review references in the "White Paper" to NBAC. Our goals are to ensure that the totality of the issues referred to NBAC from this group is realistic given NBAC's broad charter. We also need to identify alternative ways to respond to the ACHRE's recommendations if referral to NBAC is

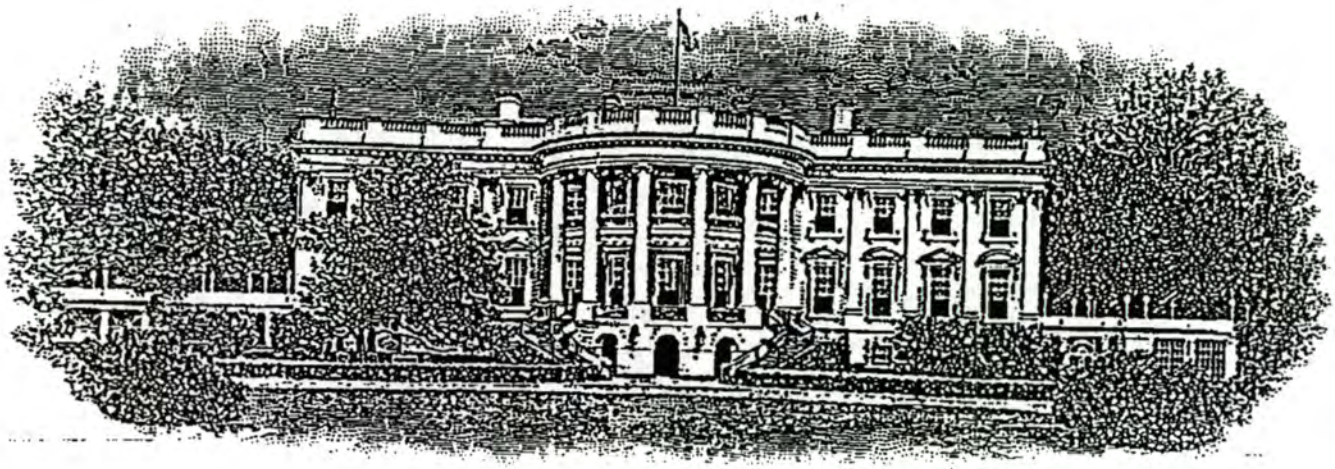
inappropriate. Resolution of what issues should be referred to NBAC is a very high priority. Our expectation is that, by June 14, OSTP and NIH staff will recommend what should be referred to NBAC.

- Uranium Miners: The Department of Justice has led a working group to put forward options, which we propose to discuss at the next meeting.
- Marshall Islanders: DOE will work with the Department of Interior to identify outstanding issues and propose options.
- Nasopharyngeal Radiation: The Department of Defense (DOD) will work with the Centers for Disease Control and Prevention (CDC) and the Department of Veterans Affairs (VA) to identify outstanding issues and options. This issue was not discussed at the meeting, but we believe that it would be useful to get CDC's view about an appropriate public health notification for those who underwent this treatment. We recognize that this issue falls outside the scope of ACHRE's charter.
- Atomic Veterans: Although we did not discuss this issue extensively at the meeting, it presents difficult and controversial policy issues. It is important that we spend substantial time on the 20th discussing the pros and cons of the options. DOD agreed to work with the VA to identify outstanding issues and provide options to resolve them.

We look forward to our next meeting on Thursday the 20th. Please call either of us if you have any questions (456-2216). You can also use e-mail: Regas_D@a1.eop.gov.

The White House

96 JUN 26 P12 : 00



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: William Frank
Phil Caplan
Neil Otchin
Harold Gracey
Susan Mather
Rachel Levinson
TJ Glauthier
Eric Macris
Janis Stoklosa
Earl Ferguson
Arnauld Nicogossian
Wendy Baldwin
Gary Ellis
Eva Plaza
Pat Glynn
Tara O'Toole
Robert Nordhaus
Steve Galson
Lisa Blatt
Lori Azim
Elly Melamed
Gordon Sopher
Joan Ma Pierre
Claud Bailey
John Pereira

FROM: Diane Regas, DPC
(202) 456-5589

PAGES: 3

Sorry about all the mess — should be 3 pages w/cover page.

THE WHITE HOUSE

WASHINGTON

June 25, 1996

MEMORANDUM FOR THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: **DIANE REGAS** Diane Regas

SUBJECT: **SUMMARY OF MEETING (JUNE 20)**

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AGENDA

Interagency Working Group on Human Radiation Experiments

June 6, 1996

I. Introductions

II. Short Term Objectives -- Goals and Timeframes

III. Identification of Outstanding Issues in Key Areas

a. Compensation - Polen Statement from DOJ from early draft

b. Notification - ~~www~~, ~~obtain~~ records in one place, but not beyond comm's recommendation

c. Expectations for NBAC

d. Uranium Miners

e. Marshall Islanders

f. Nasopharyngeal Radiation

g. Atomic Veterans

h. Other

IV. Process for Resolving Issues.

AGENDA

Friday, April 15, 1994
3:00 PM
Room 472, OEOB

I. Introductions

II. Congressional Briefing

Tuesday, April 19, 1994
3:30 PM
Indian Treaty Room, OEOB

To do:
-lead Agency representative
-document collection instructions
-total $ spent
-Hotline summary
-downloading of data summary
-contractor indemnification question

III. Advisory Committee Meeting

April 21-22, 1994
Washington Ramada, Thomas Circle

To do:
-Draft statements of principals (close of business, Monday 4/18)
-Press kits for release
-Coordinate presentations of Agency representatives for Friday am, 4/22

PROPOSED AGENDA ITEMS – ISSUES REQUIRING INTERAGENCY COLLABORATION IN IONIZING RADIATION STUDY
(Prepared by HHS)

1. **Published Literature Search**

The National Library of Medicine is exploring a number of approaches for the systematic search of indexed publications. There are two major steps in the process:

a. **Identification of key words and method of search -- Interagency consensus and eventually Committee agreement is required;**

b. **Identified publications then need to be reviewed and a determination made as to whether the experimental work conducted meets the criteria. Note that pilot studies at NIH show a number of publications which describe experimental work whose nature is not clear. Some sort of panel is needed to provide at least a provisional adjudication and clearer definitions so that material can be compiled for the Committee for further review.**

2. **Repository for Published Documents**

Various of those who have reviewed this field before point out that many (perhaps most) of the experiments are described, at least in part, in scientific reviews and publications. (Indeed, for the plutonium experiments, I was surprised to discover the descriptive detail provided in two such publications.) I would propose that an effort be made to begin assembling such publications at an early date and at one site. By indexing papers by experiment or release, considerable material should be able to be assembled reasonably quickly. This would be useful reference material for those searching for more detailed records, for the Advisory Committee, for the press and for the public.

3. **Prioritization of Work**

It seems to me that past experiments must be judged according to two standards:

a. **informed consent; and**

b. **whether exposure to ionizing radiation exceeded acceptable maximum limits. The latter standard would suggest the possibility of assigning experiments to one of three categories:**

I. Exposure to ionizing radiation was less than accepted limits both at the time and by today's standards;

II. Exposure to ionizing radiation was less than accepted limits by standards at the time but could be viewed as excessive today (thus implying a special need for follow-up of patients); and

III. Exposure to ionizing radiation was greater than accepted limits both at the time and by today's standards (such experiments would command the highest priority for detailed follow-up).

To divide experiments by category, we need to ascertain what the standards were at various points in time from 1944 to 1974 and what comparable standards are today. I am told that the AEC published standards beginning in the earliest days post-war. If this approach seems reasonable to all Agencies, we need to compile this information at the earliest possible date and to begin to categorize experiments similarly across government.

4. Information and Databases of Use or Possible Use to All Agencies

a. Radioisotope shipment data to identify sites where work was in progress; and

b. Names of physicians licensed by the AEC to administer radioisotopes.

