EXECUTIVE SUMMARY
ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS
MEETING OF 5-6 JULY 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments conducted its fourth meeting on 5 and 6 July 1994, at the Vista Hotel, 1400 M Street, N.W., Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 5 JULY 1994

The Advisory Committee was called to order by Mr. Philip Caplan, Special Assistant to the President for Cabinet Affairs. The Committee chair, Dr. Ruth Faden, stated that the Committee had four main objectives for the next two days: Reviewing staff efforts to date and providing guidance on how best to allocate staff effort in the future; briefing staff and committee members on areas of importance; listening to public comment during the public comments period; and moving the work of the Committee forward.

3.0 STAFF BRIEFING: UPDATE ON ETHICS DATA COLLECTION EFFORTS

Committee staff member Jonathan Moreno provided an update on the status of the agency's ethics data collection effort.

3.1 Mr. Moreno concentrated on the Department of Defense (DoD) and the Department of Energy (DOE)/Atomic Energy Commission (AEC).

3.1.1 The focus of the DoD search revolved around the 1953 Secretary of Defense Wilson Memorandum and seemed to indicate that prior to 1953 there was a regulatory vacuum regarding use of humans in radiation experimentation.

3.1.2 There also were indications that the tenets set down in the 1953 Wilson Memorandum were not excepted by all DoD components and that there was a great degree of concern about Soviet progress in the areas of radiological warfare (RW), biological warfare (BW) and chemical warfare (CW).

3.1.3 One area of DOE research centered on the debate and disagreement concerning the level of and necessity for fully informed consent on the part of human experiment subjects.

3.1.4 Another area of DOE research centered on statements made by AEC officials in the early 1950's that the Commission was not participating in human use experimentation, when in fact this was not true.

4.0 SUBCOMMITTEE REPORT: ETHICS DATA COLLECTION

The Committee chair, Dr. Faden, provided a briefing on the progress of the Ethics Data Collection Subcommittee on behalf of that Subcommittee's chair, Dr. Ruth Macklin, who was not present at this series of meetings.

4.1 Dr. Faden stated that the Subcommittee has focused on continuing the ethics data collection.

4.1.1 Dr. Faden indicated that there was an immediate need for information on the practice of using humans in biomedical and ionizing radiation research.

4.1.2 Information on the historical practice of research and its relationship to historical policy for conducting research was also needed.

4.1.3 The Subcommittee proposed conducting an oral history project with the intent of elucidating actual practices (as compared to the policy guidelines) of investigators. The project would entail identifying 15 to 20 investigators, approximately 10 in the field of ionizing radiation and 10 from another field, focusing on practices in the 1940's and 1950's. The project would be conducted by experienced oral historians and guided by an expert panel consisting of oral historians, biomedical ethicists, and other experts from pertinent fields.

4.1.4 The Subcommittee was also concerned with the portion of the Advisory Committee's mandate that called for an evaluation of the current state of ethical policies and practices related to human experimentation.

4.1.5 The Subcommittee proposed that, in light of the absence of information on current practices, a second project be initiated to review a sample of protocols currently being implemented that involved ionizing radiation and another nonradiation related field. Funding agencies would be asked to provide lists of grant proposals to the Committee for review by Committee members and staff. The purpose of the project was to answer questions such as the following

- To what extent are humans exposed to more than minimal risk during research?
- Is there an offsetting benefit for the subject to compensate for the risks incurred?
- Is there any evidence that current informed consent procedures are adequate?
- Are 'vulnerable' groups being especially singled out for use in experimentation?

Dr. Faden proposed this Project be led by Dr. Katz.

4.1.6 The Subcommittee proposed a third project that would entail interviewing patients that may be involved in experiments. The plan is to identify 10 institutions (five academic

institutions and five Government agencies) that received the highest volume of Federal funds for research involving humans and inviting these institutions to participate in this project. The focus of the project would be on medical/radiological oncology and would involve interviewing patients in waiting rooms that may or may not currently be subjects in research projects. The project would involve getting permission to review patient/subject medical files and verifying any information collected during the interview with the patient/subject primary care giver (at that institution).

