

Advisory Committee on Human Radiation Experiments

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MEMORANDUM

FROM: Stephen Klaidman, Director of Communications

DATE: May 16, 1994

RE: Selected material for discussion at meeting of May 18-19

You will find the following material in this packet:

1. A copy of the table of contents of the briefing book supplied to Advisory Committee members
2. A staff cover memo to the members of the Advisory Committee
3. Tab G, which is a staff review of the DOE record collection effort.
4. Tab H, which is a staff review of the HHS record collection effort and one attachment
5. Tab I, which is a staff memo on agency ethical standards and related DOD and AEC documents
6. Tabs L to O, which are a series of staff memos dealing with procedural matters related to experiments and the disposition of federal records
8. Staff biographies

If you have questions about any of these documents, please call me at (202) 254-9817.



BRIEFING BOOK #2
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
MEETING #2 (May 18-19, 1994)

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Pocket:	Katz, Jay, Human Experimentation and Human Rights, 38 <i>Saint Louis University Law Journal</i> 7-54 (Fall 1993)

Memorandum

To: Members of Advisory Committee on Human Radiation Experiments
From: Advisory Committee Staff
Date: May 12, 1994
Re: Briefing Materials and Meeting Logistics

1. Meeting Logistics.

- May 18. We have arranged for the committee to be fingerprinted for your security clearance at DOE Headquarters, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC at 8:00 am. on the meeting days (your choice of Wednesday or Thursday). If you are staying at the Vista Hotel, you must take a cab (allow 10 minutes). You will be met by Virginia Johnson who will escort you through the process. Please note that breakfast arrangements are to be made on your own. The meeting begins at 9:00 am in the Washington Room of the Ramada Plaza Hotel, 10 Thomas Circle, NW, Washington. We have arranged for the committee to eat a buffet lunch in a separate room at the meeting site. Payment for lunch will be reimbursed under your per diem. The committee recently received an invitation to a reception from The Symposium on Openness and Secrecy in the Nuclear Age, sponsored by the National Press Club. We will forward more information as soon as possible. We have arranged for the committee and staff to eat dinner together at America in Union Station. Spouses are welcome. Again, payment for lunch will be reimbursed under your per diem.
- May 19. See notes above about fingerprinting. The meeting will again be held in the Washington Room of the Ramada Plaza Hotel. The meeting starts at 9 am and will adjourn by 3:00 pm.

2. Agenda:

Three educational briefings are scheduled for this meeting:

- Radiation and Its Effects (Henry Royal),
- Ethical Principles of Human Experimentation (Ruth Macklin),
- History of Human Experimentation in the United States (Susan Lederer),

Recommended reading for Dr. Macklin's presentation can be found in the briefing book for the first meeting behind Tab 4:

(1) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of

Research (Washington, D.C., 1978), and

(2) Protection of Human Subjects--Department of Health and Human Services (Title 45 Code of Federal Regulations part 46).

Educational briefings currently scheduled for the June meeting are:

- Historical Research Methods (Susan Lederer),
- History of Human Experimentation (Jay Katz), and
- Remedies (Ken Feinberg).
- Risk Communication (Steve Klaidman)

3. Briefing Materials. Enclosed are briefing materials prepared by the committee staff for the second meeting of the Advisory Committee on May 18-19. Documents noted on the table of contents but not included in the briefing book will be forwarded to you under separate cover as soon as possible. The next mailing will also include recent press clips.

At the initial meeting, the Committee directed the staff to:

- 1) meet with agencies and assess the status of their document reviews;
- 2) provide information on the state of agency ethics codes and policies from 1940-present regarding research involving human subjects;
- 3) assemble documentation on the Cincinnati, Plutonium injection and Green Run experiments, in order that the Committee may consider methodological approaches; and
- 4) prepare a memo on Outreach opportunities.

In this mailing we enclose:

1. Memos on data collection activities in the Department of Energy. (A memo on the Department of Health and Human Services will follow shortly; work on other agencies is underway).
2. A memo (and related documentation) on agency ethical standards.
3. Selections of documents on the three experiments.. (The cover memos summarize additional data which has not been transmitted. Please let us know if you want any further documents, or if you wish further descriptions.).
4. A memo on Public Outreach will follow shortly.

We believe the briefing book contains much that is of interest (and, of course, perhaps too much paper as well). From the vantage of staff's necessarily brief review, the documents have already demonstrated that the perspectives of differing disciplines (and people) are key to unlocking the myriad of facts and questions that can quickly overwhelm us all. From this vantage, even at this early stage, the enclosed materials illustrate ways in which the initial document dragnet approach, while still underway, now needs to be supplemented by a more directed, investigative approach.

Specific methodological points follow from this, each illustrated by particular documents:

1. One important observation is the degree to which the activities of the various agencies may be interrelated. Copies of a document no longer held by an agency may exist in another agency's files. An example is a 1950 letter, found by staff in the Department of Defense collection at the National Archives, which reviews for the Public Health Service a grant proposal for an isotope experiment. (Preliminary Report on HHS, Attachment B)
2. A single document may suggest many new areas of inquiry. An example is the 1953 classified memorandum from the Secretary of Defense to the Secretaries of the services establishing ethical standards that are essentially the Nuremberg Code. Why did the Secretary of Defense issue such a document at that time? Why was it classified "top secret"? Was it intended to apply only to members of the armed forces, or also to work by civilians funded by the Department of Defense? What actions were taken to implement this document? Staff learned of the next step along the trail: a memo from the Secretaries of the Services one week later transmitting this standard to the Joint Chiefs of Staff. What happened next? (Ethics Report)
3. Documents which are not directly related to a specific experiment may still provide an important tool for understanding the context in which an experiment was undertaken. For example, CIA reports to President Truman in September 1949 concerning the possibility of a Soviet atomic bomb test help illuminate the purpose behind the "Green Run" test in December 1949. (Green Run documents)
4. The relationship between secrecy and openness (classified and published research) may be better understood when projects and investigators are traced across agency lines. For example, when the Cincinnati researcher applied to the Department of Defense for funds to study whole body radiation, he was urged to consult with another investigator who had earlier done classified work for the Manhattan Project (which became AEC (DOE) on plutonium injection. (Cincinnati and plutonium injection documents)
5. Great efficiency may be achieved by cross-referencing of material from different agencies. For example, the AEC's published reports on isotope distribution should aid HHS in eliminating animal and plant studies from its list of grants awarded. (Preliminary Report on HHS, Attachment A)

We look forward to your discussion of these materials. Our expectation is that they will help the Committee begin to perceive that it is following threads in a story(ies), and not simply dragging a net through an ocean of data.

Tab G

**Staff Memo--Methodological Review of
Agency Data Collection Efforts:
Department of Energy**

May 12, 1994

PRELIMINARY REPORT TO THE ADVISORY COMMITTEE-
DEPARTMENT OF ENERGY DOCUMENT COLLECTION

Committee Staff was briefed by DOE staff on May 4, 1994,¹ and this meeting was followed up by phone inquiries. This report is based on Staff's best understanding of the DOE search at this time, and is subject to elaboration and revision. This memo 1) provides background on DOE and its records; 2) summarizes DOE's search strategy and activities to date; 3) discusses lessons learned from the search to date, and questions raised by staff; and 4) provides options and recommendations for the next steps to be taken by DOE and the Committee.

I. SUMMARY

RECORDS DOE estimates that it has 500,000 cubic feet of records just at its nine field offices throughout the country. An indeterminate further amount of field office records is maintained at Federal records centers and National Archives facilities around the country. A very large but presently unknown quantity of headquarters office records of DOE and its

DOE staff in attendance included Search Team Director Mr. Glenn Podonsky agency historians, records management staff, hotline staff, staff from the office of security evaluations, and Ms. Ellen Weiss, who will shortly join DOE to take a lead role in radiation experiment documentation. Committee staff present were Faith Bulger, Jim David, Dan Guttman, Gregg Herken, and Ron Neumann.

predecessors are still at headquarters offices, Federal records centers, and the National Archives. Both past and present contractors of DOE and its predecessors also have an indeterminate number of records.

SEARCH STRATEGY DOE has committed significant resources to its search efforts, and promises the continued effort needed to complete the location and retrieval of relevant documents. DOE states that within several months it will complete a comprehensive record series guide which will identify all pertinent collections of records at its field offices, headquarters offices, Federal records centers, and the National Archives.

SEARCH LIMITS DOE acknowledges that the search has been fundamentally constrained by a history of poor record management; indeed, it hopes that the search will permit it to improve records management practices.

*DOE acknowledges that the search has been further hampered by 1) incomplete field office understanding of Headquarters' guidance; 2) instances of contractor resistance to assistance in search efforts; and 3) instances of "malicious compliance" (e.g., incorrect representation that documents do not exist).

QUALITY CONTROLS The work of the teams at the nine field offices is reported periodically to the management team at Headquarters. Additionally, separate Headquarters teams have started to visit each field office to monitor the work done to date and to assist in the identification and retrieval of

documents.

SEARCH OPPORTUNITIES DOE agrees that headquarters files should be a "rich" source of data (e.g., files of the Atomic Energy Commission's (AEC) Executive Secretariat and the AEC's Division of Biology and Medicine), as well as the files of the Joint Committee on Atomic Energy of Congress.

* DOE agrees that licensing data of radioisotopes produced and supplied by its predecessors may lead to information on experiments conducted by other governmental agencies and private sector institutions which is not obtainable elsewhere (or at least not obtainable from one single source). DOE is still undertaking to locate the records of the licensing process.

* Through the years, DOE and its predecessors have conducted a number of projects and experiments with or for other agencies, including some in the biomedical research field. DOE says data on this "work for others" may provide information on experiments performed by it for other agencies. However, in recent years DOE top management has not been able to obtain complete data on its current "work for others" program, evidently in part because of classification problems.

* DOE believes that some DOE contractors are likely to be "rich" sources of data that are not available in any other collections. A directive to the field from Secretary O'Leary has alerted contractors to the importance of the search.

* While DOE has not analyzed its hotline data to determine precisely how many calls relate to experiments, data is

computerized and amenable to creative sorting.

CLASSIFICATION DOE's search Team does not believe it currently has knowledge of (and access to) all collections of classified headquarters office records. Records to which it lacks access may include data on "work for others" and on intentional release experiments. The search Team reports that it has, since February, been unsuccessful in ongoing information requests to the DOE Office of Nonproliferation and National Security, which evidently controls or has knowledge of the documents.

* DOE acknowledged that it cannot now say whether relevant public sources of data (e.g., AEC annual reports to Congress and isotope licensing reports) had classified supplements which are still not publicly available. DOE will look into this.

II. BACKGROUND

A. Organizational History

The Department of Energy (DOE) is the successor agency to the Manhattan Engineering District (MED), Atomic Energy Commission (AEC), and the Energy Research And Development Administration (ERDA). The MED was established in 1942 under the U.S. Army to build the atomic bomb. As part of this effort, it conducted an extensive biomedical research program both at its own facilities and at various contractors. Beginning in 1946, the MED also started to distribute radioisotopes produced at its facilities to domestic and foreign applicants for several purposes, including biomedical research. The MED was replaced on

January 1, 1947, by the civilian-run AEC, which continued a wide-ranging biomedical research program at its own facilities and at numerous contractors. Additionally, it maintained the program of distributing radioisotopes produced at AEC installations to domestic and foreign users. The AEC was succeeded by ERDA in 1974, which in turn was replaced by the DOE in 1977. When ERDA was created in 1974, the responsibilities for the civilian nuclear power program were transferred to the newly-established Nuclear Regulatory Commission.

DOE and its predecessors have relied substantially on contractors to manage and perform its work. Today, DOE's workforce approximates 20,000 civil servants and perhaps 150,000 or more contractor employees. Contractors have historically managed the facilities at Oak Ridge, Los Alamos, Hanford, and other sites at the core of the nuclear weapons complex. "Management and operating" (M&O) contractors have included universities (e.g., U. of California), nonprofits (e.g., Battelle), and profitmaking entities (e.g., Dupont, Union Carbide, Westinghouse).

B. Organizational History/MED and AEC Biomedical Research

The Medical Section of the MED was created in August 1943. Among other things, it had responsibility for directing and coordinating the extensive biomedical research programs conducted at MED facilities and by contractors. It was apparently succeeded by the Medical Division in 1946. From late 1943 until the establishment of the AEC on January 1, 1947, the Medical Section

and Medical Division were located at Oak Ridge, Tennessee.

In mid-1946 the Medical Advisory Committee was created to advise the Medical Division on a number of issues, including the future biomedical research program. Beginning in 1946 the MED started to distribute radioisotopes for purposes that included biomedical research. The Interim Advisory Committee on Isotope Distribution Policy was created in 1946 to provide guidelines in this area, including the use of radioisotopes in humans.

The AEC established the Interim Medical Advisory Committee in early 1947 to act as a bridge between the MED's Medical Division and Medical Advisory Committee and successor organizations to be created by the AEC. In September 1947, the Advisory Committee on Biology and Medicine (ACBM) was created to review medical and biological research and health programs and to advise the AEC on policies in these areas. The following year the AEC established the Division of Biology and Medicine to direct and coordinate the AEC effort in these areas, and the ACBM became its principal advisory committee. These organizations continued in existence until 1974, when ERDA was created, at which time the Division of Biology and Medicine became the Biological and Environmental Research Division.

On January 1, 1948, the Advisory Committee on Isotope Distribution replaced the Interim Committee on Isotope Distribution Policy. The Subcommittee on Human Applications was created at the same time to advise on policies and standards for the regulation and licensing of uses of radioisotopes in humans.

In 1958 the Subcommittee on Human Applications was succeeded by the Advisory Committee on the Medical Use of Isotopes.

III. DOE RECORDS: BASICS

A. Location and Organization

Records of DOE and its predecessors are currently housed at numerous headquarters offices, nine field offices, and National Archives facilities and Federal records centers here and throughout the country. The volumes of materials maintained by the field offices alone approximate 500,000 cubic feet.

DOE recordkeeping practices have been critiqued in detail in a 1988 National Archives report and a 1992 General Accounting Office report. Agency staff volunteered that the present search confirms that agency records management has been substantially deficient.² The search has confirmed that the record-keeping practices of individual headquarters and field offices varies widely, the result being "very dysfunctional," with "no real recordkeeping system." DOE reports that it found that some field offices have indices, "but not in any way comprehensive." Some offices have transferred few, if any, of their records and those of their predecessors outside their custody. Others have transferred or destroyed large portions of their records and those of their predecessors, with in many cases only poor records being kept of these transfers and destructions.

² Indeed, DOE views the search as an opportunity to bring order to DOE records management.

Because of the prominent roles contractors have historically played in DOE's activities, contractor records are an important component of agency records. Some contractor records are embedded in the records of headquarters and field offices. DOE is exploring access to records of both current and former contractors. Examples of the latter include the Universities of Chicago and Rochester, which may be rich sources of data because of their extensive biomedical research for the MED and AEC.

B. Document Destruction Policy

Since the 1940s document destruction at DOE and its predecessors have been guided by a series of Records Retention and Disposition Schedules. The current one has been in effect for about 30 years. (Prior ones are on microfiche at the National Archives, and copies will be provided to the Committee.) Additionally, DOE will examine all the Schedules and provide a list of collections of potentially relevant records that likely have been destroyed.

DOE said the Schedules, when adhered to, provide a limited guide. In the cases of some records, Schedules are very precise as to what should be retained and what should be destroyed; in other cases they are not. Over the years, this has lead to sometimes widely varying records retention and destruction practices.

Records on what has been destroyed are generally poor. In some cases there is simply no record of destruction. In others, records documenting records destruction contain inadequate

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descriptions of the records in question. Moreover, there is no one location where all "record destruction records" are stored.

IV. SEARCH LOGIC

A. Guidelines

In December 1993, each of the nine DOE field offices around the country established teams to begin examining their holdings for relevant records. Detailed guidance was thereafter issued by DOE headquarters on February 22, April 12, and April 21, and April 27 to all headquarters offices and field offices on the inventorying, processing, declassifying, and dissemination of human radiation experiments records.

B. Experiment Definition

In addition to "radiation experiments," the guidance sought documents on "any intentional non-ionizing exposure of humans to controlled substances or toxic chemical substances."

C. Staff

The DOE program is under the direction of Dr. Tara O'Toole, Assistant Secretary for Environment, Safety, and Health. The day-to-day management is led by Glenn Podonsky, Deputy Assistant Secretary for Security Evaluations, Environment, Safety, and Health. Presently, each field office has a 20-30 person multi-disciplinary team working full-time on the effort. DOE headquarters has approximately 45 people working full-time on the effort, including health professionals, records managers, archivists, and historians.

D. Use of Agency Historians, Published Literature,
and Interviews

DOE historians are part of the DOE search group.

DOE's Office of Scientific and Technical Information (OSTI) has created an annotated database which contains "annotated references to published and unpublished studies produced by the Department of Energy, its predecessors agencies, and Departmental contractors since 1943."³ The Committee has the database on disk as well as hardcopy. DOE is using the database as an aid in its document search.

Informal interviews of mostly retired personnel have been conducted by some field offices as part of their efforts to identify pertinent collections of records and specific experiments. The names of the personnel interviewed, as well as any notes, will be provided shortly.

E. Activities

Field Offices

DOE is in the process of conducting a "sweep" of its

³ The database includes "information on the biological effects or dosimetry of ionizing radiations or radioactive isotopes using humans as the experimental subject [and] may include studies of experimental nuclear medicine and radiation accidents involving human injury or death."

Staff's brief review of the database suggests that the breadth and quality of data on given experiments varies considerably, depending on the material being abstracted.

The hardcopy version of the database is segmented by performing organization (e.g., specific university, hospital, public agency)

field offices. According to the April 27, 1994 "Inventory Assistance and Document Retrieval Team Procedures," the "actual scope of each team's activities" will be "determined by the organization of each site's records system and the status of each sites...document inventory and retrieval program."

The document states that each site must have a "records search strategy and an inventory plan" that is a "blueprint" for site activities. In addition, each site must file a bimonthly report ("Search Strategy and Record Inventory Report") with DOE Headquarters.

The guidance provides that "potential collections or sources" will be identified, then "records within the collection are inventoried." (April 27; at 6). Following the completion of an "inventory form"⁴, individual documents are identified for retrieval, and described in a "records provenance form." Documents are to be photocopied, along with any provenance forms/information. A document collection log is to be completed for all photocopies.

Following the first "sweep" DOE is planning a second sweep of the field offices. The second sweep will concentrate on an

⁴ Among other data, the inventory form requires a description of the record series title, an estimate of the percentage that are classified, and a ranking (1-3) of likelihood that experiment related data is present. In addition, "if known or easy to determine," data on specific experiments (title, investigator, etc.) should be provided.

intensive document retrieval effort.

Headquarters Offices

The search of headquarters offices records is being conducted along the same lines as that of the field office records. Initially, pertinent collections of records are being identified and reported on the "inventory form." This will be followed by the retrieval and photocopying of documents, and then the completion of the "records provenance form" and document collection log.

National Archives and Federal Records Centers

DOE agrees that the National Archives contain some critical collections (e.g., the National Archives here in Washington, D.C. has the 1947-1958 AEC Executive Secretariat files). It is presently collecting all the available finding aids to these collections from the National Archives facilities around the nation. With the exception of the holdings in the National Archives in Atlanta, however, DOE is not currently planning to review any of the collections because the National Archives has assumed both physical and legal custody and control of them. DOE states that it must work with the Committee and the National Archives to assure timely retrieval and declassification of documents of interest.

Similarly, DOE acknowledges that the Federal records centers contain significant collections. Headquarters teams are reviewing the transmittal forms (Standard Form 135s) prepared when these collections were shipped to the records centers to

identify relevant collections. Once these collections are identified and inventoried, both field office and headquarters teams will begin the document retrieval and indexing process.

Contractors/Grantees

As noted, DOE has alerted current contractors to search and inventory documents as provided in the guidance to DOE field offices; however, this guidance does not apply to former contractors.

V. WORK PRODUCT

DOE says that its sweep of the field offices will result in three products for Committee use. First, DOE will provide organizational histories and inventory documents (which describe relevant record sources). Second, DOE will provide abstracts of experiments. Third, DOE will provide copies of individual documents that are related to radiation experiments.

DOE is working with a contractor, Reynolds Electric, which has helped DOE catalog radiation-related documents assembled in response to concerns about the "downwinders". The plan is that as relevant documents are identified, hard copies will be transmitted to Washington for abstracting and full text inclusion in a CDROM database.⁵

The Department's initial (December 1993) call for documents

⁵ DOE noted that while documents will necessarily be reviewed prior to transmission to the Committee (and public), the review will be to determine basic relevance---i.e., there is no single individual or group which is reviewing the documents as a whole on a coordinating basis.

produced about 6,000 documents. The bulk of these are the "plutonium injection" and "Markey collection" documents, which had been collected previously. In addition, the 270,000 document "downwinder" collection (which DOE believes may contain relevant data) is now available on microfilm (fiche) in Washington. (It is accessible to keyword search.)