5. Execution of Record Review at Grantee Institutions

It is probable that the bulk of human experimentation was conducted in a comparably few institutions or by its institutional investigators. Several Agencies may have participated in funding such studies or collaborated in the funding -- including HHS, DOE, DOD, VA and NASA. Thus, special reviews of records may be required at a number of research centers. An agreed upon methodology and assignment of responsibility will be needed to avoid separate investigations by each of the Agencies.

6. Definitional Problems

We will need to be explicitly clear as to which investigations clearly represent human experimentation and which represent accepted therapeutic and/or diagnostic procedures. The present straightforward definition will probably

handle the majority of investigations but some already appear to fall in a "gray" area. I would propose that a working group be constituted to maintain an active review of this problem, to review questionable investigations and to define explicitly what was included and what was not so that there is uniform treatment across all Agencies. These decisions will, of course, have to be discussed with and agreed upon by the Advisory Committee.

7. Working Executive

For many of the reasons noted above and to assure rapid exchange of information turned up by one Agency which may impact another, I would propose that a working executive be constituted, led by the three most affected (HHS, DOE and DOD), but with appropriate participation by each of the others.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
SEPTEMBER 12-13, 1994

The Ramada Plaza Hotel ✥ Federal Hall ✥ 10 Thomas Circle, NW ✥ Washington, D.C.

AGENDA

Monday, September 12

9:00 AM	Call to Order *Phil Caplan, Special Assistant to the President for Cabinet Affairs*
9:05	Welcome and Orientation to Meeting *Ruth Faden, Chair*
9:10	New Staff Introductions, Staff Structure and Current Project Assignments (TAB C) *Jeffrey Kahn*
9:15	Approval of Minutes of July 25-26, 1994 Meeting *Ruth Faden*
9:20	Staff Report: Update on Ethics Policies and Procedures (TAB I) *Jonathan Moreno*
9:45	Staff Report: Human Experimentation in Connection with Atomic Bomb Tests (TAB F) *Gregg Herken and Dan Guttman*
(10:05)	Committee Question and Answer Period
10:25	Break
10:45	Staff Report: Management Theme: Pilot Case Study (TAB G) Oak Ridge *Donald Weightman and Dan Guttman*
(11:05)	Staff Report: Management Theme: Pilot Case Study (TAB G) (continued) Los Alamos *Barbara Berney and Dan Guttman*
(11:15)	Committee Question and Answer Period

11:25 Update on Agency Data Collection Efforts (TAB H)
Ruth Faden

11:45 Reports from Subcommittees
Outreach
Reed Tuckson

12:10 Lunch

1:30 Reports from Subcommittees
(approx. 20-25 minutes allotted for each report and committee discussion)

Protocol Review (TAB E)
Ruth Macklin and Jay Katz

Subject Interviews (TAB E)
Ruth Faden

Oral History (TAB E)
Sue Lederer

Intentional Releases and Exposures/Experiments of Opportunity (TAB L)
Nancy Oleinick and Duncan Thomas

Biomedical Research
Mary Ann Stevenson

3:30 Break

3:45 Public Comment Period

5:00 Meeting Adjourned

Tuesday, September 13

9:00 AM Opening Remarks
Ruth Faden

9:05	Briefing: Radiation Dosimetry *Henry Royal*
9:30	Discussion of Committee Strategy and Direction *Moderator: Ruth Faden*
10:30	Break
10:45	Discussion of Committee Strategy and Direction (continued)
12:00	Lunch
1:20	Declassification *Donald Weightman*
	Interim Report *Dan Guttman and Anna Mastroianni*
	Discussion of Committee Strategy and Direction (continued)
2:55	Closing Remarks *Ruth Faden*
3:00	Meeting Adjourned *Phil Caplan, Special Assistant to the President for Cabinet Affairs*

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

September 12-13, 1994
Ramada Plaza Hotel
10 Thomas Circle
Washington, D.C. 20005
202/ 842-1300

October 12-13, 1994
The Press Club of San Francisco
555 Post Street
San Francisco, CA 94102
415/775-7800

November 14-15, 1994
Location not determined

December 15-16, 1994
Omni Shoreham Hotel
500 Calvert Street, N.W.
Washington, D.C. 20008
202/234-0700

January 19-20, 1995
Omni Shoreham Hotel
2500 Calvert Street, N.W.
Washington, D.C. 20008

February 16-17, 1995
Location not determined

March 16-17, 1995
Location not determined

April 10-11, 1995
Location not determined

*****DRAFT*****

Contact: Stephen Klaidman

202/254-9795

Press Advisory: ACHRE meeting of September 12-13.

The Advisory Committee on Human Radiation Experiments will discuss several staff memoranda reporting on research findings from government agencies:

Intentional Releases of Radioactivity. The Committee staff will summarize a number of intentional releases of radionuclides, including releases enumerated in the Committee's charter and those that have been reported in documents released by government agencies this year.

Planning of Human Subject Experiments. The Committee will hear reports on continuing research into Cold War records of the civilian and military planning agencies which were involved in a broad range of animal and human tests, including the Department of Defense's Joint Panel on the Medical Aspects of Atomic Warfare and the Committee on Medical Sciences.

The Committee will discuss staff reports that indicate some human experimentation was planned and in some cases appears to have been carried out in conjunction with 1950s weapons tests.

The Committee will hear a report on staff document searches which show that the Central Intelligence Agency participated in deliberations of the Department of Defense's Joint Panel on the Medical Aspects of Atomic Warfare and the Committee on Medical Sciences. The CIA had reported to the Committee that it found no documents indicating that the CIA conducted or sponsored human radiation experiments or that the CIA held records that included information about studies conducted by other agencies.

- easter: - deposit records somewhere
1) after turned over to Carte.

- should be decided by Tues

-

2) Total amt. of $ all agencies are spending for Dog. Strategy

3). What are we doing with those people. records after they get them. what now.

might be someth

1) ~~cut be @ 10:00~~

~~Steve Galson will be there~~

5) be ~~2:30~~ what does CAV used? - unavailable on Sun

6) Hear from T.J.? on
mediation / conversation
questions

7) Some agencies, gov to have trouble
docuntry by a good job -

8) Hire new people
b/c bigger than expected

Sanitization

Tracking mind

9) How my records search
+ what

10) what is govt's position on lawsuits

Radiation

- coordinate Secretarial statements
  draft by C.O.B Monday

- Cong briefing
  * - collection of all documents
  * - 100 copies of each ~~[illegible]~~ bring to briefing
  - contractor indemnification questions
  - have DOE there or Chairman do it
  * - Hotline - # of calls
  * - data downloaded to Agencies
  - Adv Committee update - role of Dan

- follow up with DOJ - list of questions

10:00 - 10:45
- speakers - order?
- list of commitments
- briefing paper for each Sec - list of potential Q+A from Dan
- Cong lunch Tom, - 3:00

* 3:00
1) - CIA - needs to explain what they did
2) Smithsonian structure
3) ~~[illegible]~~
4) Afternoon session

- conflicts - Steve Neuwirth
- list to me by ~~[illegible]~~ noon Tuesday
- guidance on afternoon sessions
  come to 2:00 + explain

- Cathy Wagner

AGENDA

Friday, April 15, 1994
10:00 AM
Ward Room

AGENDA for Press Kit

I. Status of Nominations

II. Draft Agenda

welcome + thank you

- independence + integrity expertise

-Opening by Christine, Ruth

-Testimony of Principals - notes as to who to leave early

-Conflicts - look at room

-Member of Congress Testimony (Congressional Courtesy Calls) Marty

Dan will work out

-Reception (Thursday evening) group photo outside

- Jane quits - overall **-Friday morning session**

- Christine → to call Mark

Glenn + Marty

III. Press Strategy

Dan will be main pt of contact

-statements. press packets

-press availability

- 15 + 5 staffers
- 10 spouse
25-30 staff

- 35-40 committee
- 6-7 principals
- 15 staff
60 people

Troy Thornton - MAC - NO
on the Hill
sometime in May

Tracy-

Says Glenn + Marty want to test by Mon afternoon.