4.1.7 The Subcommittee called for these proposals to be approved. The oral history project was approved if a panel of experts believed it could be validly conducted. The proposal to review a sampling of current protocols was also approved. The majority of the Committee discussion period focused on the feasibility and practicability of the third proposal – to interview possible patients that may be involved in research. The discussion focused on problems of patient confidentiality, the degree of likelihood that an adequate sample of subjects could be found by interviewing patients in waiting rooms; and whether or not this proposal could be later seen as violating the standards of ethics that the Committee was created to review.

4.1.8 The Committee decided to send this proposal back to Subcommittee for more preliminary review.

5.0 SUBCOMMITTEE REPORT: SCOPE AND PRIORITIES SUBCOMMITTEE

Committee member Dr. Duncan Thomas briefed the Committee on the status of the Scope and Priorities Subcommittee.

5.1 The Subcommittee focused on the issue of intentional releases, especially attempting to draw the limits of what was in the scope of the Committee and what was not.

5.1.1 The first priority was the intentional releases identified in the Executive Order that established the Committee. These were definitely within the scope of the Committee.

5.1.2 There were, however, a large number of 'borderline' incidences that were not clearly within the scope of the Committee.

5.1.3 The main issue the Subcommittee focused on when evaluating these 'borderline' incidents were

- Whether harm was done
- Whether there were secret aspects to any of these incidents
- What type of information was provided to the subjects
- To what extent the experiment was conducted for the purpose of researching human health effects of radiation.

5.1.4 The first group examined was Marshall Islanders. The question to be answered by the Committee was whether testing done there constituted a human radiation experiment.

5.1.5 The second group examined was atomic veterans. This group was divided into two sub-categories. First, those involved in clean up activities (i.e., ship and aircraft decontamination). It was thought by the Subcommittee that this category fell under occupational exposure, not under the scope of the Committee's mandate. Second, any experimentation involving human performance measurements after exposure to radiation. The feeling of the Subcommittee was that some of these exposures were very experimental in nature and may well fall under the scope of the Committee.

5.1.6 The third group examined was Uranium miners. The Subcommittee believed that it was difficult to see any experimental aspects related to this group, although deep ethical questions are raised in this area.

5.1.7 The fourth group examined was the 'Down-Winders'. The feeling of the Subcommittee was that this group was not an experimental category, but questions were raised about the quality of information provided to the public and the possible misrepresentation of data.

5.1.8 The last group examined was the Department of Energy (DOE) nuclear facility workers. The feeling of the Subcommittee was that this group was clearly occupational, and not within the Committee's scope.

5.1.9 The ensuing discussion focused on the desire of Committee members to fully review all available information before eliminating groups, the need to determine what other information and other groups were still "undiscovered" and the need for the Subcommittee to begin to focus on the area of Committee priorities.

6.0 SUBCOMMITTEE REPORT: COLD WAR SUBCOMMITTEE

Committee member Dr. Maryanne Stevenson briefed the Committee on the progress of the Cold War Subcommittee.

6.1 The Subcommittee had focused on developing methodological aids through which the large quantity of information the Committee was receiving could be examined.

6.1.1 The first methodological aid was the development of a form. The purpose of the form was to sharpen and define the criteria that are of interest in respect to each experiment.

6.1.2 Dr. Faden stated that the Committee was free to critique the form after the next days briefing on the Pilot Project which used the form as a tool for digesting information.

6.1.3 The second methodological aid was the development of 'groupings' of experiments. The idea was to develop groups of experiments that could be examined together because they shared common features. These groupings were, effectively, a working classification scheme.

7.0 SUBCOMMITTEE REPORT: OUTREACH SUBCOMMITTEE

The chair of the Outreach Subcommittee, Dr. Reed Tuckson, was unable to make the Committee meetings because of overseas travel complications. Committee staff member Mr. Steve Klaidman briefed the Committee on Dr. Tuckson's behalf.