VI. HOTLINE ("Helpline")

In December, DOE established a toll-free hotline. On January 26, 1994 the hotline was expanded so that calls would be routed to other agencies, as appropriate.

The hotline has functioned to collect information which is to be forwarded to the appropriate agency for personal contact. To date, the hotline has served to collect information, and not to direct callers to assistance. DOE intends to provide caseworkers who will work with callers on followup; eg, help them obtain medical records and further data on experiments in which they (or relatives) may have been involved. DOE will shortly be able to cross-reference callers to the documents searched, and thus be able to furnish documents when applicable.

DOE officials estimate that of the more than 20,000 calls received to date, less than half relate to radiation experiments. (Other calls involve citizens concerned about radiation, veterans who may have been exposed during service, and individuals who have undergone radiation treatment.)

Hotline data is computerized, and can be sorted by a

number of categories.

VII. DOE'S LESSONS LEARNED

DOE identified both obstacles and successes. Obstacles have included:

- * A basic problem is the general lack of indices. As noted above, DOE estimates that just at its nine field offices there is over 500,000 cubic feet of documents, for which there are very few inventories or indices. There is no estimate for the amount of documents still at DOE headquarters, as well as at the National Archives and Federal records centers throughout the nation, but it is undoubtedly a massive amount. With some notable exceptions, there are few comprehensive indices to these collections either.

- * DOE encountered resistance to the search, including:

- Contractors at Los Alamos and Chicago initially resisted the search, seeking a non-disclosure agreement from DOE.

- Contractors at Hanford (Westinghouse and Pacific Northwest Laboratories) have delayed assisting on grounds that more funding is needed.

- Episodes of "malicious compliance" occurred--e.g., offices stated that documents cannot be located, when they can be.

- * DOE has not asked former contractors to identify or search records in their possession. Legal and financial questions will likely arise in this regard. For example, the University of

Chicago is no longer under contract to DOE and there is no mechanism to fund a search of their extensive holdings.

* The quality of field office compliance varies considerably. Further guidance was issued following field office statements that the initial guidance was not adequately comprehensible; there is still trouble understanding instructions. Following the initial searches, some sites have good indices of relevant records; others "don't know what they've looked through."

* "Work for others" documentation is hard to come by. Historically, DOE (including DOE contractors) has performed work for other federal agencies. A 1991 study commissioned by Secretary Watkins was able to locate only 90% of work performed for others during the 1989-91 period. Evidently much data and identification was classified and/or hidden in code words.

*Some relevant records may not be retrievable to Washington, DC. In particular, DOE indicated that the 14,000 (approximate) medical records maintained by Brookhaven may require review at the site.

DOE reported successes include:

* DOE believes the substantial resources and people devoted to the effort reflect Secretary O'Leary's deep commitment to openness in government and the need to locate and disclose information relating to human experiments.

* DOE believes that, as noted at the onset, it will soon have a complete guide to relevant DOE records.

* DOE reports that the work done by some sites has been excellent (Staff has not looked at this documentation yet).

* DOE reported some retrieval of potentially broad historic import, e.g., the search of the Chicago field office located several thousand notebooks kept by the Metallurgical Laboratory (part of the Manhattan Project), at least five of which appeared to be relevant to experimentation. (Some of the notebooks are radioactive, and must be treated).

VIII. STAFF QUESTIONS REGARDING SEARCH LOGIC

In addition to issues identified by DOE, Committee staff raised a number of questions regarding search logic. The areas addressed included:

* Publicly available AEC reports -- Staff's preliminary review of a limited number of publicly-available AEC reports from the late 1940s through the 1960s reveals potential experiments and data sources that do not appear to have otherwise been identified. DOE has not "systematically" mined these sources.

* Headquarters documents -- As noted above, the MED and AEC were both major sponsors of biomedical research and suppliers and licensors of radioisotopes. Potentially relevant AEC headquarters records include, for example, documents from the AEC Executive Secretariat files; and minutes, transcripts, and reports of the Advisory Committee on Biology and Medicine. DOE agrees MED and AEC Headquarters documents are likely to be a "rich" source. The question is. what is the best approach?

* Isotope licensing documents -- DOE agrees that MED and AEC isotope licensing documents may be of significant use in directing further searches. Preliminary inquiries by DOE of the Nuclear Regulatory Commission indicate that the latter may very well have the post-1957 documents, and DOE is following this up. However, DOE has not yet located pre-1957 documents.

* Classified documents

---On staff inquiry, it developed that the DOE search has not included an undetermined number (and class) of classified collections. For example, files of the AEC's Division of Intelligence and any successors likely contain(ed) relevant materials on intentional releases, such as Green Run. (In addition, such files likely contain(ed) data on "work for others" information shared among intelligence agencies.) At the May 4 meeting the DOE Team said they had not been successful in gaining access to these files, despite inquiries that began in February. In subsequent discussions, the Team reported to Staff that it was still seeking the information, but had not yet obtained information on the nature and/or magnitude of any such files. (Staff understands that the files in question, to the extent they exist, are now within the control, or known to, DOE's Office of Nonproliferation and National Security.)

---DOE has not yet determined whether classified supplements exist to otherwise publicly-available reports (e.g., the AEC annual reports to Congress) and, if so, what pertinent information they may contain.

---It is believed that many of the records ultimately retrieved from the numerous repositories around the nation will be classified. Perhaps most of these are still classified for the simple reason they have never been reviewed for declassification. As a relevant example, DOE stated that one of the three or four boxes of minutes of the Advisory Committee on Biology and Medicine in the custody of the History Division is still classified. These minutes are likely to be an essential source of information. Staff asked DOE to determine the time required to declassify this box. DOE agreed to report back.

* Congressional Joint Committee on Atomic Energy -- The AEC was overseen by this Committee. The Committee's records could be an excellent source of high-level policy or summary information. Almost all the Committee's records are in the National Archives in Washington, D.C., but many are still classified. It remains to be determined who will examine and, if necessary, declassify relevant documents.

IX. OPTIONS AND RECOMMENDATIONS

At the initial Committee meeting DOE, as well as other agencies, invited the Committee to engage with it in its document search effort, and to suggest search alternatives and directions. In discussions with DOE (and other agencies) Staff has sought to make plain that the Committee's suggestions must come from the Committee, and not Staff. In light of the foregoing discussion of DOE's search, the following are a list of currently available

options that Staff believes merit the Committee's consideration.

In proposing that the Committee adopt these (and/or alternative) options, the intent is not to fashion a straitjacket, but to provide a working basis on which the Committee and DOE can begin to move forward.

Staff emphasizes that the options are not mutually exclusive. In particular, Staff believes that searches for documents at the Headquarters level and searches for documentation of specific experiments at the field level should, if well conceived, be mutually reinforcing.⁶ The extent to which particular options should be immediately pursued should depend on consideration of resource costs, time constraints, quality controls, and short and longterm payoff potential.

The options that follow include suggestions for 1) Committee advice/direction to DOE; 2) Committee action; 3) Committee direction to Staff.

A. Recommendation/Options for Committee Advice to DOE

SUMMARY. DOE has already committed substantial resources to the first option---a broad sweep to inventory all relevant document sources, with the ultimate goal of retrieving relevant documents. Staff recommends that this course be continued, but, as noted further below, that Staff be directed to

⁶ For example, headquarters documents may not only provide policy context for specific experiments, but may also provide specific information on the location, nature, and interrelation of experiments.

provide means of monitoring the connection between the resources committed and the results achieved. Staff recommends that options 2-4, which have potentially high near term payoff, also be immediately pursued. Staff understands that DOE is in agreement, and is prepared to work with staff. Options 5-7 essentially call on DOE to provide the Committee with previously collected data, and should require limited resources. As to Option 8, DOE and Staff agree that the National Archives are a rich source of documents, and the only question is the most efficient means to mine them.

OPTIONS. 1. DOE should proceed with the strategy of developing, in the near future, a comprehensive (record series) guide which will identify pertinent collections of records at field and headquarters offices, and in the Federal records centers and the National Archives. DOE should produce, as a component of this strategy 1) narratives on the relevant organizational history of each site, and an inventory of relevant record sources; 2) summary data on individual experiments; 3) hard copy and electronically formatted documents.

2. DOE should immediately focus on collections of highlevel documents which can be immediately retrieved and made available.

Requires of the Agency:

---identification of relevant policy offices and groups (e.g., congressional Joint Committee on Atomic Energy, AEC Advisory Committee on Biology and Medicine), and

location and provision of minutes, reports, policy directives, etc.

Potential Benefits:

- Policy documents.
- Documents indicating relation among experiments, and possible experiments not previously identified.
- Documents showing activities conducted/sponsored by other agencies.

3. DOE should focus on defining categories of classified documents not previously addressed which may contain relevant documents (e.g., interagency intelligence committees, classified supplements to public materials).

Requires of the agency:

- survey and inventory classified records collections not encompassed in search to date.
- determine extent to which otherwise public materials (eg, AEC annual reports, Congressional Committee documents) contained classified components.

Potentially produces:

- same as in "2" above.
- data on activities of other agencies.

4. Focus on documentation of AEC radioisotope licensing process.

Requires of the agency:

- Continued inquiry into process.
- Coordination with NRC.

Potentially produces:

---Central listing of governmental and non-governmental users of radioisotopes, with information that separates human and non-human experiments.

---Method to narrow searches by other agencies , such as HHS and its predecessors (where they sponsored/conducted radioisotope work)

5. Provide the Committee with "work for others" study performed for Secretary Watkins.

Requires of the agency:

---Provision of existing study.

Potentially produces:

---Committee understanding of "work for others" records.

---experiments performed for others.

---Strategy to deal with work for others (which can lead to identification of experiments sponsored by other agencies).

6. Provide documents supporting the 1974 Inspector General report on plutonium injection experiments.

Requires of the agency:

--location of documents previously collected.

Potentially produces:

---Extensive data on the plutonium injection experiments.

---Invaluable contextual documentation on the relation between an early experiment and Manhattan Project activities.

7. Provide the Hotline database to the Committee.

Requires of the agency:

---provision of existing database.

Produces:

---Possible sorts of data to assist in prioritizing experiments for further Committee study.

8. Identify the most efficient means of accessing data under control of the National Archives.

Requires of the agency:

---Coordination with Committee and Archives staffs.

Produces:

--- Most efficient access to rich data.

B. Direct Committee Action

Staff suggests that the Committee must provide guidance on whether, when, and how to seek data in the possession of non-Federal entities. In the case of DOE the Committee's policy need presently address only former contractors (since DOE has already sought data from present contractors). As noted, DOE believes the U. of Chicago and the U. Of Rochester are rich sources. In the case of other agencies, eg HHS, the policy may also have to address present contractors.

Staff suggests that the Committee begin to think about this question now, and reserve a policy choice for the next session. The policy requires consideration of:

- kinds of documentation Committee may ultimately wish to seek from non-Federal entities.

- most efficient and least burdensome collection means.

- selection criteria.

- whether and when access should be through DOE or the Committee directly (DOE access being limited to document production).

- access protocol (eg, who is authorized to initiate contact with institutions? what procedure should be followed? what basis for selecting particular institutions?)

The Committee should also provide for the development of parallel policy on collection of non-documentary data from non-Federal entities (e.g., interview data).

C. Committee-Directed Staff Action

Staff Recommends that the Committee direct it to:

1. Continue communications with DOE on the matters discussed in this memo. (DOE and Staff agree that immediate discussions between Staff and DOE historians regarding particular document collections would be of great value.)

2. Provide options on the means to monitor the relation between DOE's field search effort and the quality and amounts of relevant documents actually retrieved.

As noted, the numbers of new documents retrieved to date are in the low thousands, but the universe to which substantial search resources are directed is in the many millions. DOE believes the effort will be a valuable longterm contribution to the improvement of its records management. This may well be the case, and worth effort in that context. However, is the effort likely to be worth it from the Committee's perspective (particularly given time constraints)?

Staff asked DOE to provide a sense of the expected payoff (in new documents) from the large search effort. DOE was not able to provide assurance about the orders of magnitude of relevant documents that will be turned up. DOE emphasized that any present estimate would be speculative. By way of example, however, DOE's Richland field office estimated it has approximately 150,000 cubic feet of documents and that 30,000 cubic feet will be set aside as potentially relevant. DOE emphasized, however, that Headquarters cannot presently verify this estimate.

3. Develop alternatives for accessing data located at non-Federal entities.

4. Facilitate exchange of DOE information with other agencies, including possibilities for enhanced interagency coordination.

5. Develop options for organizing DOE-provided data (in connection with data from other sources) for use by Committee and public.

Tab H

**Staff Memo--Methodological Review of
Agency Data Collection Efforts:
Department of Health and Human Services**

Preliminary Report to the Advisory Committee on Human Radiation Experiments

The Department of Health and Human Services

Dated for Distribution May 13, 1994

This preliminary report includes the following: (1) the sources of information on which this report is based; (2) a synopsis of the report; (3) a brief organizational history of the Department of Health and Human Services (HHS); (4) a description of the status of the HHS search; (5) a description of agency concerns; (6) staff analysis of the HHS search; and (7) staff recommendations for future action.

I. Informational Sources

HHS representatives briefed committee staff on the status of the HHS document search and retrieval in a meeting on April 29, 1994¹ and several subsequent telephone conversations. HHS provided informational documents on its search effort at the April 29 meeting and in subsequent contacts. This preliminary report is based on the documentation and descriptions by HHS representatives of HHS search efforts as of May 9, 1994. The committee staff has not verified or audited whether the work reported by HHS was actually completed.

II. Synopsis

- The information contained in this preliminary report is based on the staff's best understanding of the HHS search at this time and is subject to elaboration and revision.

(A) Extent of Interagency Coordination and Co-funding of Human Radiation Experiments

- It is likely that many human radiation experiments or investigators identified by HHS had multiple federal agency sponsors.
- In 1979, PHS conducted an agency-wide document retrieval process for all of its documents related to its efforts to monitor the health effects of the nuclear weapons testing program. As a result of this search, high level documents were located that appear to demonstrate formal coordination between the AEC and the PHS. (See Attachment C).

¹Advisory Committee staff - designate (Dan Guttman, Faith Bulger, Jim David, Ron Neumann, and Gil Whitemore) met with Dr. Wendy Baldwin, Dr. Gary Ellis, and Dr. Kathy Hudson of HHS on April 29, 1994.

- HHS has not systematically coordinated its search with other agencies. For example, HHS could cross reference its records with the AEC records. Attachment A contains sample pages from AEC's radioisotope license information and the semi-annual and annual reports of the AEC. In addition, the Advisory Committee staff located archived boxes containing PHS documents from the 1950s in the Office of the Secretary of Defense files in the National Archives. Attachment B contains an example of a letter reviewing a PHS grant application that was found also in the Office of the Secretary of Defense files in the National Archives.

(B) Classification

- HHS recently discovered that it has classified documents within its control and a declassification officer. We have requested a report on the status of HHS classified documents.
- HHS acknowledges that Division of Radiological Health employees conducted classified research for the AEC.

(C) Constraints on HHS Search

- HHS believes that there may be additional information on experiments or researchers supported by the NIH extramural program at the grantee institutions. NIH believes that it possesses only a brief description of extramural awards for the 1946-1961 period and that the most fruitful sources of information for extramural awards are located either in (1) the proprietary records of grantee research institutions or (2) published medical or scientific literature. Record retrieval from grantee or contractor institutions raises logistical, economic and possibly legal issues.

(D) Limitations of HHS Current Search

- The search efforts at NIH particularly, but HHS generally, to date have focused primarily on locating documents related to actual experiments, not headquarters or central office files. From our information, it appears that FDA attempted to reconstruct relevant predecessor offices and trace records for these offices. It is unclear, from our information, to what extent PHS files of key headquarter offices were searched for information related to human radiation experiments. For example, it is unclear whether HHS has checked the Surgeon General's office files.
- HHS' search did not include documents like the ongoing CDC study of the health effects of the Green Run test. HHS takes the position, as it did in the initial Committee meeting, that "follow up" epidemiological studies are not human radiation experiments within the purview of the Committee charter. HHS explained that including these types of "follow

up" studies in the document search will increase the volume of documents exponentially.

- NIH has devoted about 2,500 person hours to the search effort; when provided, the person hours expended on the other PHS agencies' searched are noted in the report.

(E) Results to Date

- Thus far, FDA has identified 18 human radiation experiments from its search of the Bureau of Radiological Health files; NIH has identified 200 relevant intramural experiments to date from its internal review of the NIH Clinical Center Medical Board minutes and the Radiation Safety Committee minutes. NIH is currently in the process of compiling a composite list of intramural human radiation experiments. NIH has not yet been able to create a list of human radiation experiments sponsored or funded through its extramural awards, because of a lack of available information and lack of control over the records at grantee institutions.

III. Brief Organization History

The Department of Health and Human Services (HHS) is the principal federal agency charged with advancing the health of Americans and providing essential human services. The existence of a Department-level organization began with the creation of the Federal Security Agency (FSA) in 1939. Its successor, the Department of Health, Education, and Welfare (DHEW), was established in 1953. The contemporary structure of the Department dates to 1980, when HEW was reorganized and renamed the Department of Health and Human Services. The United States Public Health Service (PHS) is one of five components of HHS.

PHS is the primary health agency of the federal government. It is administered by the Assistant Secretary for Health, who reports to the Secretary of the DHHS. The Surgeon General serves as an advisor to the Assistant Secretary and to the general public. The Surgeon General is delegated administrative responsibilities that include oversight of PHS's Commissioned Corps, a uniformed service of health professionals that comprises about 15 % of PHS's work force. In addition to an Office of the Assistant Secretary for Health (OASH), PHS consists of eight agencies: the Agency for Health Care Policy and Research (AHCPR), the Agency for Toxic Substance and Disease Registry (ATSDR), the Centers for Disease Control and Prevention (CDC & P), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA). Attachment D is a recent organizational chart for PHS. In this report a general overview will be given for PHS as a whole, followed by brief sketches to describe PHS's hospital system, NIH, FDA, CDC and IHS.

PHS began as the Marine Hospital Service, created by an Act of Congress in 1789, to provide care to merchant seamen. It was operated under the auspices of the Treasury

Department. The Service was reorganized in 1870, and the first Supervisory Surgeon (later called the Surgeon General) was appointed the following year. In 1912 the agency was given its current name, to reflect a growing number and variety of duties. Beyond the traditional role of service to federal beneficiaries, activities included research at the Hygienic Laboratory (the predecessor of NIH), field studies, quarantine, and the inspection of immigrants. At the time of PHS's transfer to the new Federal Security Administration in 1939, PHS consisted of 12 separate Divisions, each organized by type of activity; Division heads reported directly to the Surgeon General.²

Since World War II, there have been three major reorganizations of the PHS. The first occurred in 1943 and 1944, when the PHS's Divisions were gathered into four "Bureau" units: the Office of the Surgeon General (OSG), the National Institutes of Health (NIH), a new Bureau of Medical Services (BMS), and a new Bureau of State Services (BSS). The second change took place between 1966 and 1968. A series of reorganizations resulted in the transfer of the Surgeon General's line authority to HEW's Assistant Secretary for Health and Scientific Affairs (1968) and splitting of the agency briefly into five components (1966-67) and then into three (1968) including FDA, NIH, and the Health Services and Mental Health Administration (HSMHA). The third major reorganization occurred in 1973 and strengthened the Assistant Secretary's role, among other things. CDC was given agency status in 1973. IHS was elevated to agency status in 1988.

PHS's first responsibility, one carried out until the early 1980s, was the delivery of health care to merchant seamen and other federal beneficiaries, through a network of hospitals and outpatient clinics. Until 1943, PHS's Division of Marine Hospitals and Relief administered the network of facilities. At that time, the new Bureau of Medical Services assumed the old Division's functions and retained them, save for a brief period (1966-67) in which duties were split between a new Federal Health Programs Service and a short-lived Bureau of Health Services. In 1981, the last of the PHS hospitals and clinics were closed.

The National Institutes of Health began as the Laboratory of Hygiene in 1887 and was renamed the National Institute of Health in 1930. Within NIH, a number of Divisions continued and expanded the Hygienic Laboratory's program of in-house, or intramural, research. NIH activities encompassed a variety of disciplines such as industrial hygiene, physiology, and field studies of public health methods.³ The National Cancer Institute was created in 1937 and was authorized to award research grants.⁴ Beginning in the 1940s, NIH greatly expanded its programs

² With the advent of World War II, the FSA also housed the Office of Health, Welfare, and Related Defense Activities from 1940-1941, the Office of Defense, Health and Welfare Services from 1941-1943, and the Office of Community War Services from 1943-1947.