Tentative Agenda

THURSDAY, APRIL 20

7:45 AM (if at Grand Hotel)	Breakfast Briefing on administrative matters
	White House Counsel [conflect of interest; FACA] DOE [Security Clearances] Steve Klaidman, Committee Staff [Press]
	NOTE: 8:00 AM Breakfast if at Washington Plaza

Washington Plaza Hotel

9:30	Call to Order Designated Federal Official
	Welcomes and Introductions Ruth Faden, Chair
9:40	Welcome [tentative] ~~Vice President Gore~~
9:45	Briefing by InterAgency Working Group [need names and ordering of officials]
10:45	Break
11:00	Conflict of Interest Briefing and Discussion [White House Counsel Designee]
12:00 noon	Lunch
1:15 PM	Committee Mission Ruth Faden, Chair
1:20	Introductory Comments Dan Guttman, Executive Director
1:25	Discussion of Committee Mission Moderator: Ruth Faden, Chair

Missions

Structure of this event

- What is order of Exec's
- Q+A from Cmte. Members
- Sarah Ryan
- Pig Room + Map Room
- Members from my people + Cathick

3:00	Break
3:15	Public Comment
5:00	Meeting Adjourned
5:30	Reception [White House arranging]

FRIDAY, APRIL 22

9:00 AM	Opening Remarks Ruth Faden, Chair
9:05	Committee Discussion Moderator: Ruth Faden
9:30	Briefing by Interagency Working Group: Document Retrieval and Data Collection Efforts [need names of officials]
10:30	Break
10:45	Briefing (continued) [need names] Committee Question and Answer Period Moderator: Ruth Faden
12:00 noon	Lunch
1:15 PM	Discussion of Committee Mission (Revisited) Moderator: Ruth Faden, Chair
2:30	Future Meetings Ruth Faden, Chair
3:00	Meeting Adjourned

- what exact query has been done
- check w/ Chiefs of Staffs
- all money - get names from Tara

- Cathy Wakem
Counsel's office

RADIATION MEETING:

TO DO LIST as of April 10, 1994

-change Tuesday April 12 meeting to Friday April 15 at 3:00 PM
-plan on congressional briefings (1 House, 1 Senate) on Tuesday, April 19
-settle outstanding legal issues in preparation of briefing:
-rework draft contractor letter to include definition of human radiation experiments
-contractor indemnfication: do we need official legal opinion? what do we say at briefing?

-Friday, April 15 - 10:00 AM next Adv Committee meeting GET ROOM

MEETING:

-schedule all Secretaries for 10:30 Thursday morning
-script out statements
-"trip meeting" Monday, 18th
-what sort of event on Friday morning, April 22 with POTUS? Where?
-reports on "what each agency has done" for Friday must be coordinated.
-check w/ Sarah Ryan on Friday event
- To DO memo on what needs to be done in next 10 days

ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTS

FUTURE PUBLIC MEETING DATES

MAY 18-19, 1994	**WASHINGTON, DC** **RAMADA PLAZA HOTEL** **10 THOMAS CIRCLE**
JUNE 13-14, 1994	**WASHINGTON, DC**
JULY 5-6, 1994	**WASHINGTON, DC**
JULY 25-26, 1994	**WASHINGTON, DC**

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
JUNE 13-14, 1994

The Ramada Plaza Hotel--Washington Room--10 Thomas Circle, NW--Washington, D.C.

FINAL AGENDA

Monday, June 13

9:30 AM	Call to Order *Philip Caplan, Special Assistant to the President for Cabinet Affairs*
9:35	Welcome and Orientation to Meeting *Ruth Faden*
9:40	Introduction of New Staff *Jeffrey Kahn*
9:45	Review and Approval of Minutes of May 18-19, 1994 Meeting *Ruth Faden*
9:50	Briefing: Introduction to Remedies (Tab G) *Ken Feinberg*
(10:20)	Committee Question and Answer Period
10:35	Briefing: Risk Communication *Steve Klaidman*
(11:00)	Committee Question and Answer Period
11:10	Break
11:25	Overview of Staff Work *Dan Guttman*
11:35	Staff Report: Update on Ethics Data Collection Efforts (Tab H) *Jonathan Moreno*
11:50	Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Defense (Tab J) *Jim David and Dan Guttman*
12:30 PM	Lunch

2:00	Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Veterans Affairs (Tab I) *Denise Holmes and Dan Guttman*	
2:45	Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Energy (Tab K) *Jim David and Dan Guttman*	
3:00	Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Health and Human Services (Tab K) *Faith Bulger and Dan Guttman*	
3:15	Review of Progress of Agency Data Collection *Don Weightman*	
3:30	Report on Declassification *Dan Guttman*	
3:45	Break	
4:00	Public Comments	
5:00	Meeting Adjourned	

Tuesday, June 14

9:00 AM	Opening Remarks *Ruth Faden*	
9:05	Reports from Subcommittees:	Ethics Data Collection *Ruth Faden* Scope and Priorities *Duncan Thomas* Cold War Data Collection *Mary Ann Stevenson* Public Outreach *Reed Tuckson*
12:00 PM	Lunch	
1:30	Meetings of Subcommittees	
3:00	Meeting Adjourned	

3:00 PM
DOE

INTERAGENCY SEARCH GROUP
WEEKLY MEETING - JUNE 15, 1994

AGENDA

- **Progress and Problems (Guttman)**

July 8 **Testimony on Charity Hospital in Louisiana (O'Toole, Henderson, Soper, and staffs)**

- **Interagency correspondence and Interest Group Info (LeFurgy, Halpern)**
- **Advisory Committee meeting review**
- **Interagency staff lessons learned (LeFurgy, Halpern)**
- **Other business**
- **Proposed agenda and date for next Search Group meeting**

To: Barbara Semedo

June 15, 1994

cc: Ellyn Weiss
Al Knight
Rick Oborn
Lori Azim
Craig Lobdell

Fm: Mary Ann Freeman

Sub: Human Radiation Experiment Advisory Meeting (June 13-14, 1994)

Highlights:

Committee proposals for the final report include:
- o major focus on conventional medical experiments,
- o general summary of mass exposure incidents,
- o address compensation remedies for specific incidents,
- o Markey report experiments and other well-publicized experiments receive priority.

Committee currently has:
- o list of experiments from agencies,
- o headquarters policy documents.

Committee needs:
- o strategy,
- o sampling plan,
- o ethics perspective on scientific data gathering.

Handouts:

- o Tab F: Background materials from 5/18/94 Openness Symposium
- o Tab H: Ethics
- o Tab I: VA report
- o Tab J: DOD report
- o Tab K: DOE report

Press Attendance:

Asahi TV
Potomac TV
McClatchey News
Citizen Soldier
Wash Post (Gary Lee)
Eileen Welsome's research student
Scripps Howard/Albq. Tribune (Karen McFersun)
- o interviewed Ellyn Weiss 6/13

Future Meetings:

July 5 & 6
Vista Hotel

July 25/26
Mayflower Hotel

No August Mtg.

Advisory Committee on Human Radiation Experiments
1726 M Street NW, Suite 600, Washington, DC 20036
phone # 202/254-9795 fax # 202/254-9827

FAX COVER SHEET

NUMBER OF PAGES (INCLUDING COVER SHEET): 2

TO: Phil Caplan

FROM: Kris Crotty

DATE: 6/2/94

RE: meeting notice

(fax 456-6704)

MEMORANDUM

TO: INTERAGENCY WORKING GROUP AND SEARCH TEAMS

FROM: ADVISORY COMMITTEE STAFF

RE: NOTICE OF MEETING

The next Advisory Committee meeting will be June 13 from 9:30 a.m. to 5:30 p.m. and June 14 from 9:00 a.m. to 3:00 p.m. at the Ramada Plaza Hotel in the Washington Room, 10 Thomas Circle NW, Washington, DC.