7.1 Mr. Klaidman stated that the issues before the Outreach Subcommittee were of a very time-sensitive nature.

7.1.1 The major issue before the Subcommittee was how many field meetings were needed and where these meetings were to take place.

7.1.2 The Subcommittee evaluated this issue with three criteria in mind

- Making the Committee available to a concerned public
- Making information and perspectives of interested groups available to the Committee
- Help to publicize the Committee's work.

7.1.3 The Subcommittee proposed that three full-scale Advisory Committee field meetings be held, plus four field meetings with panels of approximately three Committee members each.

7.1.4 The cities proposed for the full-scale meetings were San Francisco, Atlanta, and Chicago. These cities were chosen because of geographic spread and because no large-scale human radiation experimentation took place in close proximity to these locations.

7.1.5 During the following Committee discussion period a counterproposal was offered calling for having only panel field meetings, possibly linked into a full-scale Committee meeting by video-conferencing.

7.1.6 The issue was returned to the Subcommittee for review with direction to at least reduce the number of proposed full-scale field hearings and an examination of the idea of only field panel meetings, augmented by video-conferencing.

8.0 NEW STAFF INTRODUCTIONS, STAFF STRUCTURE AND CURRENT PROJECT ASSIGNMENTS

Committee staff member Mr. Jeffrey Kahn introduced three new staff additions to the Committee.

8.1 Because of time constraints, staff structure and current project assignments were only briefly discussed.

9.0 COMMITTEE DISCUSSION OF GOALS AND OBJECTIVES OF THE ADVISORY COMMITTEE

Committee chair Dr. Faden and Executive Staff Director Mr. Dan Guttman briefed the Committee on the development of a draft document examining the goals and objectives of the Committee.

9.1 This document was an outgrowth of the assignment to Dr. Faden and Mr. Guttman to produce a vision document that could be used to solidify the Committee's sense of what they were doing.

9.1.1 The goal of Tuesday's briefing was to present an outline, for the Committee's benefit, so that an in-depth discussion could take place on Wednesday. In effect, this document would be the working outline for the Committee's interim and final reports.

9.1.2 The document was arranged in three sections: *Foundation*, *Focal Point, Experiments and Intentional Releases*, and *Looking to the Future*.

9.1.3 In the *Foundations* section, a subsection titled *Ethical Principles and Practices Related to Human Use in Experimentation* was envisioned. This section would focus on what the policies related to ethical procedures were, as well as what the actual practices were.

9.1.4 In the *Focal Point* section, the intent was to put various pieces together using groupings and themes. The groupings were scheduled to be discussed on Wednesday so they were not examined, however, three basic themes were identified:

- Exploitation and power differential — basically the use or misuse of vulnerable populations
- The idea of openness and full disclosure — this theme is intended to convey to the public the idea that this issue was exhaustively examined
- The level of risk that subjects involved in these experiments were exposed to.

9.1.5 In the *Looking to the Future* section, the issue of remedy was to be examined, as well as the aspect of the changing needs of national security.

9.1.6 Dr. Faden stated that the desire was to shape staff structure along the lines of the final (or near final) version of this document, because it would embody all of the issues the Committee wanted examined. It was also made clear that this document would not be finalized for quite some time, and she envisioned a lot of restructuring along the way.

10.0 PUBLIC COMMENT PERIOD

Three groups participated in the public comment period, a representative of the Government of the Marshall Islands, a representative of the people of Bikini, and a representative of the National Committee for Radiation Victims.

11.0 SUMMARY OF MEETING, 6 JULY 1994

The 6 July 1994 meeting had several key agenda points: a briefing by a Committee member, two reports on agency data collection efforts, a discussion of the possible experiment groupings, and a discussion of the draft document on goals and objectives.

12.0 COMMITTEE MEMBER BRIEFING: HISTORY OF HUMAN EXPERIMENTATION

Committee member Dr. Jay Katz conducted a one hour briefing on the history of human experimentation, as part of the Committee's continuing effort to cross-educate each other.