³ During the late 1930s and early 1940s, NIH had a Division of Industrial Hygiene to develop research and training programs for industrial hygiene, but which during World War II began to provide direct occupational medical and industrial hygiene services to the Army and state programs. While it is not known whether this Division conducted or sponsored radiation research, it was involved with air and water pollution monitoring and uranium mining studies.

⁴ By 1946, the National Cancer Institute was conducting research for the Manhattan Engineering District.

of intramural research, opening several Institutes organized by type of disease and a Clinical Center in 1953 for patient-oriented research. In addition, a program of research grants-in-aid to nongovernmental institutions -- the extramural program -- was established in 1946, with the assumption of a grants program from wartime federal authorities.

The Food and Drug Administration (FDA) was established in 1927 as the Food, Drug, and Insecticide Administration within the Department of Agriculture to enforce the Federal Food and Drug Act of 1906. The FDA remained within Agriculture until its transfer to the new FSA in 1940 and to the new HEW in 1953. In 1968 FSA became a constituent agency within PHS.

The Centers for Disease Control and Prevention (CDC) began as the Malaria Control in War Program in 1942. CDC is charged with protecting the public health from the spread of diseases and responding to public health emergencies, including radiation emergencies.⁵ The Agency for Toxic Substance and Disease Registry (ATSDR) was established in 1983 to assume the health related responsibilities of several federal environmental laws relating to the control of toxic or hazardous substances.

The Indian Health Service (IHS) has its origins in health care programs that had been operated by the Department of the Interior since 1849. Through the loan of Commissioned Corps officers, PHS has been involved in the care of American Indians since the 1920's. In 1955 all Indian health programs and responsibilities were transferred to a new PHS Division of Indian Health, located within the Bureau of Medical Services. In 1988 IHS achieved full agency status.

IV. Description of the Search

(A) HHS-wide Search

(1) Guidelines

On January 27, 1994, Secretary Shalala instructed all components of the Department of Health and Human Services (HHS) to identify all records related to experimental human exposure to ionizing radiation conducted between 1944 and 1974. An executive committee for HHS was established in January which included the Deputy Assistant Secretary for Health--Science, General Counsel, Assistant Secretary for Legislation, Assistant Secretary for Public Affairs, and Chief of Staff. This committee served to coordinate HHS-wide activities. The Committee met weekly during the first six weeks and then every two to three weeks thereafter.

⁵ A few of the CDC's operating components are the Epidemiology Program, the International Health Program, the Center for Prevention Services, the Center for Environmental Health and Injury Control, the National Institute for Occupational Safety and Health (NIOSH), and the National Center for Health Statistics, among others.

(2) Search Organization

Because most experimental medical research is either conducted or funded by the Public Health Service (PHS), PHS established a working group to coordinate the HHS records retrieval effort. This working group is co-chaired by Dr. D.A. Henderson, Deputy Assistant Secretary for Health--Science, and Dr. Wendy Baldwin, Deputy Director for Extramural Research, National Institute of Health (NIH). The group includes representatives from NIH, CDC, IHS, and FDA. The PHS working group is responsible for providing ongoing guidance and oversight for the search activities to assure the quality, comprehensiveness, and integrity of the records collection process.

(3) Search Logic and HHS-wide Key Word Search

When HHS records are retired to the Federal records center or the National Archives, a subject index for each set of records is created. These indices are known as Records Transmittal and Receipt Forms (SF 135). Each component of the Department was instructed to examine these forms for the appearance of certain key words which would suggest that the files have some information pertaining to ionizing radiation. Each agency within HHS was directed to work with the appropriate records management personnel to review every SF 135 generated by the agency between January 1, 1944 and May 30, 1974 to determine if it contains one or more of the following key words:

radiation	radiology
radioisotopes	radiological
radionuclide	radiotherapy
radioactive	x ray
radiometry	roentgen

This search generated a list representing more than 1,000 cubic feet of possibly relevant records. Most of the records identified by this search belong to NIH, although FDA and CDC also identified SF 135s containing the key words. Boxes of records identified by this search are now being searched individually.

In addition to the systematic review of SF 135 forms, each of the principal PHS agencies has established its own search strategy tailored to the types of research activities and records maintained by each agency. For those experiments conducted by PHS employees, the records that exist are likely to be found within agency files. However, most of the research supported by the PHS is conducted by research institutions located throughout the United States. Thus, most records of special interest -- research protocols, documents related to informed consent, and identities of research subjects -- will be located at awardee institutions. On March 7, 1994, HHS sent a letter to 27,000 research institutions asking that they take special measures to request that all records related to human exposure to ionizing radiation are located and preserved.

(4) Document Retention or Destruction Policies and Practices

On January 27, 1994, Secretary Shalala directed all of the HHS agencies not to destroy any records relating to human radiation experiments even under regular approved destruction schedules. Dr. Henderson, the Deputy Assistant Secretary for Health and Science, and Dr. Baldwin, the Deputy Director for Extramural Research, jointly requested HHS grantee institutions likewise to locate and retain any documents in their possession relating to human radiation experiments. Further investigation is necessary into the HHS current document retention and destruction policy and records management policies. Committee staff plans to meet with PHS records management personnel to develop a better understanding of the records management practices at HHS and the HHS search process.

It may not be possible to determine what the current or past practices are at the individual agencies within HHS and their predecessors, what the document retention and destruction policies are at the grantee institutions, or what level of compliance with the HHS directive can be expected from grantee institutions.

(B) Individual Agency Search Logic: NIH

NIH formed the NIH Human Radiation Studies Task Force. The Task Force is comprised of 25 people representing various divisions at NIH and spearheads the NIH document search effort. The Task Force has met weekly since January 27, 1994. Its present search strategies include:

1. identification of the records of NIH extramural awards;
2. identification of the records of intramural research conducted at the NIH;
3. oral interviews of selected senior NIH staff;
4. pilot program review of literature related to extramural awards;
5. review of stored NIH records by searching for 11 key words on the agency's record disposition form;
6. evaluation of calls referred to NIH from the Department of Energy 1-800 helpline; and
7. response to media and congressional interests in "flagship incidents."

Since January 1994, NIH has devoted approximately 4-5 persons per day to these strategies, approximately 2,500 person hours. A brief elaboration on each strategy follows:

(1) Identification of the records of NIH extramural awards

The NIH Division of Research Grants (DRG) is responsible for managing records related to the extramural program. DRG has nominal records for the period from 1946-1961. DRG files are available only in paper copy for the years 1946 to 1961. Attachment E is a sample page from DRG's grant records for the 1946-1961 period. The information for 1946-1961 available from

DRG records includes:

- (a) a list of projects funded after review by the study section and the members of the section;⁶
- (b) the name of the principal investigator;
- (c) the name of the investigator's institution;
- (d) the title of the proposal; and
- (e) the years funded.

From 1962 to the present, DRG information has been computerized. At some point, the DRG records contain more information about the research.

Since grant titles in these records can be general, reviewing titles alone is unlikely to be helpful in identifying human subjects and relevant experiments. NIH staff currently are considering several ways of using this limited information in this search. Presently, the NIH titles are being hand searched for the period from 1946-1961 and searched by computer from 1962-1974 for matches with "rad" or any of 39 terms, as follows:

calcium isotopes	radioactivity
calcium-45	radiology
calcium-47	radium
carbon isotopes	radiotherapy
chromium-51	strontium
cobalt-60	thorium
krypton-85	thorotrast
iodine isotopes	radiopharmacology
iodine-125	radiological implant
iodine-131	radiological health
iodine-132	barium
irradiate	fluorine
leukemia induced radiation	tritium
plutonium	potassium
radiation	sodium
radiation effects	zinc
radiation injury	

NIH believes that limiting the records search by using an institution name, investigator name, or a focused literature search may be more helpful and a reasonable use of time and resources. NIH notes that reliable documentation in the award information on whether human

⁶However, this information is not available for most years in the 1946-1961 period.

subjects were involved may not exist in many cases for the period 1946-1971.⁷

NIH representatives and Committee staff discussed the logic of a search directed at records maintained by organizational components. Identification of the relevant institutional offices and procedures at NIH and its predecessors, if any, is the first step. When an application for a grant comes to NIH, it is assigned to a study section, which is the peer review group that makes the initial evaluation. Since the 1940s, NIH has had a Radiation (Radiobiology) Study Section. A computer search found 400 awards that had been reviewed by this Section in 1962, the first year of computer data. A hand search uncovered 15 awards reviewed by the Radiation Study Section in 1946. Thus, it appears that from 1946 to 1961, the Radiation Study Section reviewed between 15 and 400 grants that were awarded per year.

However, NIH is not aware of any records of the criteria used to determine which proposals were sent to which study sections. Thus it is possible that other study sections (e.g., Physiology) may also have reviewed human radiation experiment grant proposals. In fact, documentation exists demonstrating that requests for funding involving human radiation experiments did go through the NIH/FSA Physiology Review Section in 1950. (See Attachment B).

Study Section sessions are conducted as closed meetings. Today, there are no minutes of Study Section meetings, but summary statements of peer review recommendations are recorded for each grant. Any past records are believed to have been destroyed, according to NIH. However, Committee staff have found documents related to NIH/FSA grant application review in the archived records of other agencies. Attachment B includes a negative evaluation by a reviewer returned to the Physiology Section on a 1950 proposal to use Iodine 131 tracers on children.

After review by a study section, a grant proposal would have been reviewed by one of the Advisory Councils for the different Institutes at NIH. The Advisory Councils are comprised of scientists, laypersons, and other federal officials (serving in an *ex officio* capacity). According to NIH, Advisory Councils generally meet three times a year in open session; the minutes are archived. However, this may not have always been the case. They also meet in closed sessions when discussing individual grant applications. The documentation of any review of a grant proposal by an Advisory Council is believed by NIH to have probably been destroyed or lost. According to NIH, the Advisory Council minutes have not yet been located. The time period in question is beyond the normal record destruction period. Other documentation of the NIH peer review process or other types of documents may be in the files of individuals who participated in the reviews.⁸ As part of its search, the NIH Task Force mailed two sets of letters to the directors

⁷In some situations, where the grant record information does not show whether human subjects are involved, even a subsequent literature search may also not provide this information.

⁸NIH stated that interagency radiation health groups apparently have been established periodically. The HHS representative to the 1970 Interagency Radiation Health Group has files on these meetings.

of the 20 Institutes and Centers at NIH requesting them to search their files for protocols of intramural human radiation experiments.

HHS states that the vast majority of the records of the NIH extramural grant program are most likely housed at grantee institutions. On March 7, 1994, HHS informed 27,000 grantee institutions by letter to locate and preserve relevant records. HHS has not yet directed any grantee institution except the University of Cincinnati to collect or retrieve records. HHS has some authority to audit these institutions under its grant management authority, which may possibly allow NIH to request and retrieve documents from institutions that received an NIH grant.

(2) Identification of the records of intramural research conducted at NIH

The NIH intramural research program conducts protocols (experiments) at the Clinical Center, which has been in existence from 1953 to the present, and several offsite hospitals including St. Elizabeth's Hospital in Washington and Francis Scott Key Medical Center in Baltimore. The Medical Record Department possesses records for the 245,000 patients admitted to the Clinical Center since it opened in 1953. Much of NIH's clinical work is experimental in nature, and much deals with radioactive substances. Inactive records are housed on microfiche offsite at the National Underground Storage (Boyers, PA). Inactive medical records from the NIH Clinical Center are estimated at between 500 million and 1 billion pages of material. NIH therefore believes that it cannot search feasibly for all relevant documents related to human radiation experiments without further refinement of the experiments most relevant to the Committee's work, either by experiment type, particular patients, or certain years or investigators.

NIH staff reviewed the Medical Board minutes⁹ and the Radiation Safety Committee minutes from the Clinical Center. NIH plans to review the Clinical Research Committee minutes. NIH staff is compiling a list of human radiation experiments at NIH intramural program and the protocols, titles, and investigators from these minutes. NIH staff currently have identified approximately 200 experiments conducted at the Clinical Center that either deviated from standard procedure or involved healthy volunteers. NIH believes that the medical records for these patients and healthy volunteers are in its possession.

(3) Oral interviews of selected senior NIH staff

Seven current NIH employees who were authorized radiation users and members of the Radiation Safety Committee from 1944-1974 were interviewed. Five specific questions were asked:

- * Which investigators were conducting human radiation experiments prior to 1955?
- * Where were the experiments conducted?

⁹The Medical Board reviewed "controverted protocols."

- * How did NIH handle its oversight responsibility for protocols involving ionizing radiation?
- * Where can we find the records of these protocols?
- * What was the nature of the research?

These interviews led to the discovery of one previously unidentified investigator at NIH that was added to the list that NIH is currently compiling relative to human radiation experiments.

(4) Pilot program review of literature related to extramural grants

NIH is not aware of any programs at NIH related to human radiation research that were not public or any research that NIH funded or sponsored through its extramural program that was not published in the scientific or medical literature if it qualified for publication.

As a pilot program to determine the value, effectiveness, and cost of a published literature search, NIH employed two medical librarians to track the published literature related to the 16 grants that the Radiation Study Section reviewed in 1946. Each librarian was asked to pull all of the relevant published articles for 8 of the 16 investigators. After reviewing approximately 300-400 articles each,¹⁰ less than 100 articles relating to human research remained.¹¹ Even in early years, one award could spawn a large number of articles. The abstracting of the 100 remaining articles involved the greatest effort.¹²

(5) Review of stored NIH records by searching for 10 key words on the SF 135

The SF 135 key word search located 1,200 boxes of NIH records at the Federal records center in Suitland, Maryland. The NIH Task Force plans to search these boxes. However, as of May 3, the SF 135 search at NIH did not involve opening any stored boxes to determine the actual contents of any box. HHS plans to go only to the Federal records center in Suitland during this search.

(6) Evaluation of calls referred to HHS by the Department of Energy 1-800 helpline

HHS has had twenty calls referred to it by the DOE. NIH is coordinating the responses to these referrals. Sixteen callers provided what HHS considered "insufficient information to be linked to any identified DHHS activity." Four callers provided information that HHS believed could be pursued. In fact, three of these callers were patients at the NIH Clinical Center, and

¹⁰ It costs \$3.00 to pull one article; there were 600-800 articles relating to the 16 grants.

¹¹ In some cases, the literature did not even note whether human subjects were involved.

¹² As discussed later, it may be possible to cross check against AEC records to reduce the number of articles that need to be abstracted.

therefore, their medical records are at NIH. NIH has been unable to contact the fourth caller because his phone is currently disconnected. For the other callers, HHS correspondence consisted of a form letter sent to each of the 16 callers stating that these callers cannot be linked to any identified HHS activity at this time.

(7) Response to media and congressional interest in "flagship incidents"

In response to intense media interest and Congressional hearings on Dr. Saenger's experiments at the University of Cincinnati and planned upcoming hearings on New Orleans' Charity Hospital, HHS has undertaken searches targeted at its activities related to these locales or experiments. HHS provided a statement related to the whole body irradiation experiments at the University of Cincinnati to the Subcommittee on Administrative Law and Governmental Relations of the House Judiciary Committee on April 14, 1994.

NIH discovered that it had funded Dr. Saenger for various projects totalling a \$1 million in support, instead of the \$11,000 of which it previously had been aware. Dr. Saenger was receiving funding as a participant in training grants and a general clinical research center grant, as well as funding as a principal investigator. In addition, NIH funding is represented in more general support for research at Cincinnati. NIH funded eight hospital beds at the University of Cincinnati, one of which Dr. Saenger used for his research.

HHS requested that the University of Cincinnati review its files for records reflecting any involvement or funding from HHS of Dr. Saenger's work. The University of Cincinnati has notified NIH that it did not uncover any documents related to particular NIH grants for the years in question.

(C) Individual Agency Search Logic: FDA

The FDA mapped out a strategy to determine whether the FDA or any of its predecessor agencies had any direct or indirect involvement with ionizing radiation tests on humans at any time from 1944 through May 1974. FDA interviewed past and present employees and conducted the SF 135 key word scan. The key word search was conducted on the records holdings at the National Archives and at the Federal records center in Suitland. FDA concluded (based on the word search, and the interviews) that the Center for Food Safety and Applied Nutrition did not give grants to support human radiation research and did not conduct any such research. The Office of Regulatory Affairs, which manages the FDA field offices, did not conduct any radiation research on humans during this period and never had a grant program. The Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research have both had some role in regulating radiopharmaceutical products but have not had "direct involvement in the human testing of (radiopharmaceutical) drugs and/or biological products" on humans.

The word search revealed that the only FDA records reflecting the key words belonged to

the Center for Devices and Radiological Health (CDRH) and its predecessors. FDA concluded that the CDRH, which is the successor organization to several radiological health organizations located within the PHS until their functions were transferred to the FDA in 1971, had documents reflecting an involvement in human radiation experiments. FDA identified and examined 20 separate accessions (shipments) from the CDRH to the Federal records center; an FDA scientist from the CDRH's Office of Health Physics and an agency historian reviewed these records at Suitland. The CDRH's Office of Health Physics conducted a search of the published literature, in house publications, and records of grants and contracts administered by the Bureau of Radiological Health.

FDA notified HHS of 18 studies that clearly involved human radiation experiments from the Bureau of Radiological Health files. All of the FDA documentation will be available to the committee when requested. Ten of these 18 studies involved multiple agency sponsorship. In addition, FDA is aware of classified research being conducted under its predecessor's auspices. Oral histories at the PHS Division of Radiological Health's Southwest Radiological Health Laboratory in Las Vegas revealed that about one-fifth of the lab's 1000 workers were involved in classified research for the Atomic Energy Commission. The AEC reimbursed the Division for this work. Division researchers were not privy to the results, and no Division records have been identified from this period.

FDA has sent the March 7, 1994 HHS memorandum regarding preservation and retention of any experiment records to the 27 institutions involved in these 18 experiments. FDA is also working with archivists at the National Academy of Sciences (NAS) and the Center for the American History of Radiology to examine correspondence and other records donated by scientists or administrators who had worked for the federal government in the field of radiation.¹³ FDA is interested primarily in the records of scientists who worked for FDA and the Bureau of Radiological Health.

No estimate of the number of person hours expended on this search strategy has been provided.

(D) Individual Agency Search Logic: CDC

CDC also has pursued several different strategies to locate human radiation records. These strategies are outlined below.

- (1) Using HHS' key word search, CDC reviewed SF 135s and SF 258s (which are apparently another records management form) maintained by CDC and the ATSDR for shipments of CDC and ATSDR records to the National Archives and to the Federal records centers. The SF 135/SF 258s represent CDC documents from 1953 to the present that were sent to the Federal records centers and those documents from 1960 to the present that were sent

¹³The NAS Archives also contain records of the Biological Effects of Atomic Radiation (BEAR) Committee which met from 1955 to 1964. One subcommittee of the BEAR committee apparently had access to the AEC biomedical data to study the pathological effects of atomic radiation.

to the National Archives. The word search identified 21 shipments from CDC to a Federal records center with references to radiation; nine of these inventoried shipments already have been destroyed under the Federal record center's approved destruction schedule. No ATSDR references to radiation were identified.

Review effort: 40 person hours

- (2) CDC reviewed its files from 1943 to 1994 to determine if any radiation related activities were conducted by the CDC and its parent agencies. It also reviewed its organizational charts and mission statements. Until the National Center for Environmental Health (NCEH) was created in 1980, the organizational charts and mission statements did not contain any references to radiation.
No estimate of the number of person hours expended on this search strategy has been provided.
- (3) ATSDR reviewed its files for radiation-related activities, including those of the former CDC Superfund Implementation Group. ATSDR reports that "No radiation related activities matching the White House definition were found while searching the Superfund Implementation Group files."
No estimate of the number of person hours expended on this search strategy has been provided.
- (4) CDC and ATSDR working group has developed a plan to identify officials who should have knowledge of historic CDC activities. Staffing charts were reviewed back to 1951 to identify key officials of CDC components, such as, Directors and Deputy Directors of CDC. A roster has been created, including NIOSH officials, for the HHS to contact regarding their knowledge of radiation activities. These officials will be separated into two broad categories: those officials with knowledge of groups or individuals conducting radiation related work, and those with specific knowledge of that work. They will be questioned and their knowledge will be documented. This information will be used to focus CDC's search.
Review effort: 32 person hours
- (5) CDC reviewed its AEC and Nuclear Regulatory Commission (NRC) licenses. The original license issued to CDC by AEC was dated 9/22/60. The license specifically prohibits CDC use of "byproduct material" "in or on human beings." The CDC Radiation Safety Officer (RSO) reviewed the radiation records in the Radiation Safety Office and did not find any exceptions permitting human radiation exposures.
Review effort: 20 person hours
- (6) CDC searched its listing that begins in 1966 of all of the protocols submitted for review for the protection of human subjects. These protocols were reviewed by Ad Hoc Review committees until 1983, when Institutional Review Boards (IRBs) began these reviews.