Future meetings are set for the following dates with location to be announced:

Monday-Tuesday, September 12-13, 1994

Wednesday-Thursday, October 12-13, 1994

Monday-Tuesday, November 14-15, 1994

Thursday-Friday, December 15-16, 1994

Thursday-Friday, January 19-20, 1995

Thursday-Friday, February 16-17, 1995

Thursday-Friday, March 16-17, 1995

Monday-Tuesday, April 10-11, 1995

HUMAN RADIATION EXPERIMENTS SEARCH GROUP WEEKLY MEETINGS

URGENT FAX

DATE: MAY 12, 1994

TO: STEVEN GALSON, DOE, 202-586-0956
GLENN PODONSKY, DOE, 301-903-5492
BOB ALVAREZ, DOE, 202-586-3042
GARY ELLIS, HHS, 301-402-2071
ELLYN WEISS, CONSULTANT, 202-841-0460
GORDON SOPER, DOD, 703-695-0476
DENNY WISELY, DOD, 703-602-0046
KATHY HUDSON, DHHS, 202-690-7360
PHIL CAPLAN, WH, 202-456-2572
SUSAN MATHER, VA, 202-535-7572
D.A. HENDERSON, HHS, 202-690-7360

FROM: LORI AZIM, DOE, 202-586-5319 (PHONE)
202-586-0956 (FAX)

 # PAGES: 8 (NOT INCLUDING COVER)

***PLEASE MAKE CORRECTIONS TO MINUTES IF NEEDED AND RETURN TO LORETTA YOUNG (FAX 202-586-0956) BY 9:00 AM, MAY 19, 1994. ***

INTERAGENCY SEARCH GROUP
WEEKLY MEETING - MAY 3, 1994

AGENDA

- **Introductions (Galson)**
  - **Ellyn Weiss**
- **Project Sunshine/Chicago Baby Project, 1956 (Galson)**
- **Feedback from first Advisory Committee meeting**
- **White House update (Caplan)**
- **Agencies meetings with Advisory Committee staff updates**
- **Helpline issues**
- **Update on future Advisory Committee public meetings (Azim)**
- **Computer database - interagency linkage (Bailey, Wisely?)**
- **Other business**
- **Proposed agenda and date for next Search Group meeting**

DRAFT

Human Radiation Experimentation
Search Group Meeting
Minutes
May 3, 1994

In Attendance :

Steven Galson	Energy	202-586-6151
Lori Azim	Energy	202-586-5319
Glenn Podonsky	Energy	301-903-3777
Bob Alvarez	Energy	202-586-4640
Ellyn Weiss	Consult.	202-775-0600
Gary Ellis	HHS	301-496-7005
Denny Wisely	Defense	703-602-1365
Kathy Hudson	HHS	202-690-6811
Gordon Soper	Defense	703-697-5561
Susan Mather	Vet.Aff.	202-535-7182
D.A. Henderson	HHS	202-690-6811
Phil Caplan	White House	202-456-6704

Ellyn Weiss:

Assistant Attorney General Massachusetts/Environmental Protection (previous).
District of Columbia since 1978.
Harmon & Weiss, a public interest law firm (previous).
Practices as a litigator, primarily nuclear.
Currently taking leave from her partnership at Foley, Wagg & Elliott.
Worked at Department of Energy (DOE) during transition 1992/93.

Project Sunshine/Chicago Baby Project (Galson):

Approximately 64 babies were incinerated to determine radioactive fallout concentrations in their bodies. Babies were not all stillborn or premature babies. It is not known whether aborted fetuses were used. Marshall Islands was mentioned as a possible location for retrieving babies.

May have to go to individual doctors for records, because may not be in government archives.

These experiments are not directly part of the Advisory Committee Charter, but are sensational enough to generate interest.

Issue 1: Why were these experiments kept secret?

- o 1957 testimony by Dr. Libby discovered
- o Classified because weapons information was thought to be in the

DRAFT

records, but later found the documents were overclassified. Almost all were declassified in 1957.

- o Until two weeks ago, at least six were still classified. Reasons unknown, because all that was removed during declassification was the "CLASSIFIED" marking.

Issue 2: Were consents given? If so, were they adequate?

- o Galson thinks no, but Ellis thinks speculation is premature.

Could concern Defense because RAND was within the Air Force at the time.
HHS is searching, because co-funding was the norm.

Advisory Committee Meeting Agency Feedback:

HHS felt that the meeting went well and were impressed with the bonding among Committee members and the members' understanding of governmental priorities.

It is agreed that the Advisory Committee will not try immediately to expand the scope of their Charter because they have more than anyone could handle right now. The amount of work is immense.

- o Search Group should maintain good communication with the Committee to determine early where the Committee is going with expansion issue, so the Interagency Working Group (IAWG) can have open communication.
- o Advisory Committee should be convinced that agencies are doing their best to find everything.

Advisory Committee asked member Ken Feinberg to do a survey of compensation models. The White House will share research already in public arena with Feinberg to save the Committee's time.

White House Update (Caplan):

President Clinton thought the reception for the Advisory Committee and their staff went well. The President knows of the Committee's importance.

White House counsel can no longer be Advisory Committee Federal Advisory Committee Act (FACA) counsel. Needs to transfer to DOE General Counsel. Advisory Committee has been informed.

DRAFT

Agencies Meetings with Advisory Committee staff:

HHS: Mostly question answering. Informational briefing on the records collection effort. The staff was very interested in total documents searched and what documents have been examined. The staff was very interested in documents that describe the ethics of the time. So far, the staff has asked the agency for all information gathered thusfar. Staff especially intrigued by the intermingling of documents.

Advisory Committee has license to hold the government's feet to the fire and they are taking this opportunity very seriously.
Once Advisory Committee sees the agencies are forthcoming, they will begin to trust?

It is essential for the agencies to establish credibility, trust, etc.

Helpline issues:

Defense needs assistance in figuring out the software. Will send fax to Podonsky.

Veterans' Affairs is receiving 10-20 % MILITARY hospitals, not VA.

Future Advisory Committee Meetings (Azim):

Handout [attached].
No meetings in August.
Advisory Committee will do outreach to encourage public/subjects attendance at meetings.

Computer Database:

Defense database is going very well.
Agencies can get technical advice on the telephone from Defense.

Veterans' Affairs will issue directive to require each hospital to inventory documents until the Advisory Committee gives more direction.

DOE met with Defense and DOE is making progress within DOE but is having problems with interagency applications. Another agency meeting is needed to smooth wrinkles. Defense will take the lead. Invite Advisory Committee staff.

Other Business:

Marshall Islands:

Defense received letters from Dingell and Miller on this issue.
White House says to tell them that IAWG is not including Marshall Islands in the review because the experiments are not in the Charter, will open a Pandora's box,

DRAFT

and DOE has opened all Marshall Islands records to the public and the Marshall Islands government .
White House wants to review agency letters on this subject.
Advisory Committee/Ruth Faden must understand the rationale for the Marshall Islands decision. DOE will inform Faden/Committee May 4, 1994.

Literature Search:

More traditional research must be done (just sit down and read the literature).
Most of the experiments were in the literature.
In house literature should also be examined.

Money:

Costs for the next year must be determined. Agencies should individually work with the Advisory Committee on this.

Contractor Problems:

Justice has come up with a letter for agencies to use if problems with contractor cooperation arise. [attached]

Next meeting May 24, 1994 at 3:00 PM.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

FUTURE PUBLIC MEETING DATES

MAY 18-19, 1994	**WASHINGTON, DC** **RAMADA PLAZA HOTEL** **10 THOMAS CIRCLE**
JUNE 13-14, 1994	**WASHINGTON, DC**
JULY 5-6, 1994	**WASHINGTON, DC**
JULY 25-26, 1994	**WASHINGTON, DC**

Draft letter to Radiation Experiment Contractors/grantees

Dear _____ :

The purpose of this letter is to notify you of the Federal Government's ongoing investigation into the nature and scope of human radiation experiments conducted by or on behalf of the Federal Government since 1944, and to request formally that you locate and preserve any records of such experiments. We are contacting you because our records reflect that, pursuant to [select one: contract[s] with.../...grant[s] from] this department [or ____, a predecessor of this department,] your institution participated in human radiation experiments that fall within the scope of the investigation.