12.1 Dr. Katz provided the Committee with a series of steps that medical ethics have taken since the beginning of the nineteenth century. The general trend was toward increased need for informed consent from the subject of experiments, as well as increased responsibility for researchers to insure that adequate steps have been taken to obtain truly informed consent. Several key steps in this process have been: the 1900 Prussian Ministry of Medical Affairs directive on human experiments, which demanded unequivocal consent of the subject; the 1947 Nurenberg Code which calls for the consent of the experiment subject; and the 1969 World Medical Association's Declaration of Helsinki, which contained less strident informed consent language than that embodied in the Nurenberg Code.

13.0 STAFF REPORT: METHODOLOGICAL REVIEW OF AGENCY DATA COLLECTION EFFORTS -- CENTRAL INTELLIGENCE AGENCY (CIA)

Committee staff member Mr. Gary Stern briefed the Committee on the progress of the CIA's record search.

13.1 Mr. Stern stated that the CIA had uncovered no records of any involvement in human radiation experimentation, even in conjunction with the MKULTRA project that focused on manipulation of people by chemical and other means.

13.1.1 Several documents led the staff to believe that there was at least a possibility that the CIA was involved in human radiation experimentation. A 1963 CIA Inspector General report referred to radiological materials (along with a number of other substances) as a possible material to be used in MKULTRA. Additionally, in a 1977 report it was apparent that all possible materials, with the exception of radiological material, had been covered.

13.1.2 To date, the CIA had conducted a computer search of over 34 million records, had hand searched 480,000 records, and had conducted 50 interviews with personnel associated with the MKULTRA program, and it found no indication that the CIA had participated in any human radiation experiments.

13.1.3 The Committee staff met with CIA officials on 16 June 1994.

13.1.4 The CIA has not focused on some issues of concern to the Advisory Committee, including information on intentional releases and records on the development of ethics policies related to human use experimentation.

13.1.5 The staff requested the Committee request the CIA to:

- Provide information on contemporaneous intelligence on Soviet experimentation that could have influenced the United States' experimentation program. A special emphasis should be placed on intentional releases of radiological material
- Provide documents that highlight the level of perceived threat from the Soviet Union that could have also influenced the United States' conduct of these tests
- Initiate a search for historical information on ethics and ethical standards
- Continue to search for records on CIA involvement in human radiation experimentation.

13.1.6 The Committee authorized the staff to continue to work toward the goals indicated above.

14.0 STAFF REPORT: METHODOLOGICAL REVIEW OF AGENCY DATA COLLECTION EFFORT--NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Committee staff member Mr. Mark Goodman briefed the Committee on the NASA's record search.

14.1 NASA was set up along a functional, programmatic field center structure so that only a limited number of records repositories needed to be checked. However, the headquarters structure had changed several times since NASA's inception in 1958, so headquarters searches were more complicated.

14.1.1 NASA had completed a database search and identified 189 publications related to several dozen experiments. Of these, NASA believed four studies indicated deliberate radiation exposure to humans, including at least one study of total body irradiation. A series of interviews of cognizant officials had also taken place.

14.1.2 NASA would like to work with the Committee on establishing the parameters of the record search, for example whether incidental exposure to radiation is included in the Committee's purview.

14.1.3 Staff requested guidance from the Committee. The staff recommended conducting interviews with NASA officials if no ethics documents could be located for NASA. The staff requested guidance from the Committee on what to do if no documentation related to the experiments could be located.

14.1.4 The Committee advised the staff to continue working along the same plan.

15.0 UPDATE ON AGENCY DATA COLLECTION EFFORTS: OTHER AGENCIES

Dr. Faden briefed the Committee on the status of other agency data collection efforts.

15.1 The Department of Veterans Affairs (DVA) had agreed to search for records related to its Atomic Medicine Division (AMD), but to date no records had been forwarded to the Committee.

15.1.1 The Committee staff had identified some DVA-related policy records, but to date no records had been received by the Committee.