CDC searched the entries through 1975; no protocols were identified including human radiation exposure.

Review effort: 5 person hours

- (7) Because CDC did not have grant authority until 1980, the CDC used contracts as its funding mechanism. CDC maintained two handwritten logs for contracts in this time period. Each contract was entered in a single line entry with the date issued, RFP number, CDC program, award date, contract number, contractor, contract dollar amount, contract type, and a brief single sentence description. These logs were manually reviewed for radiation experimentation references. Six references were identified, and all were for either X ray film, X ray development equipment or X ray machines. The descriptions are "vague," but none specify "non-diagnostic use." CDC's approved Records Control Schedule results in the destruction of procurement records after seven years. According to CDC, no records exist before 1975 except the logs.

Review effort: 2 person hours

- (8) Research projects by the CDC and the ATSDR

CDC reports that it did not expose humans to radionuclides. However, CDC has conducted and is conducting several "follow up" studies for other government agencies and their contractors who did sponsor or conduct activities that exposed human beings to radiation. HHS takes the position that these CDC "follow up" studies and documentation from them do not fall within the definition of human radiation experiment as embodied in the Executive Order establishing the Committee. If these records are included in the documentation and search process, these "follow up" studies and their extensive supporting documentation will increase exponentially the number of CDC documents, according to HHS. CDC has documents from the following studies:

- (a) Hanford Environmental Dose Reconstruction Project

These documents relate to "follow-up" on activities at Hanford that include the Green Run test. The contractor, Pacific Northwest Laboratories (PNL), estimates that there is one cubic foot of documents relating to Green Run that are either derivative reports or "sanitized versions of classified documents." PNL estimates that 3% of the Green Run documents remain classified. The original documents are the property of the Department of Defense.

- (b) Hanford Thyroid Disease Study

CDC is studying the prevalence of thyroid disease in subjects exposed to Iodine 131 from the historic operations at Hanford. From 1989 to the present, over 750 people who were born in the Hanford area in the 1940s have agreed to participate in a pilot phase of the study.

(c) Idaho National Engineering Laboratory Dose Reconstruction

CDC's contractor is conducting a dose reconstruction project at DOE's Idaho National Engineering Laboratory (INEL). *CDC's contractor recently located documentation of intentional releases of environmental radiation at INEL and the intentional exposure of volunteer human test subjects that were not explicitly listed in the advisory committee charter.* DOE has been formally notified of this discovery. The documents related to the releases are in DOE's or the National Oceanic and Atmospheric Administration's (NOAA) possession.

(d) Mortality and Cancer Frequency Among Military Nuclear Test (SMOKY)

Three thousand participants were exposed to radiation in a 1957 military nuclear test in Nevada.

(e) Oregon prisoner follow-up

CDC consulted with the State of Oregon's Department of Human Resources from 1989 to 1990 in the development of tracking and medical follow up protocol for the prisoner test subjects intentionally irradiated between 1963 and 1973 by a contractor for the AEC. HHS represents that the State of Oregon has the documents.

(E) Individual Agency Search Logic: Indian Health Service

The IHS has pursued several different but complementary strategies to locate records or information about radiation research involving American Indian and Alaskan Native (AI/AN) people. Many IHS strategies are similar to those by other PHS agencies and, indeed, were adapted from them. The IHS strategies, as reported by IHS, are discussed below:

- (1) Using the HHS-IHS keywords, IHS manually reviewed all IHS SF 135s for all environmental health records, and for any other category (not individual medical records) that might be related to radiation research. In its searches, IHS used the original HHS keywords plus "uranium" and "plutonium;" this augmented list is called the "HHS-IHS keywords." No records were found. IHS also asked its Record Officers and Medical Records Staff in all 12 administrative Areas for location of on-site stored records concerning research, environmental health, and any other categories possibly related to such work. No records were found.
- (2) Using the HHS-IHS keyword search, IHS manually reviewed every single file from the beginning of the Office of Research and Development (ORD) through December 1975. ORD was the IHS research unit that began near Tucson in 1969; it is now the Office for Health Program Research and Development (OHPRD). No files had been archived; all were available for review. There were no references to radiation experiments or

intentional releases of radiation. Six records contained one or more keywords. Three of the six records referred to epidemiological studies about exposure to low-level environmental radiation, not exposure by experiment or by intentional release of radiation. (The studies were: a radiation ecology study in northern Alaska from nuclear fallout; a study in Utah and neighboring states of long-term exposure to nuclear bomb test fallout; and a study of Navajo people exposed to radiation from uranium mine tailings.) The remaining 3 of the 6 records referred to diagnostic x-rays that were done for routine care and not as part of any experiment. (The studies were: pulmonary disease among White Mountain Apache children; ankylosing spondylitis among Ute adults; and histocompatibility antigens among Apache adults with diagnosed reactive arthritis.)

- (3) IHS located the logs of grants and contracts issued by IHS before June, 1974 irrespective of the apparent category, research or otherwise. Using the HHS-IHS keywords, IHS manually reviewed the titles and any description of each grant or contract in the logs. No title or description contained any keyword.
- (4) IHS asked the Medical Imaging Program Officer of each administrative Area to do a manual search of their records before June 1974. These records are primarily of the radiation exposures of staff doing x-rays; the concern was that there might be a reference to experiments involving medical imaging if any had been done in IHS facilities. The search is not complete; so far, no relevant records have been found.
- (5) IHS asked the administrative Area Officers of Environmental Health to do a manual search of their files, similar to that described in (4). The search is not complete, but so far, no relevant records have been found.
- (6) IHS asked the counterparts in Records Management in the Bureau of Indian Affairs (BIA), Department of Interior, to search its SF 135s and any relevant unarchived records, using the HHS-IHS keywords. The BIA was the predecessor to the IHS until 1955. The BIA search is not yet complete.
- (7) IHS asked the Native American Research Information System (NARIS), U. Oklahoma, to conduct a computer search of its records using the HHS-IHS keywords. NARIS has a computerized database of articles, reports of government grants and contracts, books, etc. concerning AI/AN.¹⁴ Many of the entries are reports of the results of grants or contracts awarded by the federal or tribal governments and not available in other computer databases. Most of the almost 14,000 entries are not medical. The search could not be done in one pass using all keywords in a Boolean logic "key 1 or key 2 or key 3."

¹⁴The NARIS database appears incomplete. It did not print out the famous article in the New England Journal of Medicine of a case-control study proving the high incidence of lung cancer among non-smoking Navajo uranium miners (Samet J, Key C, *et al.* Uranium mining and lung cancer in Navajo men. *NEJM* 198a; 310:1481-1484.)

Because a separate search was done for each keyword, the results have duplicate entries. The title and abstracts of 104 total entries were printed out.

No entries were directly relevant. Most of the entries concerned environmental impact reports, diagnostic use of x-rays in articles about diseases, epidemiological monitoring studies of fallout or uranium mining, or policy assessments or proposals.

- (8) IHS interviewed people who would be likely to know about any such research in Indian country by IHS or anyone else. The initial list of people included the four living former Directors of the IHS (a fifth former Director had already died), and the four former directors of research in the IHS. No-one remembered a single radiation experiment carried out by IHS or anyone else involving AIAN people or intentional release of radiation on or near Indian reservations.
- (9) IHS asked the above mentioned interviewees to suggest names of others who might know if research had been done. The number of "secondary offspring" suggested by the people initially interviewed doubles the initial list. Most of the "secondary offspring" are "old hands" in environmental health. Those interviews are in progress, and so far no relevant information has been found.
- (10) IHS also asked the above mentioned interviewees to suggest other sources of information. One source suggested a report done by LaDonna Harris about 15 years ago documenting environmental health hazards, especially radiation. IHS is obtaining the report.
- (11) In a research project in 1955 at the Arctic Aeromedical Laboratory, Ladd Air Force Base, Fairbanks Alaska, a U.S. Air Force researcher studying thyroid metabolism gave diagnostic doses of Iodine 131 to 102 healthy people, including 2 adolescents; Athapaskan Indians of interior Alaska (from the villages of Arctic Village and Ft. Yukoa); coastal Eskimos (Wainwright, Point Lay, and Point Hope), and inland Eskimos (Anaktuvuk Pass). This study made headlines in Alaska when revealed by Alaska Senator Frank Murkowski in April 1993. The dose used was up to 65 microcuries of I-131. (The current diagnostic test is 200 microcuries of I-123.) Although a higher number of microcuries is used for I-123, the amount of radiation effectively delivered by the 1955 Alaska diagnostic tests was ten times that used currently, due to the shorter half-life and weaker type of radiation of I-123. I-131 is the current iodine nucleotide to ablate the thyroid as a treatment of, for instance, thyroid cancer; the ablation dose is 30 millicuries, about .002 the dose used in the Alaska study.

One of the IHS people pursuing the IHS strategies knew about this study from the previous news reports and obtained a copy of this research report. The report lists the names, ages and home villages of each volunteer subject. There was no record or reference to informed consent. A copy of the report has been sent to the PHS Human

Radiation Studies Working Group, and to the Chief Medical Officer of the IHS to determine possible follow up of the subjects of this experiment.

In summary, IHS found no records or memory of any radiation experiments *by IHS*. IHS found one study *by others*; the Air Force gave diagnostic I-131 to healthy adults to study thyroid metabolism. Given the concerns of all of the former IHS Directors for the public health impact of radiation exposure on AI/AN communities, IHS does not believe that it is likely that other research has been done on AI/AN people. However, the Air Force study was not detected by the formal strategies pursued by IHS. Thus, IHS cannot say for sure that no other experiment had been done. IHS continues to pursue the remaining strategies mentioned above. No estimate of the number of person hours expended on these search strategies has been provided.

(F) Individual Agency Search Logic: Public Health Service Hospitals

Although the PHS hospitals have not been operating under the PHS since 1981, they have been identified by PHS as entities that once conducted or sponsored human radiation research. According to HHS, the PHS hospital records are located either in the Office of the Assistant Secretary for Health (if shipped offsite with the appropriate SF 135, they were subjected to the key word search) or in the regions in the Health Resources and Service Administration (also subjected to an SF 135 search if properly shipped). Patient records are kept at what used to be called the National Leprosarium and is today the Hansen's Disease Center in Carville, Louisiana. Records can only be retrieved by patient name according to HHS. Much more explanation is needed to develop the picture regarding records that may exist from these PHS hospitals, and any radiation research that they may have conducted or funded. No estimate of the number of person hours expended on this search strategy has been provided.

(G) Individual Agency Search Logic: Other HHS Agencies

HHS believes that its other agency components would not have been likely to conduct or sponsor human radiation experiments. For example, the Social Security Administration, the Health Care Financing Administration, the Family Support Administration, and the Office of Human Development Service were not likely to be involved in human radiation experiments. For these agencies, the HHS required an SF 135 search with the key word list. These agencies were to document the results of the key word search to the HHS.

V. Agency Observations and Concerns

HHS made a number of observations and expressed a number of concerns. The NIH raised three separate types of concerns: (1) agency record keeping (i.e., grant list) that cannot distinguish relevant experiments; (2) a potentially unmanageable number of documents related to

experiments known to have occurred intramurally (for example the medical records corresponding to the 200 experiments identified to date by NIH at the Clinical Center); and (3) the potentially large number of documents at grantee institutions. NIH believes that the bulk of existing documentation of human radiation experiments sponsored or funded by NIH is located at the grantee or awardee institutions for the extramural program.

HHS requested further refinement of the definition of human radiation experiment in the Advisory Committee charter, or at least a prioritization or categorization scheme with which to better define, limit, or direct the search for potentially responsive records. HHS believes that the Executive mandate is extremely broad and requests that the Committee provide specific guidance or interpretation of the charge to HHS in order to clearly focus its search to assure that the Committee receives relevant and helpful documentation.

HHS suggested some criteria that could be considered to set parameters on the search for relevant documents, for example, the level of exposure or dose, particular populations of subjects, types of experiments, certain investigators, or particular institutions. NIH's literature searches indicate that while exposure information may be available, informed consent information probably is not available from the published literature in the earlier periods. HHS raised the question of whether documentation of an experiment is of any practical use to the Committee if information about consent or whether subjects were humans or non-human animals is not available. HHS queried if experiments could be categorized or prioritized as high, medium, and low priority or whether a set of criteria could be developed to sort experiments into categories with different priority.

NIH also has a concern that the definition of human radiation experiment excludes only "common and routine clinical practices" and "established diagnosis and treatment methods." All of the work done at the NIH Clinical Center is experimental in nature, and much of it involves radiation. The records for all of the 245,000 patients at the Clinical Center number between 500 million and one billion documents. NIH intramural program was able to identify 200 relevant human radiation experiments to date. While the medical records that correspond to this group of patients should be considerably less, NIH is not aware of any apparent way to link the protocol titles to medical records.

NIH is willing to computerize the pre-1962 Radiation Study Section grants for cross referencing. NIH would enter these records into its existing database with the format that it uses for its other records. NIH was amenable to adopting a classification system similar to the DOD format, if useful to the Committee. NIH is also willing to focus on the grants that were reviewed by the Radiation Study Section in the pre-1962 period.

NIH recognizes that no search strategy identified by NIH is expected to retrieve all items of potential interest.

VI. Committee Staff Analysis of the HHS Search

(A) Limitations of Search Techniques

HHS has set certain parameters for its search. No documents after 1974 were included in this search. HHS adopted its official federal policy for the protection of human subjects in research in 1974. However, post-1974 practices may be an issue for the Committee. The staff has not yet explored the types of information available or the strategies that might be pursued for retrieving relevant documents after 1974. Additionally, HHS excluded CDC records related to any epidemiological "follow up" studies because HHS believed that these studies were not within the purview of the Committee's Charter.

The quality of the HHS search is constrained by record-keeping practices, due to the nature of the NIH extramural process, the different practices among various agencies and offices, and both major and minor reorganizations of PHS. HHS records management personnel believe that most of the relevant records would not be physically in the agency's possession but rather in storage or the archives. It is doubtful that HHS has adequate records, inventories, or finding aids for its own documents still in its possession, and large numbers of records could be in its possession.

HHS acknowledges that the SF 135 search is a limited search tool with obvious flaws. SF 135 forms are only filled out when records are sent to storage, and SF 135 descriptions are too often cursory. Depending on the circumstances, the detail and quality of the description on the SF 135 can vary considerably. The key words used by HHS focused on scientific terms, not relevant agency offices. Any records that are currently in agency's files would not be located with an SF 135 search. An SF 135 search is insufficient for locating records in the National Archives. The SF 135 search is useful as a starting point to locate radiation experiments, but the search is not reliable for identifying the bulk of relevant records.

(B) Better Quality Assurance

HHS needs a strategy that will provide a higher level of assurance that the relevant files not yet archived have been identified, searched, and documented. The level of effort expended on the review of files could be increased and should be directed towards searching the central files of relevant offices. Some, but not all of HHS' search appears to have been well-documented. Some but not all of HHS' search was formal and structured and designed to produce confidence in the results. FDA's process for reviewing the Bureau of Radiological Health files appears to be a good example of a well designed and documented search. CDC's interview process also is a good example of a more comprehensive interview procedure.

(C) Response to the Public

HHS has responded to the public in two direct ways. First, HHS has responded by letter

to the twenty or so telephone queries that were referred to the HHS from the DOE helpline. HHS, however, could supplement its follow up letter to the callers with a second letter requesting any written documentation that the callers have related to their exposure to radiation, and a written narrative explaining their knowledge of their exposure. This approach was helpful to the Department of Energy when it initiated the Helpline.

Second, in response to public controversies, HHS has initiated one intensive search for records related to the University of Cincinnati experiments and is planning to search for documents related to the New Orleans Charity Hospital experiments. These searches are resource intensive, but have proven to be informative. For example, HHS learned that it had actually provided more funding than it realized, and in different ways.

(D) Revised Approach to the Interview Strategy

The scope of the interview process of the former and present employees who may have had experience or involvement with human radiation experiments could be expanded. Within NIH, for example, the scope of the current interview process, as of May 6, 1994, was limited to seven individuals who were each asked only five questions. An overall interview strategy could be designed that is integrated with the other strategies of the search. Points of particular interest should be identified for discussion, including co-funding relationships, classified projects, people who may have been involved in reviewing human radiation experiments, and the criteria for assigning grant applications to the Radiation Study Section as opposed to other study sections. Attachment B documents an application that was assigned to the Physiology Study Section.

VII. Committee Staff Recommendations

At this time, the tasks of quality assurance and historical research are not easily separable. Assuring the quality of HHS' search overlaps with refining its search efforts in ways most likely to be useful to the Committee. Once search strategies have been refined, the quality assurance task may become more distinct from the historical research itself. Options for historical research are *not* mutually exclusive (as may be the case later for options concerning ethical standards or compensation schemes), but may need to be prioritized due to limited time and resources.

The options presented to the Committee options are organized by activities that would be carried out by (A) HHS as recommended by the Committee, (B) the Committee itself, or (C) the Committee staff as directed by the Committee. HHS supports Options Two, Three, and Four as valid approaches to focusing its search for relevant records. Option One, in the staff's opinion, is the most significant recommendation that the Committee can make regarding HHS in particular, and perhaps the Interagency Working Group in general. Option Five can be exercised to facilitate Option One. Option Six is also important for public outreach. Options Seven through Eleven also are recommended.

(A) Committee-requested Action by the Department of Health and Human Services

- (1) Option One: Revise search strategy to locate higher-level policies and evidence of the policies and practices of interagency coordination or co-funding

HHS' search has indicated that many of the experimenters it funded were co-funded by other federal agencies. HHS' search reinforces the concept the multi-agency sponsorship research or researchers is fairly common. For example, during HHS' intensive search for records related to the University of Cincinnati, HHS found greater evidence of its own funding of Dr. Saenger than HHS previously realized. This result suggests that co-funding was not an anomaly for many of the relevant PHS agencies. The current HHS search process will not locate documents that explain the relationship between agencies that co-funded researcher or co-sponsored human radiation experiments.

The Committee could request HHS to revise its search strategy to include a search for higher-level documents reflecting the policies and practices of interagency co-funding. The likelihood of the existence of relevant documents is suggested by several factors. For example, some documents that HHS has been unable to locate reflecting the PHS review process for grant funding were discovered in the DOD files in the National Archives by Committee staff. The presence of these documents in DOD files suggest closer coordination between HHS and other agencies than HHS may have realized. Also, PHS has previously located Memoranda of Understanding between AEC and PHS regarding studies of the health effects of offsite exposure to the fallout from the nuclear testing program (Attachment C) in a 1979 document search. Thus, PHS has conducted an agency-wide document search and uncovered evidence of important high level coordination between AEC and PHS. A similar search strategy might be reproduced for our present purposes.

Additionally, HHS has found that its predecessor's own employees conducted classified research for the AEC. The policies and procedures that would have applied to these experiments probably cannot be obtained by the present search. Moreover, the HHS SF 135 search did not focus on high level policy or co-funding relationships.

This option requires that HHS devise a search strategy for records of higher level policies for reviewing human experiments and co-funding or coordination between more than one federal agency. For example, one search strategy can focus on relevant HHS policy offices and offices engaged in interagency liaison. Similarly, interviews can be structured to elicit information on the interrelationships of co-funding agencies. HHS can draw on other agencies' records as well. Staff proposes that the Committee advise HHS develop a search strategy, in conjunction with the Committee and staff as appropriate, calculated to efficiently locate higher level policy documents evidencing coordination or multi-agency sponsorship.

This option could produce documents about the formation and implementation (by expression or implication) of HHS policies applicable to the sponsorship or funding of human

radiation experiments or investigators; documents indicating whether these policies and practices were any different from those governing other types of human experimentation; documents demonstrating experiments which require special scrutiny; and documents leading to the discovery of relevant documents possessed by other agencies.

- (2) Option Two: Coordinate with DOE to create a search strategy for identifying extramural awards related to human experiments with radioisotopes

HHS agrees that it could focus its search on the Radiation Study Section grants awarded before 1961 (which as noted earlier probably range from 15 to 400 a year). Staff recommend that HHS could focus further by using the AEC summaries of isotope distribution to eliminate plant and animal studies from the Radiation Study Section experiments and to provide additional information on isotope use. AEC data may also identify journal articles based on certain experiments and additional co-funded projects by cross-checking with AEC annual reports and related reports. This option requires copies of AEC reports and minimal staff time. It produces additional information regarding investigators, location, and support.

- (3) Option Three: Prioritize document retrieval related to extramural records, for now, by focusing on non-isotope experiments

HHS's review of the Radiation Study Section grants awarded before 1961 also can be focused by eliminating isotope experiments for now and retrieving records related to the non-isotope experiments. Staff recommends this option because HHS may be an important source of information on non-isotope experiments. This option requires a search strategy that identifies non-isotope experiments on human subjects; may require more costly literature search; and may involve a series of investigative strategies, including for example, research on citations used in the literature for whole or partial body irradiation experiments, interviews, secondary literature searches, and an examination of AEC or other relevant governmental reports. The option may also require selection of either particular experiments or development of selection criteria applicable to the data available. The selection criteria might, for example, include the principal investigator's name, title of the experiment, location, purpose of experiment, cooperation of investigator's institution, and a search at these institutions for records. This option could produce detailed experimental records, as in the Cincinnati case study.