"Human radiation experiments" within the scope of the investigation includes experiments on individuals involving intentional exposure to ionizing radiation, excluding common and routine clinical practices, and experiments involving intentional environmental releases of radiation that were designed either to test human health effects or to test the extent of human exposure to ionizing radiation.

Information previously made public reflects a diversity of purposes for human radiation experiments conducted during the past fifty years. Many experiments advanced the state of medical and scientific understanding of radiation and resulted in enhanced use of radiation as a diagnostic and therapeutic tool. However, some experiments raise questions concerning the nature and purpose for the experiments, selection of test subjects, and whether test subjects gave informed consent to participate in the experiments.

The Clinton Administration has directed [this department], as a member of the Human Radiation Interagency Working Group, and in cooperation with an independent Advisory Committee on Human Radiation Experiments, to conduct a full and open investigation to obtain answers to these important questions. The results of the investigation will be considered in formulating an appropriate response to the subjects of such experiments.

Under Executive Order No. 12891 (January 15, 1994), the President directed all government agencies to provide the Advisory Committee on Human Radiation Experiments with information on such experiments. [This Department] has been an active participant in the proceedings of the Working Group and is assisting the Advisory Committee. In this role, we will need to examine any existing records that were generated in performance of the experiments. Any documents or records pertaining to human radiation experiments that you possess or the existence of which you know should be identified and preserved in order that they may be considered in the proceedings of the Human Radiation

Interagency Working Group and the Advisory Committee on Human Radiation Experiments. At a later date, we will make arrangements to obtain access to any such records in your custody or under your control.

If you have any questions concerning this matter, please do not hesitate to contact _____.

Thank you for your continued cooperation in this matter.

Sincerely yours,

202/456-6704

Advisory Committee on Human Radiation Experiments
1726 M Street NW, Suite 600, Washington, DC 20036
phone # 202/254-9795 fax # 202/254-9827

FAX COVER SHEET

NUMBER OF PAGES (INCLUDING COVER SHEET) : 3

TO: Phil Caplan

FROM: Jerry Garcia

DATE: May 17, 1994

RE: Agenda.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
MAY 18-19, 1994

The Ramada Plaza Hotel --Washington Room--10 Thomas Circle, NW--Washington, DC

AGENDA

Wednesday, May 18

9:00 AM	Call to Order *Philip Caplan, Special Assistant to the President for Cabinet Affairs*
9:05	Welcome and Orientation to Second Meeting *Ruth Faden, Chair*
9:10	Introductions: New Staff *Ruth Faden*
9:15	Briefing: Health Effects of Radiation *Henry Royal*
(9:50)	Committee Question and Answer Period *Moderator: Ruth Faden*
10:10	Briefing: Ethical Principles of Human Experimentation *Ruth Macklin*
(10:35)	Committee Question and Answer Period *Moderator: Ruth Faden*
10:50	Break
11:05	Briefing: History of Human Experimentation in the United States *Susan Lederer*
(11:35)	Committee Question and Answer Period *Moderator: Ruth Faden*
11:50	Review of Agency Ethical Standards: Progress Report *Staff Presentation*
	Committee Discussion *Moderator: Ruth Faden*
12:30PM	Lunch

1:45 Methodological Case Studies: "Cincinnati Experiments," "Plutonium Injection Experiments," and "Green Run"
Staff Presentations

Committee Discussion
Moderator: Ruth Faden

3:00 Break

3:15 Public Comment Period
Moderator: Ruth Faden

5:00 Meeting Adjourned

Thursday, May 19

9:00 AM Opening Remarks
Ruth Faden

9:05 Conflict of Interest Presentation
Kathleen Whalen, Assistant Counsel to the President

(9:25) Committee Question and Answer Period
Moderator: Ruth Faden

9:35 Methodological Review of Agency Data Collection Efforts: Department of Energy
Staff Presentation

Committee Discussion
Moderator: Dan Guttman, Executive Director

11:00 Break

11:15 Methodological Review of Agency Data Collection Efforts: Department of Health and Human Services
Staff Presentation

Committee Discussion
Moderator: Dan Guttman

12:30 PM Lunch

1:45 Committee Discussion: Committee/Staff Working Relationships and Formation of Subcommittees
Moderator: Ruth Faden

2:55 Closing Remarks
Ruth Faden

3:00 Meeting Adjournment

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING
JULY 25-26, 1994

Stouffer Mayflower Hotel✣1127 Connecticut Avenue, N.W.✣Washington, D.C. 20036

FINAL AGENDA

Monday July 25 (Colonial Room)

9:00 am	Call to Order
9:05 am	Welcome and Orientation to Meeting *Ruth Faden, Chair*
9:10 am	Briefing: Regulation of Contemporary Radioactive Drug Research (Tab L) *Barry Siegel, Professor of Radiology and Medicine and Director of the Division of Nuclear Medicine, Mallinckrodt Institute of Radiology*
(9:30 am)	Committee Question and Answer Period
9:45 am	Briefing: History of Radiation Protection Standards (Tab M) *Gil Whittemore*
(10:00 am)	Committee Question and Answer Period
10:10 am	Briefing: An Epidemiologic Perspective on Low-Dose Radiation Risks (Tab N) *Duncan Thomas*
(10:40 am)	Committee Question and Answer Period
10:50 am	Break
11:05	Update on Agency Data Collection Efforts *Ruth Faden*
11:20 am	Staff Reports: Early History (1940s and 1950s) (Tab F) Overview *Ruth Faden, Dan Guttman*

(11:25 am) History of Ethics Policies relating to Human Radiation Experiments
Jonathan Moreno

(11:30 am) "Functional" History of Human Radiation Experiments
Gregg Herken

(11:35 am) History of Government Regulation and Control of Human Radiation Experiments
Dan Guttman

(11:40 am) Committee Question and Answer Period

12:30 pm Lunch

1:45 pm New Staff Introductions, Staff Structure and Current Project Assignments (Tab C)
Jeffrey Kahn

1:55 pm Staff Report: Experimental Grouping -- Total Body Irradiation (Tab H)
Gary Stern, Ron Neumann, Dan Guttman

(2:05 pm) Committee Question and Answer Period

2:30 pm Staff Report: Abstraction of "Markey Experiments" and Department of Energy Experiments (Tab I)
Gil Whittemore, Jonathan Engel, Dan Guttman

(2:40 pm) Committee Question and Answer Period

3:10 pm Break

3:30 pm Public Comment Period (Tab P)

5:00 pm Meeting Adjourned

Tuesday, July 26 (State Room)

9:00 am	Opening Remarks *Ruth Faden*
9:05 am	Approval of Minutes of July 5-6 Meeting *Ruth Faden*
9:10 am	Interim Report *Ruth Faden*
9:20 am	Reports from Subcommittees (Tab E)
10:45 am	Break
11:00 am	Committee Discussion of Goals and Objectives of the Advisory Committee, Experiment Groupings, and Restructuring of Committee Members' Work *Moderator: Ruth Faden*
12:30 pm	Lunch
1:45 pm	Discussion of Goals and Objectives of the Advisory Committee, Experiment Groupings, and Restructuring of Committee Members' Work (continued) *Moderator: Ruth Faden*
3:00 pm	Meeting Adjourned