15.1.2 Not much information had been forwarded to the Committee from Veterans Administration (VA) field offices.

15.1.3 Dr. Faden commented that DVA was at a "pretty preliminary stage" in the record search process.

15.1.4 The Committee staff was working with the Department of Health and Human Services (DHHS) to try to find an efficient and effective means to locate policy documents and experiment information that correspond to the Committee's priorities.

15.1.5 The Committee staff had told DHHS to temporarily suspend its search for information on the large number of studies that were not linked to national security or military purpose issues.

15.1.6 DHHS was instructed to focus on searching for information that linked DHHS and its predecessors to the DoD and the DOE.

15.1.7 The DOE was continuing to actively participate in identifying records related to human radiation experiments, including working on headquarters policy records.

15.1.8 One group of DOE that the Committee staff had identified in its search was the Division of Intelligence, but no records had been located there at this time. Apparently, most of the pertinent records were destroyed in the late 1970's, however, that is not yet known for certain.

15.1.9 The Committee had requested numerous records be declassified, and in at least two instances, the DoD had responded within the Committee established timeframe of three weeks.

15.1.10 Dr. Faden characterized the Committees feelings on this issue by stating, "Today [the Committee] is not unhappy" with the progress of the agencies.

16.0 OVERVIEW OF INFORMATION SYSTEMS MANAGEMENT AND EXPERIMENTAL GROUPINGS

Mr. Guttman introduced the discussion of Information Systems Management by stating that the present plan and staff structure was designed as a means to organize information and develop means to examine information on experiments. He then introduced Committee staffer, Mr. David Saumweber who briefed the Committee on the Information Systems Management.

16.1 To date the Committee had received to date 15,000 to 20,000 pages of records from various agencies.

16.1.1 The on-line system, Lotus Notes, was being used as a records management system and to provide Committee members and staff access to the records.

16.1.2 When records are received at the Committee, a quick review is done to determine their significance and to identify "hot docs." The criteria used to review these records were established by Committee members and senior Committee staff.

17.0 PILOT PROJECT: ABSTRACTION OF MARKEY REPORT EXPERIMENTS

Committee staff members Mr. Gil Whittemore and Mr. Jonathan Engel made this presentation to the Committee.

17.1 The pilot project entailed taking the form developed by the Cold War Subcommittee and using it as a tool to examine real life experiment records. In its final version, the form would assist in the development of the experiment database and could be used as a finding aid to the records.

17.1.1 Mr. Engel used the form in evaluating the information the Committee had on the 61 experiments identified in the Markey report. One crucial problem experienced when conducting the pilot project was economy of time. Even when using fact sheets on each experiment provided by Rep. Markey's office and filling out the form in an abbreviated way, it took one and a half days to review 61 experiments. If original documents were used instead of fact sheets (as would be necessary in most cases) the time to complete each form would be quite lengthy.

18.0 POSSIBLE GROUPINGS

Various Committee staff presented briefings on four possible groupings of experiments: *Government Purpose*, *Total Body Irradiation*, *Radiological Warfare*, and *Intentional Releases*.

18.1 The objective of the briefings was to justify the proposal for the experiments being grouped in this way.

18.1.1 The experiments were to be grouped in this way more as a means of "covering the waterfront" than of developing categories that put every experiment in one and only one group.

18.1.2 While no formal consensus was reached on the validity of these groupings, the Committee members did not seem to object to these classifications.

19.0 COMMITTEE DISCUSSION: DRAFT OUTLINE OF GOALS/OBJECTIVES DOCUMENTS

Dr. Faden moderated a Committee discussion on the goals/objectives document. She indicated that the desire was to develop a consensus among Committee members on the basic structure of the interim and final reports so that the Committee staff can be realigned to reflect the goals of the Committee.

19.1 This one and a hour discussion period focused on what should be included in the report, not necessarily the structure. It was felt that this would allow the Committee staff to most efficiently structure itself, while allowing the Committee the flexibility to continue to work on the organization of the report.

19.1.1 The two main areas of discussion were in what groupings to use and what themes should predominate. Those groupings and themes proposed in the draft document developed by Dr. Faden and Mr. Guttman remained the backbone of the Committee report.

Brian H. Thompson
DoD RECC