- (4) Option Four: Limit search of Clinical Center documents

In order to focus the HHS search of intramural records, the Committee could recommend that HHS exclude, for now, experiments whose use of ionizing radiation involves only medical procedures that can be considered routine, diagnostic, or therapeutic either by today's or contemporaneous standards. In the alternative, the Committee could recommend that HHS begin collecting records related to the 200 projects noted by the NIH staff. The Committee could also consider requesting that HHS limit its document retrieval efforts to experiments that have been identified as having available consent forms.

This option requires the Committee to recommend selection criteria to be applied by HHS staff; skilled personnel to make evaluative selection judgments; and time to review the intramural records. This option produces faster retrieval of records that are potentially of greater interest to the Committee. This option can be exercised alone or in combination with Options One, Two, or Three.

(5) Option Five: Interview knowledgeable individuals with a particular purpose

Interviews with former and current researchers and administrators could provide significant new leads, as already demonstrated by the interview strategies being implemented to date by HHS. The resources and usefulness of the interviews can be maximized if the interviews are conducted with an objective in mind, for example, with regard to understanding co-funding relationships, particular types of experiments, specific investigators, certain programs, or policies and practices that applied to those researchers who conducted secret or classified biomedical research in the relevant period, if any. This option produces recollections of commonly accepted research practices and policies at the time; relationships between the agencies; recollection of specific experiments; and voluntary provision of documents.

Option Six: Written documentation from Helpline callers

The Committee could recommend that HHS respond with a second follow up letter to the Helpline callers requesting any documentation or written statements that the callers may have. This option requires minimal staff time and produces potentially useful contacts with former subjects; dates and locations of experiments; and an expanded list of potential interviewees. It can also assist HHS in determining if the callers have relevant information or were somehow associated with a radiation experiment.

(B) Direct Committee Action

Option Seven: Develop Criteria for HHS Experiments of Greatest Interest

The Committee can develop criteria for selecting from the list of known HHS experiments those which are of greatest interest to the Committee. This option requires Committee discussion based on case studies and summary lists to be provided by HHS, and agency allocation of appropriate staff to apply selection criteria. It may produce documents of more immediate use to the Committee. It may also assist HHS in focusing its search.

(C) Committee-directed Staff Action

(1) Option Eight: Continuing Oversight

The Committee staff can continue contact with agency staff regarding agency response to Committee recommendations concerning revision of search strategy; prioritization of the existing search strategy; and collection of relevant documents related to staff tasks as designated by the Committee.

(2) Option Nine: Information Exchange Between Agencies

The Committee staff can be authorized to facilitate exchange of information among agencies (e.g., provision of DOE's Isotope Distribution Reports to HHS). The Committee staff can be authorized to coordinate search strategies among agencies (e.g., HHS focuses on non-isotope experiments while DOE focuses on isotope experiments).

(3) Option Ten: Development of Selection Criteria

The Committee staff can be authorized to develop possible criteria for selecting experiments of immediate interest to the Committee, based on Committee discussion at meeting on May 18-19, 1994; and further discussion with agency staff.

(4) Option Eleven: Development of Database

The Committee staff can be authorized to develop a uniform database for cataloging and indexing documents on specific experiments.

PRELIMINARY REPORT ON HHS - MAY 12, 1994

- Attachment A: Sample Page from the AEC Isotopes Records;
Sample Pages from the AEC Annual and Semi-
Annual Reports to Congress
- Attachment B: Letter from Dr. Myron Prinzmetal to Dr. Ronald
E. Scantlebury, Executive Secretary, Physiology Study
Section, Federal Security Agency Dated November 17,
1950; Letter from Dr. Eugene L. Saenger to Dr. Ronald E.
Scantlebury, Physiology Study Section, NIH, Dated
November 24, 1950; Application Documents for Federal
Security Agency Grant-In-Aid Dated May 1, 1950
- Attachment C: Sample Pages from the Appendix Vol. III of the 1979 HEW
Report "Effects of Nuclear Weapons Testing on Health"
- Attachment D: Organizational Chart for PHS (as of June 21, 1993)
- Attachment E: Sample Page from DRG Records of Radiology Study
Section

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Attachment B

Staff Analysis

Letters reviewing HHS/PHS grant proposals could be an excellent source of documentation for the ethical and scientific criteria which were actually being applied at the time. Unfortunately, HHS has stated that it believes such letters are no longer in its files. However, an alternative source may have been found by one of the staff members of the Committee.

In publicly available Department of Defense documents now held by the National Archives, Jim David, now of the Committee staff, had previously found copies of letters reviewing Public Health Service grants. Apparently, when projects were seeking multiple sources of funding, agencies obtained copies of documents from other agencies. Although HHS believes that the Public Health Service itself destroyed such review letters, the Department of Defense did not destroy its copies. One such letter reviewing a 1950 grant proposal by Eugene Saenger, MD, is attached as an example.

The letter is a review of a 1950 proposal by Saenger to use Iodine-131 as a tracer to measure blood circulation time in children. The reviewer, Dr. Myron Prinzmetal, M.D., opposes the proposal:

"because of the possible unknown dangers of using radioactive substances on normal infants and children for purposes of investigation when other methods which have been shown to be completely innocuous are available ..."

This example illustrates several important methodological points for the Committee to consider:

First, the agencies are far from exhausting the possible avenues available for research. As HHS itself discovered in its own search, many projects were co-funded. The discovery of this letter indicates that co-funding generated multiple copies of important documents. In instances in which the originating agency has routinely destroyed files, copies held by other agencies may be the only source available.

Second, documents relating reasons for *rejecting* research proposals may be as crucial as documents approving proposals for determination of the ethical standards actually implemented at the time. Comparisons of rejections and acceptances may clarify the demarcation of ethical boundaries. (A more developed example of this is the article by staff member G. Whittemore on the rejection of human experimentation related to the development of a nuclear-powered bomber).

Third, such letters help determine when a medical procedure came to be regarded no longer as experimental but as routine. In this 1950 letter, the use of iodine-131 as a tracer is still regarded as a procedure with "unknown dangers."

Fourth, such documents help uncover the history of the people and procedures used for reviewing research proposals. The letter provides a number of specific clues to aid in further research:

- the name of the Public Health Service Section assigned the proposal (Physiology)
- the name of the executive secretary of that section in 1950 (Scantlebury)
- the name of the reviewer (Prinzmetal, although the use of the term "We" in the first sentence suggests others also contributed to the review)
- the institution of the reviewer (Cedars of Lebanon Hospital)
- the grant number.

In addition to the single review letter just discussed, the file also contains a copy of the grant application itself and a letter of clarification from Saenger. These have also been included for the Committee.

(C O P Y)

INSTITUTE FOR MEDICAL RESEARCH
CEDARS OF LEBANON HOSPITAL
4751 Fountain Avenue
Los Angeles 27, California

November 17, 1950

Ronald E. Scantlebury, Ph.D.
Executive Secretary
Physiology Study Section
Federal Security Agency
Bethesda 14, Maryland

Re: H-92

Dear Doctor Scantlebury:

We are opposed to this application because of the possible unknown dangers of using radioactive substances on normal infants and children for purposes of investigation when other methods which have been shown to be completely innocuous are available. If a radioactive substance should be used in an infant, one would think a substance with a much shorter half life such as NA 24 would be preferable.

Very truly yours,

/s/ Myron Prinzmetal

Myron Prinzmetal, M.D.

MP:n

COPIED: 4/19/74
RECORD GROUP: #330
ENTRY: #352
FILE: (in box #53)

UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

(COPY)

Mailing address:
Radioisotope Laboratory
K-4 General Hospital
Cincinnati 29, Ohio

November 24, 1950

Dr. Donald E. Scantlebury
Executive Secretary
Physiology Study Section
National Institutes of Health
Bethesda 14, Maryland

Reference: Your H-925

Dear Dr. Scantlebury:

The following information is submitted to cover the 3 points raised in your letter of November 15th, in regard to my application H-925.

"1. A letter from the Atomic Energy Commission that permission will be granted to use the isotopes requested (iodine-131) for the purpose indicated:"

1. In our original permit from the Atomic Energy Commission for the use of radioactive iodine-131, we are permitted to use iodine-131 for tracer studies in infants and children, giving one microcurie per kilogram of body weight. Our application and permit did not define whether such a dose would be given orally or intravenously, and no limitation was made by the Atomic Energy Commission as to the route of administration. At least 95% of this dose is absorbed into the blood. In developing this project further it now appears desirable to give the iodine-131 as radioactive di-iodofluorescein or as radioactive iodinated human serum albumin, since there will be a smaller uptake by the thyroid which will be chemically blocked before making the test. Applications for such studies are now pending with the Atomic Energy Commission. I will notify you as to the outcome as soon as possible.

In human adults approximately 35-50 microcuries of radioactive iodinated human serum albumin are used. Since radioactive di-iodofluorescein has a biological half life of 2 - 3 days as compared to a biological half life of 6.5 for radioactive sodium iodide, safe ranges for infants and children can be approached easily.

"2. Have any studies been carried out on your animals, i.e. puppies, to get a preliminary indication of the dosage required for adequate detection with your equipment:"

2. No studies as yet have been carried out on animals. One of the chief purposes in requesting this grant is to develop detecting devices which are more directional and more sensitive than the currently

available Geiger tubes. These tubes at present have large windows and if of the "needle" type are rather insensitive with high background counting rates. Geiger tubes in general have sensitivities for gamma radiation of 0.1 to 0.3% of all gamma photons, whereas scintillation counters have 30 - 40 times this sensitivity. It is planned to develop small phosphors of 3 - 6 mm. in diameter which will be quite long in relation to their diameters, so that a highly directional probing counter will be obtained. Such detecting devices should permit the use of tracer doses of about 10% the present doses which are based in part on detection by Geiger counters.

Preliminary studies of the method on puppies and dogs, approximating human infant size, will be done.

"J. A question that arose, was, in what way will the proposed method be better than existing methods of measuring circulation time in children. A statement from you on this point should be helpful:"

J. The measurement of circulation times in children by present methods is adequate only if the child is well able to cooperate and is not crying or struggling. Such methods as decholin, cyanide and ether times depend largely on subjective cooperation and hence are valueless in infants and children under the age of three years. The fluorescein method does not have a sharp end point, and also the end point is subjective to the observer and may vary with individual observers. It is our desire to develop a method of measuring circulation times which is completely objective. Also by using several detectors, several end points can be recorded simultaneously. In addition the blood volume can be determined.

The problem of accurate diagnosis of congenital heart disease in infants and children under the age of three is especially difficult, and this study will help to improve our diagnoses. We have available many patients with abnormal hearts at the Children's Hospital and our circulation time studies will be correlated with the findings of angiocardiology, cardiac catheterization, surgery and autopsy.

Respectfully submitted,

/s/ Eugene L. Saenger

Eugene L. Saenger, M.D., Director
Radioisotope Laboratory
Asst. Professor of Radiology

ELS:L

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RECORD GROUP: #350
ENTRY: #352
FILE: (in box #55)

Q 396(03) To S.S.

Budget proposed for the year 1/1/51

through 12/31/51

This date to be the same as shown given on page 1

ITEM

FUND REQUESTED FROM THE PUBLIC HEALTH SERVICE

FUND FROM OTHER SOURCES

PERSONNEL (Indicate all positions give names of professional personnel, if available)

See attached breakdown

\$ 64,275.00

\$ 8,940.00

PERMANENT EQUIPMENT NEEDED (Indicate)

None

CONSUMABLE SUPPLIES NEEDED (Indicate)

See attached breakdown

17,525.00

7,060.00

EXPENSE (Indicate)

Structural, for bed spaces: Rainwater
Leaves House None

15 patients @ \$4.10 per day, 85 days

22,475.00

SUBTOTAL

104,275.00

(Rg) XXXXXX

8,602.00

(Rg) XXXX

TOTAL FOR THE YEAR

\$ 117,207.00

\$ 15,000.00

b) Estimate of future requirements:

First additional year \$ 115,000.00

Third additional year \$ 120,000.00

Second additional year \$ 120,000.00

Fourth additional year \$ 120,000.00

PAGE 2

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APPLICATION FOR GRANT-IN-AID

C-396(02)

NUMBER: (FOR USE ONLY IN THIS CASE)

C 396(C3)

Budget proposed for the year 1/1/51 through 12/31/51

No S.S.

PERSONNEL (1(a) cont.)

		Per Mo.	Per Annum	Total
Nurse:				
Day Duty	(4)	220.00	2,640.00	10,560.00
Night Duty	(4)	230.00	2,760.00	11,040.00
Dietitian	(1)	260.00	3,120.00	3,120.00
Ward Helpers	(3)	175.00	2,100.00	6,300.00
Orderlies	(4)	190.00	2,280.00	9,120.00
Kitchen Helpers	(3)	173.50	2,082.00	6,246.00
Secretary	(1)	200.00	2,400.00	2,400.00
Janitor	(1)	185.00	2,220.00	2,220.00
				(51,006.00)

The above represents the actual number of people on our personnel rolls. The per annum figure represents the entrance salary for a beginning employee. No professional (M.D. or Ph.D.) personnel are employed on these funds.

Allowance for yearly honor merit increase for personnel:

Nurses	1,800.00
Dietitian	120.00
Ward Helpers	720.00
Orderlies	840.00
Kitchen Helpers	720.00
Secretary	360.00
Janitor	240.00

This figure represents increases already in effect and for increases anticipated for the period of this budget.

(4,800.00)

General Assistance:

Relief Dietitian (1)	(yearly basis) @ \$1,269 M.	960.00
Dietitian, relief	(1 mo. period) @ \$1,269 M.	220.00
Kitchen Helper, relief	(3 mo. period) @ \$1.001 M.	520.50
Ward Helper, relief	(3 mo. period) @ \$1.010 M.	525.00
Orderly, relief	(3 mo. period) @ \$1.096 M.	570.00

Allowance for accumulated vacation leave for personnel on permanent status (based on 1 month period):

Nurses	(8)	1,800.00
Dietitian	(1)	270.00
Ward Helpers	(3)	585.00
Orderlies	(4)	820.00
Kitchen Helpers	(3)	581.00
Secretary	(1)	230.00
Janitor	(1)	205.00

(7,286.50)

Matching contributions to the State Employees Retirement System at 5% of total gross non-academic salaries, plus a \$4.00 service charge for each participant.

5,047.40

84.00

(5,131.40)

TOTAL.....

\$68,273.90

APPLICATION FOR GRANT-IN-AID

C-396(02)

C-396(03)

No 5.3.

Aged proposed for the year 1/1/51 through 12/31/51

ESTIMABLE SUPPLIES EXPENSE (1(a) cont.)

	Total
Supplemental food for diets:	
15 patients @ \$0.65 per day, 365 days	5,475.00
Drugs, including fluids, antibiotics, heparin	5,219.00
Surgical Dressings	1,274.00
Kitchen Equipment, expendable	270.00
Glassware, syringes, surgical supplies, catheters	1,526.00
Surgical Instruments, cannulae, replacement items	
for permanent equipment on hand	\$41.00
Ray film, photographic supplies	532.00
Linens replacements	173.00
Household supplies (soap, paper towels, Lysol, etc.)	627.00
Minor repairs and maintenance of equipment	246.00
Total.....	\$17,528.00

These items are based on actual expenses incurred during past full year of operation. No additional permanent equipment is requested. Many items not covered by this request for the operation of the research ward are to be covered by the anticipated grant from the University of California of \$16,000.

PAGE 2

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APPLICATION FOR GRANT-IN-AID

C-396(C2)

C 396(C3)

No 5.3.

BUDGET SUMMARY COMPARISON SINCE ESTABLISHMENT
OF RESEARCH WARD

	<u>C-396(1)</u> <u>1948 1/</u>	<u>C-396(C2)</u> <u>1949</u>	<u>C-396(C2)</u> <u>1950</u>	<u>C-396(C3)</u> <u>1951</u>
Personal.....	35,150.56	54,111.00	60,732.00	66,223.90
Permanent Equipment.....	14,196.00	2,577.90	—	—
Consumable Supplies.....	5,500.00	14,495.00	12,743.00	17,974.00
Contractual-Rented space..	15,246.50	18,450.95	20,422.00	22,447.50
Other Expenses.....	400.00	—	—	—
Interest.....	5,573.44	7,194.73	7,511.76	8,642.93
TOTAL.....	\$79,372.50	\$97,128.58	\$101,406.76	\$117,207.43 2/

The research ward was actually opened on July 6, 1948.

As seen from the budget, the increase of \$15,754.57 is due to three major factors: (a) merit and other increases in salaries, as authorized by the University, plus the State Employment Retirement System contributions, as agreed by the United States Public Health Service and the Secretary of the Regents of the University of California, (b) increased cost of reimbursement for beds to Laguna Lodge Home from \$3.72 to \$4.10 per day per bed, and, (c) an additional \$5,000.00 is requested for drugs such as antibiotics, fluids, etc., which were underestimated last year.

PAGE 28

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All support, including that from own institution, on this or related research projects from sources other than Public Health Service

TITLE OF PROJECT

SOURCE

AMOUNT

YEARS OF SUPPORT

LABORATORY	Univ. of California School of Medicine	\$ 3,000.00	1/47 - 6/30/47
Research Yard	Univ. of California State Funds	18,000.00	11/47 - 6/30/48
LABORATORY	Univ. of California School of Medicine	3,000.00	7/1/47 - 6/30/48
Research Yard - Isotope Unit	Univ. of California State Funds	7,000.00	11/47 - 6/30/48
Research Yard - Pathology Unit	Univ. of California State Funds	20,000.00	11/47 - 6/30/48
Research Yard	Univ. of California State Funds	12,500.00	7/1/48 - 6/30/49
LABORATORY	Mitro	4,500.00	7/1/48 - 6/30/49
Research Yard - Isotope Unit	Mitro	9,500.00	7/1/48 - 6/30/49
Research Yard - Pathology Unit	Mitro	7,200.00	7/1/48 - 6/30/49
CURRENT			
Research Yard and Laboratory	Univ. of California State Funds	15,000.00	7/1/49 - 6/30/50
Research Yard - Isotope Unit	Mitro	7,400.00	7/1/49 - 6/30/50
Research Yard - Pathology Unit	Mitro	11,000.00	7/1/49 - 6/30/50
Research Yard	Damon Research Fellowship	500.00	7/1/49 - 6/30/50
PENDING			
Research Yard and Laboratory	Univ. of California State Funds	15,000.00	7/1/50 - 6/30/51
Research Yard - Isotope Unit	Mitro	5,000.00	7/1/50 - 6/30/51
Research Yard - Pathology Unit	Mitro	11,000.00	7/1/50 - 6/30/51

0-396(03) No 3.3.

Previous and current Public Health Service grants in support of this project:

GRANT NUMBER	TITLE OF PROJECT	AMOUNT	YEARS OF SUPPORT
1. Cancer Inst.	Direct Allocation - Laboratory	51,500.00	1/1/47 - 6/30/47
1. Cancer Inst.	Direct Allocation - Laboratory	99,544.50	7/1/47 - 6/30/48
36(1)	Research Yard	75,172.50	1/1/48 - 12/31/48
1. Cancer Inst.	Direct Allocation - Laboratory	117,525.00	7/1/48 - 6/30/49
36(2)	Research Yard	65,000.00	1/1/49 - 12/31/49
36(3)	Research Yard	12,000.00	1/1/49 - 12/31/49
1. Cancer Inst.	Direct Allocation - Laboratory	115,000.00	7/1/49 - 6/30/50
36(2)	Research Yard	100,408.75	1/1/50 - 12/31/50

Amount shown includes \$5 overhead

PROPOSED PLAN

Specific aims of project.

Method of procedure.

Relationship of anticipated results to general problems in field.

Facilities available including list of major items of permanent equipment.

Previous work done on this or closely related projects by the investigator.

Most important publications of investigator(s) pertaining to this problem.

Results bearing on this project obtained by other investigators.

Publications of other investigators related to this proposed project.

PAGE 4

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APPLICATION FOR GRANT-IN-AID.

4. PROPOSED PLAN (Continuation Sheet)

NUMERALS (DO NOT WRITE IN THIS SPACE)

C 396(C7)

By 5.5.