HUMAN RADIATION EXPERIMENTS SEARCH GROUP WEEKLY MEETINGS FINAL MINUTES

DATE: MAY 24, 1994

TO: **ELLYN WEISS, DOE, 202-586-6010**
PHIL CAPLAN, WH, 202-456-6704
ANNA MASTRIOANNI, ACHRE, 202-234-9827
TARA O'TOOLE, DOE, 202-586-0956
STEVEN GALSON, DOE, 202-586-0956
HEATHER STOCKWELL, DOE, 301-903-4677
GLENN PODONSKY, DOE, 301-903-5492
JIM WARE, DOE, 301-903-6338
DENNY WISELY, DOD, 703-602-5971
GORDON SOPER, DOD, 703-695-0476
MARGIE SULLIVAN, DOD, 703-695-0864
D.A. HENDERSON, DHHS, 202-690-7360
SUSAN CRANDALL, DHHS, 202-690-7360
GARY ELLIS, DHHS, 301-402-2071
WENDY BALDWIN, DHHS, 202-690-7360
HAROLD GRACEY, VA, 202-535-8667
FRANCIS HERBIG, VA, 314-289-7058 or 6496
MILTON GROSS, VA, 313-930-5864

FROM: **LORI AZIM, DOE, 202-586-5319 (PHONE)**
202-586-0956 (FAX)

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Search Group Agenda

May 24, 1994
3:00 - 4:30, DOE Rm. 7A-097

1. **Recent press coverage (Guttman, Caplan, others)**

   Prevention activities

2. **Addressing concerns of constituents that are out of the scope of the Advisory Committee (O'Toole)**

   Congressional responses

3. **Help-line referrals (Weiss)**

4. **Charity Hospital hearing (Weiss)**

5. **Defense Dept. meeting with Advisory Committee staff (Wisely)**

6. **Next meeting date**

INTERAGENCY SEARCH GROUP
WEEKLY MEETING - MAY 3, 1994

AGENDA

- **Introductions (Galson)**
  - **Ellen Weiss** – Manager of Human Experimentation Project
- **Project Sunshine/Chicago Baby Project, 1956 (Galson)**
- **Feedback from first Advisory Committee meeting**
- **White House update (Caplan)**
- **Agencies meetings with Advisory Committee staff updates**
- **Helpline issues**
- **Update on future Advisory Committee public meetings (Azim)**
- **Computer database - interagency linkage (Bailey, Wisely?)**
- **Other business**
- **Proposed agenda and date for next Search Group meeting**

THE WHITE HOUSE

WASHINGTON

April 11, 1994

MEMORANDUM FOR DISTRIBUTION

FROM: Phil Caplan

SUBJECT: **CHANGE IN MEETING -- HUMAN RADIATION**

Due to an unavoidable scheduling conflict, the meeting originally scheduled for Tuesday, April 12 at 4:00 PM ***has been changed to Friday, April 15 at 3:00 PM*** in room 472 OEOB.

Please fax the list of attendees from your agency to my office by 5:00 PM **Thursday** (456-6704-fax). Be sure to bring a legislative affairs person and try to limit the total number of people to five. If you need to bring more people, please give me a call.

Thank you.

DISTRIBUTION:

		Phone:	Fax:
DOE:	Rich Rosenzweig	586-6210	586-7644
DOE:	Tara O'Toole	586-6151	586-0956
DOD:	Rudy DeLeon	703/697-8388	703/697-9080
DOD:	Gordon Soper	703/697-5161	703/695-0476
VA:	Harold Gracey	535-8900	535-8667
HHS:	Kevin Thurm	690-6133	690-7755
NASA:	Chris Dunn	358-1827	358-2810
DOJ:	Nancy McFadden	514-9500	514-0238
Treas:	Alicia Munnell	622-2200	622-2633
CIA:	David Gries	703/351-2698	703/243-8343

WH:

George Stephanopolous, 1FL WW
Mark Gearan, 1FL WW
Phil Lader, 1FL WW
Bill Burton, 178 OEOB
Pat Griffin, 2FL WW
Tracey Thornton, EW
Jack Gibbons, 424 OEOB
Mrc Greenwood, 432.5 OEOB
Holly Gwin, 428.5 OEOB
Carol Rasco, 2FL WW
Marcia Hale, 2FL WW
John Podesta, GFL WW
Joel Klein, 2FL WW
Steve Neuwirth, 130 OEOB
George Tenet, NSC, 300 OEOB
Sylvia Matthews, 2FL WW
T.J. Glauthier, 246 OEOB
Ginny Terzano, 1FL WW

Elgie Holstein
2330 EOB
x65370

THE WHITE HOUSE

WASHINGTON

April 7, 1994

MEMORANDUM FOR DISTRIBUTION

FROM: PHIL CAPLAN

SUBJECT: Human Radiation Interagency Working Group

In advance of the Independent Advisory Committee Meeting on April 21-22, we will reconvene the Working Group for a meeting on Tuesday, April 12, 1994, at 4:00 PM in Room 180 OEOB.

We need to discuss a host of issues including the Advisory Committee meeting, congressional briefings, the work of the compensation subcommittee and the status of document collection.

Please fax the list of attendees from your agency to my office by 5:00 PM Monday (456-6704-fax). Be sure to bring a legislative affairs person and try to limit the total number of people to five. If you need to bring more people, please give me a call.

Thank you.

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George Tenet, NSC, 300 OEOB
Sylvia Matthews, 2FL WW
T.J. Glauthier, 246 OEOB
Ginny Terzano, 1FL WW

MEMORANDUM

TO: Christine Varney

FR: Phil Caplan

RE: Human Radiation - Misc. Issues

March 31, 1994

A lot has happened in the last two days so I thought it might be useful to summarize for you:

Operations Committee

The operations committee meets once a week in Tara's office. I was scheduled to go on Tuesday, but, at the last minute, Grace called a Goals 2000 meeting and I could not go. I will go to each meeting and then download to you and Tracey. In addition, the congressional contacts at each agency must be much more familiar with what is going on in their building. Therefore, I am going to suggest to each Chief of Staff that they convene weekly meetings at each agency. (Most are doing bi-weekly meetings, which may be good enough, but it will be helpful to give a gentle White House push.) Then Tracey will be able to get info from her congressional committee as well. The main culprit in this respect is DOE. Their congressional person was unprepared at the last congressional briefing in the Indian Treaty Room.

Congressional Briefing

As a result of the last briefing (it was supposed to be for "appropriations staff," but a whole range of people showed up), the Hill has gotten stirred up a bit and there is now a need to do another round of briefings. DOE is pushing to have it sooner (because they took the heat in the briefing) but nevertheless, we should try and do it before the Advisory Committee meeting on the 21-22. It will be a replay of the early briefings we did in Room 450 and you, Tara, Gordon, etc. will need to be there. Tara will hate this because she feels all she does is brief people, but the consensus of the congressional group is that it is necessary.

Working Group

I think it would be a good idea to reconvene the entire Working Group sometime before the Advisory Committee meeting. A lot has happened in the last month or so, and it would be

useful to do some planning before the 21-22. I suggest 4:00 pm on Tuesday, April 12.

Legal Issues

There are several issue that are still percolating that I need to speak with Steve Neuwirth and DOJ about:

-I have sent Steve a copy of the DOJ language on contractor destruction of documents. Once he has read it, we can then send it out.
-Other contractor issues:
  -what authority does the government have to bring action against a contractor if the contractor refuses to hand over documents?
  -what protections, if any, are available to people who conducted experiments?
  -what protections, if any, are available to entities (universities, hospitals, etc.) that sponsored experiments?

Ben 514 3389

Pat Ohyms 501-7040

Compensation Committee

T.J. Glauthier's committee has done an absolutely great job in preparing an options paper for the Working Group to consider. He would like to present it to the Working Group; I suggest that it be an agenda item for the April 12 meeting. We need to be careful that the compensation committee does not get too far out front of any part of this whole process. After their paper is complete, the committee will essentially be on hiatus until the Advisory Committee is able to get some work done. Then the Working Group (which presumably will have had time to study T.J.'s options paper) can take some of the information from Advisory Committee and begin to work with Congress. Jerry Waldron (Markey's guy) thinks this needs to happen before Congress goes home in September/October.