(a). Specific Aims of Project. The specific aim of the project is clinical research in cancer. With the cancer patient as the focal point of the investigations, the work is oriented along four broad approaches: (1) Experimental therapy, providing clinical material for other studies as well as permitting evaluation of such procedures on neoplastic diseases; (2) Physiology, particularly cardiovascular and respiratory physiology of patients with neoplastic diseases; (3) Biochemistry, including metabolic studies on cancer patients, and investigations of specific biochemical reactions; and, (4) The study of protein fractions of cancer and normal tissues of human and animal origins, utilizing physicochemical and immunochemical techniques.

(b). Method of Procedure. Patients for investigation are selected through the Consultative Tumor Board of the University of California School of Medicine, by referral of physicians of the Bay Area. Such patients as are not applicable for curative therapy by surgery or irradiation are evaluated for their applicability to experimental procedures. For admission to the research ward, each patient signs a release which indicates that the patient understands that he will be used for experimental work, and that he agrees to this and to a necropsy (See attached Release Form). Each patient receives a full clinical and pathology work-up, an observation period, and is then applied toward one or another of the investigations underway at the Laboratory (see Progress Report). Each investigative program on patients is reviewed by the Cancer Board of the University of California School of Medicine for its clinical safety.

(c). Relationship of Anticipated Results to General Problems in the Field. The results of the investigations, since they are of work being done on patients, is directly applicable to the clinical management of patients with cancer. The chief interests of the Laboratory, however, are the study of the biology, physiology and chemistry of human cancer, with particular emphasis on how the presence of various neoplastic diseases affects the human host.

(d). Facilities Available. The Laboratory and its research ward occupy two floors of a wing of the Laguna Honda Hospital. This space was made available by arrangement between the University of California and the San Francisco Department of Public Health; the Laboratory will move to its new quarters at the Medical Center toward the end of 1952. Two-thirds of the area is occupied by laboratories, including clinical biochemical laboratories, 1 hematology laboratory, 1 protein chemistry and immunochemistry laboratory, 1 clinical isotope laboratory, 1 biochemical isotope laboratory, 1 physiology laboratory and an animal room. The pathology laboratory (supported by University of California funds) is in another area. All these laboratories and the research ward are fully equipped for their designated work. Special equipment includes: electrophoresis (Lainco), preparatory ultracentrifuge (Spinco), microchemical assembly (Kirk), and a full clinical physiology complement of strain-gage indicators, recording oximeters, oscillographs, electroencephalographs, etc.

NUMBER: 100 AND TYPE IN ONE SPACE
C 396(CJ)

No S.S.

5(a). Previous Work Done on This (or closely related) Project. The Laboratory of Experimental Oncology was initiated in January 1947 and the research ward, which is supported by Grant C-396, was opened on July 6, 1948. The attached project report indicates the lines of investigation being undertaken and the publications indicate the segments of work which have been pursued to the point of publication.

5(b). Personal Publications Pertaining to this Problem. The list of 19 publications which have appeared or have been submitted during the past year are given in the progress report. Five additional papers are in the process of preparation. At least 40 copies of reprints of all publications have been submitted to the National Cancer Institute and the National Institutes of Health and additional reprint copies are not being submitted with this application at this time.

5(a). Results Bearing on This Project Obtained by Others. The wide program being undertaken at the Laboratory of Experimental Oncology would refer to such an extensive review of previous literature in cancer research that it is considered inappropriate to include this here. The paper entitled, "Experimental chemotherapy in neoplastic diseases" by Shitka and Bieman (Radiology, 53:515-529, October, 1949), for example, lists 64 references on this segment of the program alone.

It is believed that some specific investigations were first initiated at this Laboratory. These include: (1) the effects of virus infections on clinical cancer, which is now also being studied at the Memorial Hospital in New York, (2) intra-arterial catheterization including the use of chemotherapeutic agents by this route which is now also being explored at Georgetown University at Washington, D.C., and, (3) accentuation upon the exploration of cardiovascular effects of cancer.

5(b). Publications by Others on Related Work. Refer to 5(a). The listing of references from the literature for this wide program would be too extensive to justify inclusion here. References to publications by others on similar or related work are, of course, always included in the publications.

Tab I

Staff Memo--Progress Report on Collection of Agency Ethical Standards on Human Experimentation

**Progress Report on
the History of Agency Policies Regarding Research Involving Human Subjects**

At the last Advisory Committee meeting, the staff was asked to research the history of agency policies regarding research involving humans. To this end, inquiries concerning "ethical rules and regulations" have been forwarded to the following agencies and departments: DoE, DHHS, DoD, CIA, VA, and NASA (see sample letter from Ruth Faden to Harold Gracey, April 26, 1994). In addition, contact persons have been identified and initial contacts made at all the agencies. FEMA has also recently been identified as potentially relevant, as its predecessor agency was the Office of War Preparedness.

As of 1991, all agencies represented on the Interagency Working Group subscribe to the Federal Policy for the Protection of Human Subjects. This has come to be known as the Common Rule, and is based on Subpart A of the Code of Federal Regulations 45 CFR 46—Protection of Human Subjects. The Common Rule applies to research involving human subjects, but does not include policies regarding research involving fetuses, pregnant women, children, or prisoners. Prior to its implementation in 1991, policies for research involving human subjects were set agency by agency.

Some material is already available concerning policies at several agencies. The status of our effort with each agency or department is described below.

1. DHHS — The history of research involving human subjects funded by the constituents of DHHS, NIH in particular, has received considerable academic attention. Among the best treatments of the topic are Faden and Beauchamp, *A History and Theory of Informed Consent* (chapters 4 and 5 are appended); and Jay Katz et al., *Experimentation with Human Beings*. The staff intends to use these and other secondary sources as a guide for further insight and understanding in the area of oversight of research involving humans at DHHS and its precursors.
2. DoE — As an example of the kinds of materials coming to light in regard to DoE policies on human experimentation, a letter from Carroll L. Wilson, AEC [Atomic Energy Commission] General Manager, to Dr. Stafford L. Warren, UCLA, dated April 30, 1947, is appended. This letter exemplifies the kind of policy document that might only present itself through a search of archival sources. The It does not require the AEC contractors obtain signed consent forms, but that written certification of informed consent be provided by two doctors as part of an official record.
3. DoD — Early policy documents elaborating conditions of acceptable human experimentation, and one step in this policy's dissemination, are appended. It is a classified memorandum from the Office of the Secretary of Defense, from C.E. Wilson, to the Secretaries of Army, Navy and Air Force: "Use of Human Volunteers in Experimental Research," dated February 26, 1953. The second document is the same classified memorandum, with a cover letter, dated March 3, 1953, disseminating the same document to the Joint Chiefs of Staff.

The substantive portion of this memorandum is a verbatim recapitulation of the Nuremberg Code, without apparent attribution. Prof. Katz alluded to this policy during the first Advisory Committee meeting. This document and evidence of its dissemination raises a number of further questions, among them:

- Why was it thought necessary to classify the Nuremberg Code?
- How was it expected that a classified statement of policy would be efficacious?

- What processes preceded, and in addition to the Joint Chiefs dissemination document, succeed the adoption of this policy?
- How was the policy reviewed and approved?
- Did any specific incident(s) or project(s) "trigger" the promulgation of this policy at this time?
- Was this policy intended only for DoD-funded projects or was it also to apply to contractors?
- Did DoD-sponsored researchers need and have security clearances?

Further material provided by DoD to the Committee on May 10, 1994 includes no other documents before this memorandum and none between it and 1994, leaving the question of policy origins and implementation as yet unanswered. The staff seeks Committee guidance in actively pursuing these and other questions.

Conclusions and Options

In addition to the above materials pointing to pre-1962 policies on research involving humans, our investigations to date also indicate that it will be important to look for standards and policies for research on human subjects that existed between agencies as well as for those within a particular agency. For instance, a potentially informative piece of the pre-history of the Common Rule is illustrated in the appended exchange of correspondence between J.E. Moore, M.D. and Dr. A.N. Richards, dated October-November 1942). During WWII the Committee on Medical Research (CMR) distributed \$25 million to universities, hospitals, and other institutions to benefit soldiers coping with various diseases in the field. Its contracts and organizational framework were later inherited by the NIH. The CMR was asked to express its policy on "human experimentation in general" by Dr. Charles M. Carpenter of the University of Rochester School of Medicine. Following some discussion within the CMR, Dr. Richards formulated statements dated October 31, 1942. In the statements, human subject research involving risks requires that only fully informed volunteers are to be used, and consent forms signed that waive rights to damages. CMR wishes to know in detail from its contractors what human experiments are planned, but attempts to place legal responsibility for any claim of damages upon the investigator and his or her institution.

As background, we have also appended materials from the Congressional Research Service and Bioethicsline. Neither the CRS overview of policies for the protection of human research subjects nor the bibliographic search reflect the information that we have already been able to gather concerning policies in DoE and DoD, nor do they reach back in time as far as these examples.

What has been gathered so far already calls into question certain of the usual assumptions about this topic. For instance, the CRS report states that "[r]egulation and professional standards for the protection of human subjects in research and informed consent, for the most part, did not exist before the late 1940s." (p. 1) Yet the 1942 Moore-Richards correspondence indicates that fairly specific policies were already being applied. On the other hand, the 1947 Wilson letter, and the 1953 DoD memoranda, raise questions about the adequacy of implementation of these policies.

BBoskey/jjd

30 APR 1947

Dr. Stafford L. Warren
University of California
405 Hilgard Avenue
West Los Angeles, California

Dear Dr. Warren:

This is to inform you that the Commission is going ahead with its plans to extend the medical research contracts of the University of Washington, Columbia University, Western Reserve University, the University of Rochester, and the University of California (at Los Angeles), in the amounts recommended by the budgetary subcommittee of the Interim Medical Advisory Committee, as recorded in your letter to me dated April 7, 1947.

It is the hope of the Commission that such extensions of the contracts will provide a sound basis for continuing the medical research essential to the Commission's activities, pending a fuller review by the Commission of the scope of the medical program. The Commission also hopes to strengthen the position of the Universities to attract personnel of high calibre to the medical research work, by authorizing them, with the approval of the Commission, to enter into contracts of employment with key personnel for periods up to three years.

The Commission is entirely sympathetic with the view of your Committee that research personnel engaged in medical projects should be encouraged to exercise their own initiative and should be given an opportunity to devote part of their time to pursuing lines of research which appear fruitful to them, even though not immediately related to specific items in the approved program for the particular project. Accordingly, the Commission is authorizing its Area Managers to approve such research up to twenty per cent of the time of the research personnel engaged on such medical projects. When such approval is given, the Director of the medical project will be required to certify to the Commission (1) that the research is useful and is not outside the general scope of the Commission's research interests, and (2) that the research will not unduly interfere with the progress of the work on the approved program at the project. The Director also will be required to indicate separately in his reports to the Commission what research has been done under this authorization.

CONFIRMED TO BE UNCLASSIFIED
AUTHORITY: DOE/SA-20
BY R.S. DEWEY, DATE: 1/11/94

US DOE ARCHIVES

RG 326 US ATOMIC ENERGY COMMISSION

Collector General Morgan

1035

It is understood that your Committee has recommended a program for obtaining medical data of interest to the Commission in the course of treatment of patients, which may involve clinical testing. The Commission wishes to make clear to your Committee its understanding of the program which is being approved. The Commission understands that in the course of the approved program:

- a. treatment (which may involve clinical testing) will be administered to a patient only when there is expectation that it may have therapeutic effect;
- b. the decision as to the advisability of the treatment will be made by the doctor concerned.

The Commission does not intend to influence in any way the exercise of judgment by the doctor as to the administration of any particular treatment authorized under the approved program. Indeed, from the discussion at the meetings of April 3-5, it seemed evident to me that doctors would not allow their judgment on this matter to be influenced by anyone.

DOE ARCHIVES
In any such clinical testing, the Commission continues to request that the same procedure be followed which was agreed upon early in March. That procedure contemplated that it should be susceptible of proof from official records that, prior to treatment, each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment and its possible effects, and expressed his willingness to receive the treatment. In view of your recommendation, the Commission does not request that written releases be obtained in such cases, but it does request that in every case at least two doctors should certify in writing (made part of an official record) to the patient's understanding state of mind, to the explanation furnished him, and to his willingness to accept the treatment.

The Commission is interested in exploring the possibility of starting various types of training programs along the lines recommended by your Committee. It is suggested that there should be submitted in writing detailed proposals for training programs, which do not go beyond the limits of what is now practicable.

Sincerely yours,

Carroll L. Wilson
General Manager

COPY

SECRETARY OF DEFENSE
Washington

26 Feb 1953

MEMORANDUM FOR THE SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Use of Human Volunteers in Experimental Research

1. Based upon a recommendation of the Armed Forces Medical Policy Council, that human subjects be employed, under recognized safeguards, as the only feasible means for realistic evaluation and/or development of effective preventive measures of defense against atomic, biological or chemical agents, the policy set forth below will govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare.

2. By reason of the basic medical responsibility in connection with the development of defense of all types against atomic, biological and/or chemical warfare agents, Armed Services personnel and/or civilians on duty at installations engaged in such research shall be permitted to actively participate in all phases of the program, such participation shall be subject to the following conditions:

a. The voluntary consent of the human subject is absolutely essential.

(1) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by

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per S. Clements
DCR: OSD(PA)

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which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

(2) The concept of the human subject shall be in writing, his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one witness who shall attest to such signature in writing.

(a) In experiments where personnel from more than one Service are involved the Secretary of the Service which is exercising primary responsibility for conducting the experiment is designated to prepare such an instrument and coordinate it for use by all the Services having human volunteers involved in the experiment.

(3) The duty and responsibility of ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

b. The experiment should be such as to yield fruitful results for the good of society, unobtainable by other methods or means of study, and not random and unnecessary in nature.

c. The number of volunteers used shall be kept at a minimum consistent with item b., above.

d. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

e. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

f. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.

g. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

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C O P Y

h. Proper preparation should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

i. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

j. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

k. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

l. The established policy, which prohibits the use of prisoners of war in human experimentation, is continued and they will not be used under any circumstances.

3. The Secretaries of the Army, Navy and Air Force are authorized to conduct experiments in connection with the development of defenses of all types against atomic, biological and/or chemical warfare agents involving the use of human subjects within the limits proscribed above.

4. In each instance in which an experiment is proposed pursuant to this memorandum, the nature and purpose of the proposed experiment and the name of the person who will be in charge of such experiment shall be submitted for approval to the Secretary of the military department in which the proposed experiment is to be conducted. No such experiment shall be undertaken until such Secretary has approved in writing the experiment proposed, the person who will be in charge of conducting it, as well as informing the Secretary of Defense.

5. The addressees will be responsible for insuring compliance with the provisions of this memorandum within their respective Services.

/signed/
C.E. WILSON

Copies furnished:
Joint Chiefs of Staff
Research and Development Board

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~~TOP SECRET SECURITY INFORMATION~~

COPY NO. _____

J.C.S. 1965/39

3 March 1953

Pages 215 - 219, incl.

NOTE BY THE SECRETARIES

to the

JOINT CHIEFS OF STAFF

on

USE OF HUMAN VOLUNTEERS IN EXPERIMENTAL RESEARCH

The enclosed memorandum by the Secretary of Defense, dated 26 February 1953, for the Service Secretaries, is circulated for information.

W. G. LALOR,
E. H. J. CARNS,
Joint Secretariat.

115 (1-1-48) 511

SEP 11/11 7007 75

DATE 19 May 1971

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ENCLOSURE

SECRETARY OF DEFENSE

26 February 1953

MEMORANDUM FOR THE SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

Subject: Use of Human Volunteers in Experimental Research

1. Based upon a recommendation of the Armed Forces Medical Policy Council, that human subjects be employed, under recognized safeguards, as the only feasible means for realistic evaluation and/or development of effective preventive measures of defense against atomic, biological or chemical agents, the policy set forth below will govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare.

2. By reason of the basic medical responsibility in connection with the development of defenses of all types against atomic, biological and/or chemical warfare agents, Armed Services personnel and/or civilians on duty at installations engaged in such research shall be permitted to actively participate in all phases of the program, such participation shall be subject to the following conditions:

a. The voluntary consent of the human subject is absolutely essential.

(1) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and

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Enclosure

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Downgraded to UNCLASSIFIED

comprehension of the element of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

(2) The consent of the human subject shall be in writing, his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one witness who shall attest to such signature in writing.

(a) In experiments where personnel from more than one Service are involved the Secretary of the Service which is exercising primary responsibility for conducting the experiment is designated to prepare such an instrument and coordinate it for use by all the Services having human volunteers involved in the experiment.

(3) The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

b. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

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JCS 1865/39

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Enclosure

~~TOP SECRET SECURITY INFORMATION~~
SECURITY INFORMATION

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1. The established policy, which prohibits the use of prisoners of war in human experimentation, is continued and they will not be used under any circumstances.

3. The Secretaries of the Army, Navy and Air Force are authorized to conduct experiments in connection with the development of defenses of all types against atomic, biological and/or chemical warfare agents involving the use of human subjects within the limits prescribed above.

4. In each instance in which an experiment is proposed pursuant to this memorandum, the nature and purpose of the proposed experiment and the name of the person who will be in charge of such experiment shall be submitted for approval to the Secretary of the military department in which the proposed experiment is to be conducted. No such experiment shall be undertaken until such Secretary has approved in writing the experiment proposed, the person who will be in charge of conducting it, as well as informing the Secretary of Defense.

5. The addressees will be responsible for insuring compliance with the provisions of this memorandum within their respective Services.

/s/ CHARLES E. WILSON

Copies furnished:
Joint Chiefs of Staff
Research and Development Board

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~~TOP SECRET~~
JCS 1865/39

- 219 -

Enclosure

~~TOP SECRET SECURITY INFORMATION~~

7 October 1975

COPY NO. 1

NOTE TO THE HOLDERS OF JCS 1865/39, 3 MARCH 1953

on

USE OF HUMAN VOLUNTEERS IN EXPERIMENTAL RESEARCH

1. Pursuant to OSD/Classified Control Section Regrading Action #013-75, 26 September 1975, the Enclosure to JCS 1865/39 is downgraded from TOP SECRET to UNCLASSIFIED.
2. Accordingly, JCS 1865/39 is downgraded to UNCLASSIFIED.

Joint Secretariat

1st N/H of JCS 1865/39, 3 Mar 53

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C O P Y

Letter from J. E. Moore, M. D., to Dr. A. N. Richards

October 6, 1942

I have recently received a letter of enquiry from Dr. Charles M. Carpenter of the University of Rochester School of Medicine who believes that he may be able to work out a human experiment on the chemical prophylaxis of gonorrhea. He has asked me to supply him with a statement that in my opinion such human experimentation is desirable. I have in turn replied enquiring from him as to whether he wishes a statement from me on an entirely personal basis or in one of my official capacities - as Chairman of the Subcommittee on Venereal Diseases, National Research Council, or as Special Consultant, U. S. Public Health Service. In either of the latter cases I have pointed out to Dr. Carpenter that I could not make such a statement without the approval of higher authority.

May I ask you to supply me with the attitude of the Committee on Medical Research toward human experimentation in general, and toward the particular problem of human experiment in the chemical prophylaxis of gonorrhea.

Reply of A. N. Richards, Chairman, to Dr. J. E. Moore

October 9, 1942

In your letter of October 6th you ask that I advise you of the attitude of the Committee on Medical Research toward human experimentation in general, and toward the particular problem of human experiment on the chemical prophylaxis of gonorrhea.

The Committee on Medical Research will hold its next meeting on October 29th. I shall present your question to them at that time. In the meantime I have confidence that the Committee will support me in the statement that human experimentation is not only desirable, but necessary in the study of many of the problems of war medicine which confront us. When any risks are involved, volunteers only should be utilized as subjects, and these only after the risks have been fully explained and after signed statements have been obtained which shall prove that the volunteer offered his services with full knowledge and that claims for damages will be waived. An accurate record should be kept of the terms in which the risks involved were described.

In answer to the second part of your question which concerns this specific case, the Committee on Medical Research must rely on the judgment of the Responsible Investigator, supplemented by the judgment of the committee in whose field the investigation is proceeding.

R. 6. 227, 05RD, LMR, General Records

N.O. ~ ~ ~ ~ ~, U.S.A., General ~~Reed~~ ^{PAGE 2 -2 &}

Box 43, "Human Experiments - V.D." Folder

REPRODUCED AT THE NATIONAL ARCHIVES

C O P Y

(Revision of Dr. Richards' letter of October 9, 1942)
Reply of A. N. Richards, Chairman, To Dr. J. E. Moore

October 31, 1942

In your letter to me of October 6 you raised the question of the attitude of the Committee on Medical Research toward human experimentation in general and toward the particular problem of human experiment in the chemical prophylaxis of gonorrhea. I gave you a tentative reply under date of October 9 and brought the matter before the CMR at its meeting on October 29.

The statement in the second paragraph of my letter of the ninth referring to the general attitude was upheld.

"Human experimentation is not only desirable, but necessary in the study of many of the problems of war medicine which confronts us. When any risks are involved, volunteers only should be utilized as subjects, and these only after the risks have been fully explained and after signed statements have been obtained which shall prove that the volunteer offered his services with full knowledge and that claims for damages will be waived. An accurate record should be kept of the terms in which the risks involved were described."

I was instructed to recall the third paragraph of that letter and to offer in its place something to the following effect:

Whenever human experiments are planned as part of work called for in an OSRD contract recommended by CMR, the Committee on Medical Research should know in detail what they are. Further, it must be understood that legal responsibility for possible damages rests with the individual in charge of the experiments and the Institution for which he is agent. Arrangements can be made whereby both he and the Institution can be protected by insurance.

Hoping that the above statements provide adequate answer to your questions,

I am

Reply of J. E. Moore, M. D., to Dr. A. N. Richards

November 2, 1942

Thank you for your letter of October 31 outlining the attitude of the Committee on Medical Research toward human experimentation. I have forwarded a copy of your letter to Doctors C. M. Carpenter of Rochester, New York, and to Alfred Cohn of New York City, both of whom are interested in the possibility of human experimentation in gonorrhea, though neither have as yet an OSRD contract for this purpose.

TO: MEMBERS OF THE ADVISORY COMMITTEE OF HUMAN RADIATION EXPERIMENTS

FROM: ADVISORY COMMITTEE STAFF

DATE: MAY 12, 1994

RE: DOCUMENTS ON "CINCINNATI EXPERIMENTS"

What follows is a brief description of documentation related to the federally supported experiments conducted by Dr. Eugene Saenger and received by the Committee Staff from four separate sources: the Department of Defense, the Department of Health and Human Services, Representative John Bryant's office, and Mr. Gwendon Plair, an active member of patients' families group. Following that are suggestions for further documents which the staff feels may prove illuminating in completing a review of this particular federally contracted experimental work involving total body irradiation. **Items marked by an asterisk (*) are included in this packet.** (If you would like to review copies of documents that are not attached, please contact Anna Mastroianni.)

I. DOCUMENTS RECEIVED

A. From the Department of Defense

Approximately four linear feet of material were delivered to the Committee Staff from the Department of Defense concerning experiments designed and performed at Cincinnati General Hospital from 1959 through 1972 by a research team headed by Dr. Eugene Saenger. Much of the material was out of chronological order and scattered piecemeal throughout the files. All material was non-classified.

A brief description of the documents follows:

- * 1) Dr. Saenger's original 1958 grant proposal to DASA (Defense Atomic Support Agency) for the proposed study and grant reviewers comments;
- * 2) A series of ten reports recording the progress of the contracted experiments. The reports were submitted periodically from 1960 through 1972; (two samples are enclosed);
- 3) Portions of contracts stating the funding agreements between DASA and University of Cincinnati over the course of these experiments. The contracts were amended in response to applications for expansion by Dr. Saenger.
- * 4) An expanded 1967 research proposal by Drs. Friedman and Saenger presented to a research review committee at University of Cincinnati, and comments by faculty reviewers on the merits of their proposal;

- * 5) A 1972 report to the Dean of the College of Medicine of the University of Cincinnati by an ad hoc faculty committee, Dr. R. Suskind, Chairman, evaluating Dr. Saenger's research program;
- * 6) A 1972 report to the Dean of the College of Medicine of the University of Cincinnati by a committee of junior faculty, Martha Stephens, author, evaluating Dr. Saenger's research program;
- * 7) A 1972 letter by Dr. Robert McConnell, president of the American College of Radiology (ACR) to Senator Mike Gravel (Alaska) evaluating Dr. Saenger's work. A copy of this letter was also sent to Senator Edward Kennedy (Massachusetts), who had expressed interest in these experiments, and wrote several letters of inquiry to members of the University of Cincinnati officials and faculty. The files also contain material related to inquiries by Senator Kennedy's staff;
- * 8) Numerous reprints and photocopies of journal articles written by members of Dr. Saenger's research team, and documentation of various scientific proceedings (samples enclosed);
- 9) A 1972 statement from Dr. Warren Bennis, President of the University of Cincinnati, concerning the experiments;
- 10) A 1972 Dean's report offering the Medical College's official response to questions raised about the research;
- 11) A variety of internal memoranda and correspondence from the Dean's office, including drafts of the Dean's report, letters to physicians at other institutions seeking evaluation of the work, and a series of letters by the University of Cincinnati's Medical College Vice-President Edward Gall to various U.S. medical researchers discussing the merits of Dr. Saenger's work;
- * 12) A variety of newspaper articles by Cincinnati newspapers covering the Saenger experiments (one sample is enclosed). Most of these articles date from 1971-72. In addition, both the Washington Post and the New York Times covered the release of the Junior Faculty Association's report.

B. Documents Received from the Department of Health and Human Services

The Department of Health and Human Services delivered material to the Committee staff which consisted of the following:

- 1) Reprints of various publications by Dr. Saenger and other researchers involved in the Cincinnati experiments;
- * 2) A listing of all grants made to Dr. Saenger by NIH (included in Dr. Henderson's letter);

- * 3) "Statement for the Record," Dr. Donald A. Henderson, Deputy Assistant Secretary for Health--Science, U.S. Public Health Service, provided to the subcommittee on Administrative Law and Governmental Relations of the Commission on the Judiciary, U.S. House of Representatives, April, 1994.

C. Documents Received from Representative John Bryant's Office

The testimony and exhibits prepared for the April 11, 1994 hearings before the Subcommittee on Administrative Law and Governmental Relations of the House Judiciary Committee were delivered to the Committee staff by Representative John Bryant's office. A brief description follows:

- 1) Testimony from family members of three patients;
- * 2) Testimony from Dr. Gordon Soper, Principal Deputy to the Assistant Secretary of Defense for Atomic Energy [includes a DOD chronology];
- 3) Testimony of Dr. James Cox, Professor of Radiotherapy, M.D. Anderson Cancer Center;
- 4) Testimony of Dr. Joseph Steger, President, University of Cincinnati;
- 5) Testimony of Dr. David Egilman, Department of Community Medicine, Brown University;
- 6) Testimony of Dr. Martha Stephens, Professor of English, University of Cincinnati, and principal author of the 1972 Junior Faculty Association report;
- * 7) Testimony of Dr. Eugene Saenger. (Attached documentation does not include appendices to testimony.)

D. Documents Received from Mr. Gwendon Plair, Member of Concerned Relatives of Cancer Study Patients (CROCSP)

Partial medical records of three different patients in the Cincinnati study were delivered to the Committee Staff by Gwendon Plair, an active member of the patients' families group, and son of one of the patients. Mr. Plair testified at the first Committee meeting on April 21, 1994 during the public comment period.

II. **STAFF SUGGESTIONS FOR ADDITIONAL DOCUMENTATION**

Review of this material by several members of the Committee Staff suggests that a more

complete picture of the history, nature and outcome of the work supported by the DASA contract and the human experiments designed by Dr. Saenger and associates may be obtained by additional directed inquiries.

Additional documents which should be searched for and which could prove informative include:

- 1) Any documents on the original Saenger protocol for determining anti-tumor effects of total body irradiation (TBI) -- There was no separately stated protocol in the initial 1958-1959 contract proposal for evaluating reduction in tumor burden following TBI. The submitted protocol is focussed on finding accurate biological dosimetry indicators (of absorbed radiation) as well as on establishing biological data on the patients' health following irradiation. Dr. Saenger apparently did provide a written protocol evaluating TBI anti-tumor effects in 1967 (as reported in the faculty committee report).
- 2) Correspondence on psychological testing -- Sometime between 1963 and 1964, the psychological and cognitive testing component of the experiment was considerably expanded. We do not have documents to explain the reason for this enhanced psychological testing, the origins of the need to enhance this part of the experiments, and the mechanism for its support.
- 3) Original reports submitted to the ACR -- The letter by ACR President McConnell to Senator Gravel is a secondary source. It was apparently based largely on interviews conducted independently by Dr. Henry Kaplan (Stanford), Dr. Frank Hendrickson (Chicago Presbyterian-St. Lukes), and Dr. Samuel Taylor (Presbyterian-St. Lukes) with the assistance of Mr. Otha Linton of the ACR staff. It would be useful to see the original internal reports submitted by Dr. Kaplan et. al. to President McConnell's ACR office;
- 4) Dr. Saenger's bibliography -- A more thorough review of Dr. Saenger's publications is thought to be useful. A simple review of his curriculum vitae including bibliography indicated that a number of publications resulted from this contracted experimental work; these and other published articles detailing his results in using TBI for its anti-tumor effects deserve thorough reading;
- 5) Patient Records for Dunham Hospital and Cincinnati General Hospital -- How did patients enter into this study? A review of patient records from both Dunham Hospital and CGH may be helpful to determine the methods of patient recruitment and informed consent since this was apparently done by a variety of physicians, not necessarily Dr. Saenger himself or his immediate research staff;
- 6) NIH grant applications for clinical research training funding -- While DASA funded some of the research costs at Cincinnati, funding for the Clinical Training Program and the General Clinical Research Center's Metabolic Research Ward apparently came from the National Institutes of Health. It would be helpful to see the grant applications and reviews relating to this funding;

7) Documentation of Dr. Saenger's role as a staff member and later as a consultant to the Brooke Army Hospital, Lakeland Air Force Base Hospital, USPHS, and AEC Oak Ridge Program during the period 1953 to 1972. This was the period when the Cincinnati experiments were being planned, applications produced, contracts awarded, and contracted work carried out. This information may help to understand the purpose of these Cincinnati experiments.

8) Information on similar TBI human experiments contracted for at the Baylor College of Medicine and Sloan-Kettering Cancer Institute -- Drs. Vincent Collins at Baylor and James Nickson at Sloan-Kettering also had contracts from DASA during the 1950-70 decades to perform similar human radiation research. (DA 49007 MD 428 and DA 49 146 XZ 032 Baylor and at Sloan Kettering DA-49-007-MD-533, DA-49-007-MD-669, and DA-49-146-XZ-037) In recommending approval of the Cincinnati work, reviewers urged coordination with the New York and Texas research. Review of these contracts may add to the Committee's understanding of the background for all such experiments contracted for by Federal agencies.

9) All the documents received appear to have been unclassified -- In some cases, the investigator reports make express reference to a military purpose for the research. It would be interesting to know whether investigators had security clearances and access to classified documents? If so, is there documentation which might show how such clearances bear on informed consent issues?

MEMORANDUM

TO: MEMBERS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

FROM: ADVISORY COMMITTEE STAFF

DATE: MAY 12, 1994

RE: DOCUMENTS ON "PLUTONIUM INJECTION EXPERIMENTS"

Staff requested information on the plutonium injection experiments from the agency members of the Interagency Working Group and the Office of Congressman Markey. Staff received two boxes (approximately 2.5 linear feet) from the Department of Energy and additional material from the office of Congressman Markey. Further contextual documentation was provided by earlier work by staff historians.

The experiments also were the subject of the Pulitzer Prize winning series by Eileen Welsome, provided to the Committee in the first delivery of press clips.

L DOCUMENTS RECEIVED

A. From the Department of Energy (DOE)

DOE documents included unclassified and declassified documents.

1. 1974 DOE Inspector General (IG) Reports. In 1974, DOE's Office of Inspector General produced two reports on the plutonium experiments. The AEC's Director, Division of Biomedical and Environmental Research, concluded that "the inquiry uncovered certain violations of ethical standards." (See File No. 44-2-330.) The IG reports contain extensive references to contemporaneous documents and to recent interviews. As of May 10, DOE's Document Search Team told staff that DOE had not yet been able to locate the full source materials from which the IG reports were prepared.

The bulk of the DOE material is organized by patient. Files on the 18 patients were prepared by the Center for Human Radiobiology of Argonne National Laboratories (CHR). With some variation, the patient files contain a treatment history, an experimental history of the injection and the subsequent deposition and excretion analysis, correspondence between researchers, and materials on followup study, including radiochemical analyses of patient samples.

Additional material is loosely organized by document type (e.g., scientific reprints).

interviews with researchers). In addition to material on plutonium injections, the investigators also compiled topical files on polonium and uranium injections in humans and on ethical standards at the time of the experiments.

The following documents from the DOE collection are included in this briefing book:

1. 1945 records: doctor's orders, including an order to begin urine collection (0003306-3308).
2. October, 1945 abstract of monthly Met Lab (Chicago Manhattan District Lab) report. Contains information about (Chi-1), and exemplifies a research section report (0002713-2714).
3. Graph of excretion data (Chi-1), apparently produced by researchers in 1945 (0002785).
4. May 1946 monthly summary of research for Met Lab Biochemical Survey Section. Among items of interest is a reference to two plutonium inhalation cases (3021) and a summary of "plutonium therapy studies" (0003021-3025).
5. 1946 classified article, "Distribution and Excretion of Plutonium in Two Human Subjects." Includes deposition charts, hematological and excretion data (0002775, 0002746-2773).
6. 1947 entries in patient chart of Elmer Allen (Cal-3). Obtained from the record center at UC Richmond; transcribed by hand in 1974, evidently from follow-up study of experimental subjects. Entry at top of 2682 is the only recorded instance of notification and consent in the unclassified files (002681-2683).
7. 1950 report of Los Alamos Scientific laboratory (UC) and Atomic Energy Project (U of Rochester): "Distribution and Excretion of Plutonium Administered Intravenously to man." Includes statement of subject selection criteria and bibliographical information (0003069, 0003075-3096).
8. 1978 internal memo of Center for Human Radiobiology, noting the lack of a formal "Detailed Report" on certain radioactive samples. The samples were taken from the exhumed bodies of experimental subjects. Note reference to Am-241 (0002812).
9. 1981 analyses of radioactive samples, taken from exhumed body of Chi-1, as part of the followup study (0002814-2836).

B. From the Office of Congressman Markey

Congressman Markey sent the Committee copies of documents provided by the Department of Energy in January 1985 to the House Subcommittee on Energy Conservation and Power. This material includes: a 1974 factsheet, a 1983 background memorandum, a 1976 ERDA background memorandum, an undated fact sheet with a summary of patients injected, DOE response to FOIA request, the 1974 AEC investigation report # 44-2-326, Inspector General report # 44-2-330, an article on the health effects of radiation, May 1974 AEC memorandum, AEC report # LA-1151 by Langham and others, Durbin's article "Plutonium in Man: A New Look at Old Data".

Congressman Markey's office also provided the staff with copies of letters from the Congressman to Secretary O'Leary on March 15, 1994 and April 11, 1994. The March 15 letter refers to recently released documents indicating that one of those injected with plutonium (Cal-A) was also injected with Americium-241 and requests that any additional medical records be released. The April 11 letter refers to indications in recently released documents that "other experimental subjects definitely drank plutonium and still others may have been injected" and requests additional documentation.

C. Previous Research by Historians Now on Advisory Committee Staff

In addition to the documents from the Department of Energy and Congressman Markey, further contextual documentation had been previously culled from other sources by historians now on the committee staff. These collections are at the University of California Bancroft Library (Lawrence Papers), San Bruno Federal Records Center, and the National Archives. These documents indicate how the plutonium story can be further pieced together from primary sources. The following examples are included in this briefing book:

(Please note that underlining on copies is not on the original documents)

1. August 16, 1944 memo from Dr. Louis Hempelmann, Director of the Los Alamos Lab Health Group to lab Director Robert Oppenheimer. Following an accident in which a worker inhaled plutonium, Dr. Hempelmann advised that a "great deal of concern" had been generated by the inability to detect plutonium in the body, and urging study of methods of detecting plutonium in the lungs and excreta.
2. August 16, 1944 reply memo from Dr. Oppenheimer to Dr. Hempelmann. Approving the proposal, and noted that the work "may involve animal or even human experimentation."
3. August 29, 1944 memo from Dr. Hempelmann to Dr. Oppenheimer. Summarizing "the biological research program which was agreed upon."

4. January 11, 1945 report to the Manhattan Project. Concerns the "Proposed Biochemical Program at the University of California."
5. March 15, 1945 memo. The Los Alamos Health group urges Dr. Oppenheimer "to submit a request to the Manhattan Project for an intense medical research program to be concerned with detoxification of persons poisoned with plutonium."
6. March 26, 1945 memo. Dr. Hempelmann recommends that Dr. Oppenheimer request the Manhattan Project "help make arrangements for a human tracer experiment to determine the percentage of plutonium excreted daily in the urine and feces. It is suggested that a hospital patient at either Rochester or Chicago be chosen for injection of from one to ten micrograms of material and that the excreta be sent to the laboratory for analysis."
7. March 29, 1945 memo. Dr. Oppenheimer evidently forwards the March 26 memo with his endorsement.

II. STAFF SUGGESTIONS FOR ADDITIONAL DOCUMENTATION

Methodological questions occurred to Staff in its review of the plutonium injection documents. Additional documents which might be searched for include the following:

1. Documents underlying 1974 Inspector General's Reports. It appears that key documents referenced in the 1974 Inspector General reports are not presently available. These include, for example, April 4 and 6, 1945 documents confirming the shipment of 5 micrograms of plutonium, giving instructions for preparing an injection, and a "Protocol of Clinical Experiment." There may also be additional documents relating to plutonium injections in 1944 and to six subjects who drank water laced with plutonium in 1946, as noted in Congressman Markey's letters to Secretary O'Leary.
2. Contractual Documents. Presently available documents do not appear to include contractual documents under which doctors and staff performed the injections.
3. Documentation of Selection of Sites and Patients. Documentation, such as correspondence, might explain the choice of Rochester and Chicago as initial sites, and the evident choice to select and inject patients from geographically disparate locations.
4. Documentation of the relationship between plutonium and whole body radiation experiments. DOE document 5 lists as a co-author a J.J. Nickson, M.D. (See page 0002775). Other documentation indicates that, at the Defense Department's

direction, the whole body irradiation experiment done in Cincinnati was undertaken in coordination with the work of Dr. Nickson (then at Memorial Hospital in New York). (See, in the Cincinnati case study, DOD reviews of 1958 Cincinnati grant proposal and May 8, 1961 "Research Proposal for Sub-Task in Nuclear Weapons Effects Research.") Further cross-referencing is needed to explore possible relationships between isotope injection and whole body irradiation experiments.

5. Documentation Held By Contractors. The plutonium documents show the Universities of Chicago and Rochester to be central institutions in early atomic biomedical research. DOE has told staff that it believes such institutions to be potentially "rich" sources of documentation. What documents do they possess, and what actions, if any, should the Committee take to identify and access their collections?
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MEMORANDUM

TO: MEMBERS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

FROM: ADVISORY COMMITTEE STAFF

DATE: May 12, 1994

RE: DOCUMENTS RELATED TO THE "GREEN RUN" RELEASE

BACKGROUND AND METHOD

What follows is a brief description of documentation related to the intentional release of radioisotopes at Hanford, Washington, on December 2-3, 1949.

The release remained classified until the 1980s. In 1986 and 1987 the Department of Energy released thousands of pages of documents in response to public concern over possible health effects of environmental releases at Hanford. In 1987, the federal government agreed to fund, through the Center for Disease Control of HHS, the Hanford Environmental Dose Reconstruction Project. The project is directed by an independent Technical Steering Panel.

References to "Green Run" in released documents led to Freedom of Information requests for additional documentation. The 1950 test report was largely declassified in 1989. Some materials related to the purpose and planning of the release remain classified.

To gather materials for the case study, the Committee's staff contacted all the agencies in the Interagency Working Group, the office of Senator Glenn, the General Accounting Office and the Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project. Staff met at some length with representatives of the GAO to discuss, among other items, their investigation into Green Run. Documents were received from four separate sources: the Department of Energy, the Department of Defense, the office of Senator Glenn, and the Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project. Additional public documents illustrating the broader historical context of the work were retrieved by staff.

Documents included in the briefing book are marked with an asterisk. If you wish to review documents that are not attached, please contact Anna Mastroianni.

DOCUMENTS RECEIVED

I. Secondary Documents Providing an Overview

A. From Hanford Dose Reconstruction Project

- * 1. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project. "The Green Run". Fact Sheet 12. March 1992.
- * 2. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project. "Gaining Public Access to Hanford Documents". Fact Sheet 14. August 1992.
- * 3. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project. "Information Sources / Declassification of Hanford Historical Documents", undated. 1 p.

B. From the Office of Senator Glenn

- 1. General Accounting Office. *Nuclear Health and Safety: Examples of Post World War II Radiation Releases at U.S. Nuclear Sites*. GAO/RCED-94-51FS. November 1993. 19 pp. (Included in Briefing Book for first meeting, tab 7)
- * 2. "Early Health Problems of the U.S. Nuclear Weapons Industry and Their Implications for Today." Report of the Majority Staff of the Committee on Governmental Affairs, U.S. Senate, S. Prt. 101-63. December 1989. 16 pp. Pp. 8-9 discuss Green Run.