One way that T.J's committee can be very helpful is to come up with a list of questions that the Advisory Committee must answer before the Working Group can address some of the issues in the options paper.

Advisory Committee

-come over early tomorrow to discuss:
  -courtesy calls for Glenn, Kennedy. Markey, Dingell by Ruth Faden
  -executive director
  -general operating procedures (quickly and efficiently!)
  -liaison between Working Group/DOE/White House and Advisory Committee
  -POTUS involvement in 21-22

April 21-22

-What is the agenda of the meeting?
-Is there a communications strategy
-Is there a congressional strategy?
-Logistics

Problems:

-Hotline

I found out yesterday that none of the agencies have received any downloaded information from the Hotline. Tara told me early this week that it was her understanding (and it has been mine as well) that each and every week for the past 4-6 weeks, each agency was getting a download of calls. But according to the agencies yesterday, they have received nothing. Tara is on the road so I have not been able to ask her about this, but we need to solve this immediately. I will begin to do so tomorrow.

-Letters

Yesterday I was also told that DOE sent a batch of 250-500 letters to Hotline callers telling them that "their file" was sent from DOE to HHS and that "HHS was now responsible for their file" and that they should call "1800-4-CANCER" for further information. First, no one has any files. Second, this is completely insensitive, not to mention inaccurate. Third, it is unacceptable. According to HHS, the letters have been stopped. I will also raise this with Tara when she gets back. This incident worries me about the management of the DOE response..

Action list:

-weekly/bi-weekly meetings at each Agency
-Tuesday, April 11, reconvene Working Group for update and prep of Advisory Committee meeting
-presentation of Compensation Options Paper to Working Group
-list of questions for Advisory Committee to answer
-several contractor related issues to be answered by DOJ
-agenda and strategy for April 21-22.
-problem solving (Hotline and letters)

- Council Meeting w/ Members
during 21-22

HUMAN RADIATION EXPERIMENTS SEARCH GROUP WEEKLY MEETINGS

DATE: 4-8-94

TO:
PHIL CAPLAN, WH, 202-456-6704
DAN GUTTMAN, ACHRE, 202-234-9827
TARA O'TOOLE, DOE, 202-586-0956
STEVEN GALSON, DOE, 202-586-0956
HEATHER STOCKWELL, DOE, 301-903-4677
GLENN PODONSKY, DOE, 301-903-5492
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GARY ELLIS, DHHS, 301-402-2071
WENDY BALDWIN, DHHS, 202-690-7360
HAROLD GRACEY, VA, 202-535-8667
FRANCIS HERBIG, VA, 314-289-7058 or 6496
MILTON GROSS, VA, 313-930-5864

FROM: LORI AZIM, DOE, 202-586-5319 (PHONE)
202-586-0956 (FAX)

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Human Radiation Experimentation
Search Group Meeting
March 29, 1994

In Attendance:

Tara O'Toole	Energy	(202) 586-6151
Steven Galson	Energy	(202) 586-6151
Lori Azim	Energy	(202) 586-6151
Heather Stockwell	Energy	(301) 903-3721
Harold Gracey	Vet.Aff.	(202) 535-8900
Glenn Podonsky	Energy	(301) 903-3777
James Ware	Energy	(301) 903-5982
Gary Ellis	HHS	(301) 496-7005
Margie Sullivan	Defense	(703) 693-0566
Kathy Hudson	HHS	(202) 690-6811
D.A. Henderson	HHS	(202) 690-1365
Denny Wisely	Defense	(703) 602-1365
Gordon Soper	Defense	(703) 697-5561

Group wants "Hunt Club" changed to "Search Group"

Three Tiers of Records Search (O'Toole)

1. Agency-specific document search
   Examples: Documents in agency archives
2. Literature search
   Examples: Medical and scientific, non-scientific (ie: Atomic Energy Commission [AEC] Isotope List)
3. Search Group search
   Examples: Day to day document searches
   Coordination of interagency searches
   Priority searches (ie: Cincinnati experiments - These should be coordinated)
   Advisory Committee on Human Radiation Experiments requests

Group keeps abreast of all agency records search activities

Communication, both internal, interagency and intergovernmental must be effective (O'Toole)

Agency Congressional/Intergovernmental Affairs, Public Affairs offices should meet regularly with Human Experimentation staff for updates, then they must pass on information in an orderly, planned fashion to the White House, Congress, etc.

Agency Updates:

Health and Human Services

* Directions, problems, probes are being discussed.
* There is no perfect search strategy, so they will combine flawed strategies for a better result.
* No large dragnet set out yet, except SF-135 final filing form for "retired" documents. The forms are searched using relevant keywords to discover pertinent data. This is too broad, but is a start.
* Additionally, current employees are being debriefed, although their recall is uneven due to length of time, etc.
* NIOSH, CDC have found old AEC Records.
* So far, four identified sets of experiments.
* Agency not doing literature searches until everyone is aboard.

Defense

* Trying to err on the side of inclusion in their document search.
* An "all hands" letter was sent.
* Only the Services and a few of the Defense agencies are relevant offices.
* Defense wants clarification of the scope of experiments contained in the Christine Varney memo and the Advisory Committee charter. [O'Toole asked for a list of their problems.]
* Any experiment within the "Varney definition" will have a one page detailed summary of the applicable file (ie: an abstract).
* Defense has found no NEW experiments, only evidence of previously known experiments, which were part of the public record through press accounts, Congressional Markey Report, etc. Everything had already been declassified.
* Examples: Air Force has 106 possible experiments, Army has 32 (mostly Dugway), Navy has 223, and Defense Nuclear Agency has 17. Many of these numbers will end up post-1974 or reviewed by Internal Review Boards and OK. Better to err on the side of inclusion.
* Some records are now ready to go to the Advisory Committee, more will be ready later.
* "All hands" meetings are held every two weeks for information and updates.
* Comprehensiveness, integrity are ensured by documenting the search and clear accountability (O'Toole). Defense has Three Star oversight in each service, who sign off. O'Toole believes there should be clear accountability and that EVERY step of the search MUST be documented. A possibility is having a group within the Search Group conduct quality control of the searches. We want to augment information, if possible. Interagency coordination is vital. The information base must be seamless.

* Soper will check the status of the computer contractor provided by Defense to set up and maintain a common database for the agencies.
  - Search Group should set up protocols for information sharing.
  - Example, Energy has problems with medical personnel who were involved in experiments being involved in the current search at (at least) one Energy site.

Veterans' Affairs

* Two nets cast:
  1. Radioisotope research 1947-1960
  2. Radioisotope research 1960-present.
* VA knows what documents they have and where they are located but individual records have not been examined.
* Radiation therapy experimentation is a probable third net they will cast in the future.
* Agency is receiving letters from the general public and questions from veterans who participated in atmospheric testing.
* The task is huge and Gracey feels that the agency is not moving fast enough.
* Will begin inventorying when a common form is adopted.
* Search strategies should be mapped out in the Advisory Committee document to the Interagency Working Group. In the Advisory Committee's final report appendices should be included that show the document searches and how they were conducted.
* The purpose of the Search Group is to discover a proactive way to track items that appear hot.

Energy

* 470,000 cubic feet of documents to go through in the beginning. So far, approximately one-fourth are relevant (not including medical records at Brookhaven).
* Records retrieval/inventorying teams out in the field the first week of April.
* Abstracts of 1,000 relevant documents and document availability on CD ROM at the end of April.
* 270,000 records are currently available on atmospheric testing.
* Records retrieval teams will both examine the large groups of documents and address possible conflicts of interest.

Priorities

Defense has been asked to testify at field hearing conducted by a subcommittee of the Judiciary Affairs Committee in Cincinnati, Ohio on April 11, 1994. Dr. Saenger has been asked to testify. Only confirmed witness is Defense (Soper). Dr. Saenger has asked Defense for information, but there is not much to examine. Defense has examined contracts, reports, etc. and would like HHS to be fully briefed and to aid in the documents' review.

Should researchers be interviewed (such as Dr. Saenger)? O'Toole thinks not, as Ruth Faden wants the Advisory Committee to conduct interviews, although she is concerned about the lack of subpoena power. It was decided that the Advisory Committee should do the interviewing but agencies can and should sit in, as the Committee meetings are public under the Federal Advisory Committee Act.

What are the priorities for the Search Group? Too much press focus? Advisory Committee needs and desires? (No decision reached, just questions to think over.)

Freedom of Information Act requests should be kept in mind and each agency's offices of Public Affairs and Congressional/Intergovernmental Affairs should consistently be updated and informed of these issues. We do not want to be merely reacting to the press (nor should the Advisory Committee).

Proposed agenda for next week, April 5, 1994 at 2:30 PM:

Interactions with Advisory Committee
Quality Assurance strategies for document search
Computerized database
Timing of informational releases to public
Toll free telephone number strategies
Priorities

INTERAGENCY SEARCH GROUP

Name	Agency	Phone	Fax
Dan Guttman	Advis.Comm. Hum.Rad. Exp.	202-254-9797	202-254-9827
Phil Caplan	WH	202-456-2572	202-456-6704
Denny Wisely	DOD	703-602-1365	703-602-5971
Gordon Soper	DOD	703-697-5561	703-695-0476
Margie Sullivan	DOD	703-693-0566	703-695-0864
D.A. Henderson	DHHS	202-690-6811	202-690-7360
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Francis Herbig	VA	314-289-6423	314-289-7058 or 6496
Milton Gross	VA	313-930-5858	313-930-5864

LITERATURE SEARCH GROUP

Name	Agency	Phone	Fax
Milton Gross	VA	313-930-5858	313-930-5864
Heather Stockwell	DOE	301-903-3721	301-903-4677
Don Linberg	DHHS	301-496-6221	301-496-4450

HUMAN RADIATION EXPERIMENTS SEARCH GROUP WEEKLY MEETINGS

DATE: 4-13-94

TO: **PHIL CAPLAN, WH, 202-456-6704**
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INTERAGENCY SEARCH GROUP
WEEKLY MEETING - APRIL 5, 1994

AGENDA

Interactions with Advisory Committee on Human Radiation Experiments

- **Update on Advisory Committee staffing**

Toll free telephone number strategies

Quality Assurance strategies for document search techniques

Computerized database

Timing of information releases to public

Search priorities

Agency updates

Human Radiation Experimentation
Search Group Meeting
Minutes
April 5, 1994

In Attendance:

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Tim Condon	NIH/HHS	301-443-6036
Kathy Hudson	HHS	202-690-6811
Denny Wisely	Defense	703-602-1365
Gordon Soper	Defense	703-697-5561

Update on Advisory Committee Staffing (Galson)

Dan Guttman, Executive Director
Anna Mastroianni, Director Committee Affairs, Deputy Staff Director, Senior Policy and Research Analyst
Jeff Kahn, Acting Staff Director
Steve Klaidman, Public Affairs Director

Interactions with Advisory Committee

A meeting is needed between Search Group and Advisory Committee staff and Ruth Faden before the Advisory Committee's first meeting on April 21, 22, 1994.

Congressional and press briefings by the Search Group are needed before the public meeting (no date is yet set). Could cover:

- Number of documents examined
- Number of documents relevant to human radiation experimentation
- Any alarming findings
- What agencies are doing to ensure no conflict of interest, comprehensiveness and integrity of search
- What agencies are doing with the documents

Tentative activities for Advisory Committee public meeting:

- April 21: Breakfast greetings with Cabinet Secretaries and Interagency Working Group
  Press Availability
  Briefings
  Evening reception with the President
- April 22: Search group briefings on records collection activities

Advisory Committee meetings are open to the public.

Advisory Committee may not make specific compensation decisions. They can make broad recommendations on compensation strategies, relevant to groups of experiments.

Advisory Committee plans to meet monthly. Committee staff will do most of the research and review.

Who will "charge" the Committee, if Vice President Gore does not? O'Toole will find out.
Christine Varney?
Hazel O'Leary?

Packages containing information in a uniform format must be prepared for the press, public and others who attend the public meeting. O'Toole will provide. Could include:
Status of records collections activities at each agency
Helpline information
Documents examined
Documents found
Interactions with Advisory committee

Briefing materials, oral and written, for the Advisory Committee

Briefing materials must be in a uniform format.

We should ask Advisory Committee to help us with specific problems we are having. (Hudson)

Each agency must provide a coherent, comprehensive status of ongoing information gathering activities and the information retrieved. (Soper)

Agencies should have a reasonable number of records to give to the Advisory Committee on April 21, 1994 at the public meeting. Also consider giving Advisory Committee materials they can sink their teeth into, such as articles which may involve experiments.
- Soper offered University of Cincinnati experiment records from Defense and possibly information on native Alaskan experiments.
- O'Toole offered plutonium experiments and Markey records.

O'Toole will discover what Advisory Committee wants for their briefing books.

Advisory Committee/Ruth Faden is in charge of public meeting agenda.

Oral briefings:
- Spokespersons could be assigned on each topic *or* each agency can make a presentation.

- O'Toole prefers individual agency presentations on paper in briefing book and spokespersons for oral presentations.
  - Agencies should not orally discuss experiments because of liability issues and agencies should not second guess the Advisory Committee.

- Soper prefers individual agency oral presentations. Another possibility is that the primary four agencies (DOE, DOD, VA, HHS) could each speak, for brevity's sake.

- Questions for oral presentations:
  1. What agencies have done, found
  2. What agencies need from Advisory Committee
  3. What agencies face in their records searches
  4. Conflicts

Toll free telephone number strategies

Problems existed with the referral decision tree and HHS received the lion's share of the referrals. Now, algorithms have been changed and all is well.

Military calls are divided:

VA - Callers who have filed or want to file claims for benefits or were exposed while a patient in a VA hospital

DOD - Any other military callers

Quality Assurance strategies for document search techniques

Need integrity of documents and comprehensiveness of search. (Wisely)

Search Group must find out how Advisory Committee will know the study is complete?

Quality Assurance should be top item for meeting between Advisory Committee and Search Group.

Computerized database (Wisely)

Three needs to be met to create a database:

1. Reporting formats need to be standardized.
2. Reported information needs to be as complete and comprehensive as possible given time, money, and personnel constraints, and the condition of the records serving as the basis of the report.
3. The reporting format has to be compatible with existing hardware and software, and easily transferable by electronic means to facilitate reporting and information management.

Technical staff on Advisory Committee should contact Defense for demonstration.

Additionally, Defense is sorting their information by various populations.

Timing of information releases to public and press

DOE has problems with timing.

Defense problems include investigative reporters knowing more than the agency does. Defense not getting many Freedom of Information Act (FOIA) requests.

Search Group should discuss this issue with Advisory Committee staff, so no FOIA violations or other legal violations occur.

Advisory Committee should be in close contact with other investigating committees, such as those at universities (eg, MIT and UCSF).

Search priorities

Nothing to report.

Agency updates

Defense

* Has located University of Cincinnati medical files search.
  - University will not release.
  - Defense must talk to their General Counsel because Advisory Committee will want these files.

Miscellaneous

White House must coordinate between Search Group and Interagency Working Group.

Phil Caplan of White House Cabinet Affairs will begin attending Search Group meetings to aid communication.

Assignments

O'Toole: Information kit for press, public, Congressional staff
Discuss public meeting agenda with Ruth Faden
Ask Advisory Committee staff to contact Admiral Wisely for computer needs
Set up Search Group meeting with Advisory Committee staff and Ruth Faden
Determine Advisory Committee needs for briefing book

Ellis: General information on informed consent
General information on benefits of radiation in medical research