II. Primary Documents Providing Context

A. From Staff Research

- * 1. CIA. Memorandum for the President, July 6, 1948. (CIA estimates 1953 as the most probable date for Soviet completion of an atomic bomb)
- * 2. CIA. Memorandum. September 9, 1949. (CIA reports air samples indicate a possible atomic explosion in the Soviet Union)
- * 3. Robert D. Little. *A History of the Air Force Atomic Energy Program, 1943-1953*. Vol. III. Part II. Section III. Chapter VII: "Atomic Intelligence", pp. 253-254, 276, 281. (Reevaluation of the long range detection program follows conclusion of review group that evidence is conclusive the Russians carried out an atomic detonation. Much material omitted due to classification.)

- * 4. Statement by the President on Announcing the First Atomic Explosion in the USSR, September 30, 1949.

III. Primary Documents Associated with the Test Itself

A. From the Department of Energy

- * 1. "Memorandum Report - The Evolution of Iodide During Metal Dissolution." HW-3-3003. 18 pp. Pp. 1-2 included. Note recognition in Introduction that release of radioactive iodine and xenon posed a "physiological hazard."
2. Phil E. Church and C.A. Goslin, Jr.. "Characteristics of Mixing and the Dilution of Waste Stack Gases in the Atmosphere." HW-7-4086, undated. 16 pp.
3. H.M. Parker, "Hazards of Waste Storage at Hanford Works, Part I", HW-14058, August 2, 1949. 60 pp.
- * 4. "Dissolving of Twenty Day Metal at Hanford - Notes". HW-17381-Notes [Document number assigned at time of discovery in January 1993]. 65 pp. Handwritten notes apparently related to the planning of the test. Pp. 1-3, 9, 15, 18, 22, 29, 56-61 are attached as samples of the material.
- * 5. H.M. Parker. "Health Instrument Divisions: Report for Month of December, 1949", HW-15550-E DEL. January 6, 1950. 29 pp.. Pp. 1-3, 19 are attached. Note the remark on page 3 that "H.I. Divisions would resist a proposed repetition of the test."
- * 6. W. Singlevich. "H.I. Environs Report for the Month of December 1949", HW-15593, January 9, 1950. 31 pp.. Pp. 1-5 are attached.
7. M.B. Leboeuf, "Analysis of Vegetation for I-131", HW-15743, January 27, 1950. 11 pp.
- * 8. H.J. Pass and W. Singlevich. "Radioactive Contamination in the Environs of the Hanford Works for the Period October, November, December, 1949," HW-17003, March 2, 1950. 67 pp. Pp. 1-4, 53-56 are attached.
9. R.C. Thorburn. "Health Monitoring of Samples for P-10 Oxide", HW-17257, March 20, 1950. 15 pp.
- * 10. "Dissolving of Twenty Day Metal at Hanford", HW 17381. The Committee received two copies of this document: "HW 17381 DEL" and "HW 17381 DEL

REV". The two copies differ only in the amount of material deleted for security reasons. Pp. 1-8, 11-13, 30-32, 63-71 are included from HW 17381 DEL. Copies of pp. 8, 12, 13, 66, and 71 from HW 17381 DEL REV are also included since they contain material deleted from the first version but later declassified.

11. J.W. Healy, L.C. Schwendiman, and P.C. Thorburn, "Counter Calibrations in the Health Instruments Methods Group", HW-18258, July 1, 1950". 53 pp.
12. C. W. Thomas and Dan M. Polinsky, "A Tabulation of Counting Correction Factors and Decay Schemes", HW-18258-APP, November 16, 1956. 74 pp.

IV. Documents Written Several years After the Test

A. From the Department of Energy

1. "History of Airborne Contamination and Control - 200 Areas," HW-55569 RD, April 1, 1958. 7 pp.
2. J.D. Anderson. "Emitted and Decayed Values of Radionuclides in Gaseous Wastes Discharged to the Atmosphere from the Separation Facilities Through Calendar year 1972." ARH-3026. March 1, 1974. 9 pp.
3. Maurice A. Robkin. "Experimental Release of 131-I: The Green Run." *Health Physics* 62 (June 1992): 487-495.

B. From the Department of Defense

1. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project, "Hanford Dose Reconstruction Project: Finding the Facts About People at Risk." Fact Sheet 5, February 1990. 2 pp.
2. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project, "Preliminary Dose Estimates," press release, July 12, 1990. 3 pp.
3. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project, "The Green Run", Fact Sheet 12, March 1992. 4 pp.
4. Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project, "Initial Hanford Radiation Dose Estimates," undated. 20 pp.

STAFF SUGGESTIONS FOR ADDITIONAL DOCUMENTATION

1. Technical details. The Hanford Environmental Dose Reconstruction Project is already embarked upon a major effort to reconstruct the amounts of radioactivity released and their distribution.
2. Historical context. Documents relating to the specific purpose of the test run are still classified. The Committee could request declassification of these files.
3. Ethical review. Documents relating to the planning and review of the test are still classified. None of the documents received to date relate to the procedures followed in planning and approving the test. The comment in the 1949 report by Parker that "'H.I. Divisions would resist a proposed repetition of the test'" suggests that there was some prior discussion of the potential hazards of such releases. The Committee could request declassification of these documents.
4. Interagency Co-operation. As indicated by the Air Force history, a wide range of agencies were involved in the aerial surveillance program which underlay the Green Run test. Following trails across agency lines will be necessary to obtain the most complete picture possible of the process which led to the test.
5. A keyword search for the word "experiment" will not always uncover relevant material. Green Run documents, such as the handwritten lab notes, clearly indicate the test was a carefully designed experiment. However, the applicability of the term "experiment" to such a test has changed over the years. In 1992, the Dose Reconstruction Project explicitly refers to Green Run as "the experiment" (Fact Sheet 12, p. 1). But the 1949-1950 reports are more circumspect, referring to it as a "specially requested dissolving", "the dissolving of the green metal" or the "green run." This may have been for security reasons or be indicative of a different mindset from today. In any case, the methodological lesson is that scanning documents for the word "experiment" would not have unearthed these reports. More importantly, close examination of how such terms were used may help reconstruct the intellectual framework within which such tests were designed and approved.

May 12, 1994

DISPOSITION OF FEDERAL RECORDS

1. This memorandum gives a brief overview of the management and disposition of records by federal agencies. The records of the Central Intelligence Agency (CIA) and the National Aeronautics and Space Administration (NASA) will be discussed to illustrate the different policies and practices utilized.
2. With respect to the status and location of records of federal agencies, one of five possibilities applies: (1) they have been transferred to the National Archives and Records Administration (NARA), (2) they have been transferred to a Federal records center, (3) they are still with the originating agency or its successor, (4) they have been lost or destroyed, or (5) they have been taken from the agency by an official and either placed in a repository or retained by the official. Each of these five possibilities will be discussed in turn.

National Archives and Records Administration

NARA is an independent agency and is broadly charged under federal law with effecting the transfer to it of federal records and thereafter assuming their care, custody, and control. More specifically, federal law provides that records are to be transferred to NARA when they have been determined to be of sufficient historical or other value to warrant preservation and they are 30 years old or, regardless of age, when the originating agency no longer needs to use the records in its regular current business and the agency's needs will be satisfied by access to the records at NARA. As a practical matter, few, if any, agencies have even transferred all of their records over 30 years old to NARA, much less records less than 30 years old which are no longer used in the agency's regular current business.

There are two NARA facilities in the Washington, D.C. area, and twelve regional NARA facilities around the nation. Generally, agencies transfer their records to the nearest NARA facility. For this reason, the two NARA facilities in the Washington, D.C. area have many more headquarters records than the regional NARA facilities.

All records of a particular agency, and in cases of very large agencies such as the military services the records of individual headquarters and commands, are put

in a separate collection by NARA. These collections are called "record groups", and each receives its own descriptive title and number (the latter carries no significance other than being a shorthand method of referring to the collection). Presently, NARA has over 475 record groups.

Record groups vary widely in size. Some have less than 100 feet of records while others have many tens of thousands of feet of records. Most record groups are broken down into various subcollections, or "entries", which often have the records of a specific individual, office, bureau, program, etc. For almost every record group, NARA has prepared "finding aids" which to varying degrees list and describe the contents of all the entries of the record group in question. Notwithstanding this, it can be very difficult to determine exactly what is in a record group. Some finding aids simply do not contain adequate descriptions. Others are obsolete because, for example, significant additions to the record group have been made since the preparation of the finding aid. In some cases, there are no finding aids. This whole problem is compounded by the fact that some record groups still contain large amounts of classified material. (In late 1992, NARA estimated it held over 325 million pages of classified documents.) When for one reason or another it is impossible to ascertain exactly what is in a record group, the archivists who work with the collection can sometimes be of assistance. Additionally, if the transmittal forms prepared by the agency when it sent the records to NARA are sufficiently detailed and still exist they can be reviewed. In many instances, however, the only means of determining what records there are is to examine them.

With respect to CIA and NASA records at NARA, there are only a limited number. Record Group #263 at the downtown Washington, D.C. NARA has less than 1,000 feet of CIA records. Most are from the 1940s and 1950s. There are no CIA records at any other NARA. Record Group #255 at the two Washington, D.C. NARAs and several regional NARAs has a little over 5,000 feet of NASA records. The date range is from the 1940s to the early 1970s (all the records from before 1958 are those of the National Advisory Committee on Aeronautics).

Federal Records Centers

Federal records centers have been established solely to assist agencies in the storage, servicing, and processing of their records. There are no requirements for agencies to send their records to a records center. In contrast to records transferred to NARA, those transferred to a records center remain in the legal custody and control of the originating agency. There is one records center in the Washington, D.C. area and several regional ones around the country (usually co-located with the regional NARA).

Records transferred by an agency are placed in the same record group as that

agency's records at NARA. In some instances, agencies have only transferred records to a records center and not NARA, and for this reason there are more record groups at records centers than at NARA.

Unlike at NARA, there are no finding aids to review or archivists to consult to determine what records are in a particular record group. The only means of ascertaining this is to review the Standard Form 135s (SF 135s) prepared by the agencies when the records were shipped, and filed by the records centers by record group. Some agencies also keep copies of the SF 135s. Because the requirements for describing the records in these transmittal forms have changed over the years and because of occasional non-compliance with whatever requirements were in existence, the amount of detailed information in them varies widely. Some will simply set forth a one- or two-line description of the records, the dates thereof, and any security classification. Others will list not only the foregoing information, but also all the folder titles. Still others will go further and list certain information about each document included in the shipment.

Generally, there are many more classified materials at a records center than at NARA. There are many reason for this, including the fact that there is no ongoing, systematic declassification review program for records at records centers.

There are no CIA records at any records center. At the Washington, D.C. records center, there are many more NASA records in Record Group #255 than are in this record group at NARA. The date range is from 1917 to the 1980s (all the records from before 1958 are of the National Advisory Committee on Aeronautics). In all likelihood, there are additional NASA records in the record group at many of the regional records centers.

Records Still With Agencies

Records still at the originating agency or its successors are the most difficult to identify and review. There are, at best, only very incomplete indexes or inventories of such records. The records may be at any number of locations, including the originating office, a successor office, a history office, or an agency storage facility. Records on intra-agency transfers and shipments usually do not exist.

The first step in trying to find such records is to make an inquiry of the office whose records are sought. In some cases, the records management office or history office of the agency can also be of assistance in locating records. Even if the records are found, however, often they cannot be examined because of their classification or other reasons.

The amount and types of records still held by the CIA and NASA are not known; however, it is presumed that in the case of the CIA almost all of the records

it has ever created are still in its possession.

Records Which Have Been Lost Or Destroyed

Identifying records which have been lost or destroyed by an agency in most cases is an impossible task. Agencies usually retain or destroy records pursuant to guidelines established by the agency itself and, in many instances, by the agency in conjunction with NARA. These guidelines change over the years due to many factors, and there are certainly instances of non-compliance with them. Some individual offices keep detailed records on what they have destroyed, while others do not. Whatever records of destruction exist should be available in the records management offices of the agency. No agency is believed to maintain any sort of index or inventory of records that have been lost.

The contents of any CIA and NASA guidelines on records retention and destruction, as well as whether any records exist on what records they have destroyed, are not known.

Records Which Have Been Removed By Officials

Through the years, some senior military and civilian officials have engaged in the controversial practice of taking some of their office files and working papers with them when they leave government service. (This practice has been the subject of two recent General Accounting Office reports.) These items are often deposited in a repository (e.g., the Library of Congress or university library) or in some cases are retained by the official. When deposited at a repository, the official often imposes restrictions on access (e.g., that the materials will not be open to the public for a certain number of years). Additionally, in many instances the records are classified.

The amount and types of records removed by any CIA and NASA officials over the years is unknown.

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May 17, 1994

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Biographical Sketches

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FAITH ANNE BULGER, J.D.

Research Analyst

Before she joined the Advisory Committee staff, Ms. Bulger practiced environmental law for three years with Vinson and Elkins L.L.P. in Houston, Texas. As an associate, she worked with many state and Federal environmental statutes and regulatory schemes. Her practice developed into predominantly toxic tort litigation. Ms. Bulger served as a legal intern at both the National Oceanic and Atmospheric Administration and the U.S. Department of Interior. She received her Juris Doctor degree from the University of Texas and her undergraduate degree from Princeton University. In law school, she took both a bioethics course with John Robertson focusing on informed consent in human experimentation and a seminar on international human rights. Her interests are primarily related to intentional releases of radiation.

KRISTIN CROTTY

Research Associate

Ms. Crotty recently joined the staff of the Advisory Committee after working as a research assistant for the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce chaired by Rep. John Dingell (D-MI). While with the Subcommittee, she researched human radiation experiments, and workers health and safety at the nuclear weapons complex. Originally from Evanston, Illinois, Ms. Crotty attended Michigan State University majoring in Humanities with an emphasis in political sciences.

JONATHAN ENGEL, Ph.D.

Research Analyst

Dr. Engel received his Ph.D. in History of Medicine from Yale where he concentrated on History of Health Policy and Public Health, and History of Psychiatry. His dissertation focused on deinstitutionalization of mental hospitals in Maryland, and demonstrated how Federal health legislation was translated into a state policy. He has worked in OMB's Office of Information and Regulatory Affairs and HCFA's Office of Legislation and Policy, and has taught a variety of courses on topics ranging from managing the AIDS epidemic to the impact of the Freudian movement on the Vienna Jewish community. In 1987, Dr. Engel received a B.A. degree in the History of Science from Harvard University, and in 1991 an M.P.P.M. degree from the Yale School of Management.



JERRY GARCIA, M.A.

Special Assistant

Before joining the Advisory Committee staff, Mr. Garcia was owner of Results Marketing, a small marketing and public relations company for four years. As a marketing consultant he worked with clients mainly in Scandinavia and the United States Virgin Islands. In addition, he worked for Alexander Proudfoot International as a management consultant in Brussels. He holds an M.A. in Psychology from the University of Dusseldorf in Germany and a B.A. in Psychology and Rhetorical Communications from the University of Virginia.

GREGG HERKEN, Ph.D.

Senior Policy and Research Analyst

In addition to his staff duties, Dr. Herken currently is Chairman of the Department of Space History at the National Air and Space Museum and Curator of Military Space in the department. Before joining the Smithsonian, Dr. Herken taught recent American History and the History of American Foreign Policy at Oberlin College, Yale University and the California Institute of Technology. He is the author of three books, The Winning Weapon: The Atomic Bomb in the Cold War (Knopf, 1981; Princeton, 1988), Counsels of War (Knopf, 1985; Oxford, 1986), and Cardinal Choices: Presidential Science Advising from the Atomic Bomb to SDI (Oxford, 1992; Stanford, forthcoming). In 1990, he received a MacArthur research grant for a collective political biography of physicists Ernest Lawrence, Edward Teller, and Robert Oppenheimer. He received a Ph.D. in Modern American Diplomatic History from Princeton University in 1974.

DEBORAH J. HOLLAND, M.A.

Research Analyst

Ms. Holland is currently a graduate student at Northwestern University completing a Ph.D. in History with a concentration in the development of the U.S. nuclear weapons program. For three years she served as the Issues Director of the Washington-based Nuclear Control Institute. She holds a M.A. in History from Northwestern and a B.A. in American Studies from Hamilton College.

DENISE HOLMES, J.D., M.P.H.

Research Analyst

Before joining the Advisory Committee staff, Ms. Holmes was a lawyer in private practice, and a legal consultant for both the 1992 Democratic National Convention and The Washington Post. She has performed policy analysis for the United States Senate Judiciary Committee and the New York Board of Education. Ms. Holmes holds a J.D. degree from Columbia University School of Law, and a Masters in Public Health (Health Policy) from the Johns Hopkins University School of Hygiene and Public Health. She received her B.A. magna cum laude in American Studies from Mount Holyoke College.

JEFFREY KAHN, Ph.D., M.P.H.

Staff Director

Senior Policy and Research Analyst

In addition to his staff duties, Jeffrey Kahn is Assistant Professor of Bioethics and Associate Director for Graduate Studies in the Center for the Study of Bioethics of the Medical College of Wisconsin (MCW). His administrative responsibilities at MCW include directing the College's Master's program in Bioethics. Before joining the faculty at MCW, Dr. Kahn was Assistant Professor of Medical Humanities at East Carolina University School of Medicine, in Greenville, NC. Dr. Kahn's background includes study in both science and the humanities, with a Bachelor degree in Microbiology from the University of California Los Angeles, a Masters in Public Health from the Johns Hopkins University School of Hygiene and Public Health (Health Policy), and a Doctorate (Ph.D.) in Philosophy from Georgetown University, where he studied Bioethics at the Kennedy Institute of Ethics. Dr. Kahn does research and has published in a variety of areas, including theoretical bioethics, ethics and genetics, dental ethics, ethical issues in health policy, and research ethics. His experience outside the academic setting includes hospital ethics committee memberships and consultations, along with review of proposed human and animal research.

LANNY KELLER

Public Affairs Officer

Mr. Keller has been an editor, reporter, columnist and editorial writer. He is a former Executive Editor of the Baton Rouge Business Report and Editorial Page Editor of the Shreveport Journal. As an editorial writer, he won the 1990 Walker Stone Award for distinguished editorial writing in the public interest. He has been press secretary to candidates for governor and Congress, and served as assistant press secretary in the Louisiana governor's office. Mr. Keller has written extensively on public policy for regional and national publications.

JEANNE KEPPEL

Special Assistant

Before joining the Advisory Committee staff, Ms. Kepper was the Assistant Office Administrator at Green, Stewart & Farber, P.C. After receiving her B.A. from Vanderbilt University she worked as a paralegal for Schwalb, Donnenfeld, Bray & Silbert, P.C. and for Green, Stewart & Farber, P.C., a spinoff of Schwalb, Donnenfeld. An enthusiastic volunteer, Ms. Kepper is a member of the Junior League of Washington. She joins the staff of the Advisory Committee as a Special Assistant to the Staff Director and the Director of Committee Affairs.

STEPHEN KLAIDMAN

Director of Communications

In addition to his staff duties, Mr. Klaidman is currently a visiting Professor of Journalism at the Pennsylvania State University and a Fellow of the Kennedy Institute of Ethics, Georgetown University. He began his career in academia after 23 years as a journalist with The New York Times, The Washington Post,

and The International Herald Tribune. Mr. Klaidman has been a columnist, editorial writer, reporter, and editor. He has been a Senior Associate of the Institute for Health Policy Analysis at Georgetown, Director of the Undergraduate Values Project also at Georgetown, and is currently an Associate in the Department of Health Policy and Management at Johns Hopkins University. He is the author of Health in the Headlines (Oxford, 1991) and The Virtuous Journalist (Oxford, 1987, with Tom L. Beauchamp). Mr. Klaidman has been a Guest Scholar at the Woodrow Wilson Center, where he won First Prize in the Media Studies competition in 1989. In 1992, he won the Lowell Mellet Award for improving journalism through critical evaluation.

ANNA MASTROIANNI, J.D.

Director of Committee Affairs

Deputy Staff Director

Senior Policy and Research Analyst

Before joining the Advisory Committee staff, Ms. Mastroianni was a study director in the Division of Health Sciences Policy of the National Academy of Sciences' Institute of Medicine. In that position, she most recently directed a study evaluating legal and ethical issues relating to the inclusion of women in clinical studies. Previously, Ms. Mastroianni practiced health care law in Washington, DC, and served as a legal consultant to the National Research Council's Committee on Contraceptive Development. She received her Juris Doctor and undergraduate degrees from the University of Pennsylvania. Her research interests include legal and ethical issues in human subjects protection and in the "right to die" area. She currently studies health policy at the Johns Hopkins University School of Hygiene and Public Health, and is a member of the Department of Health and Human Services Advisory Workgroup on Women in Medicine.

JONATHAN D. MORENO, Ph.D.

Senior Policy and Research Analyst

In addition to his staff duties, Dr. Moreno is a Professor of Pediatrics and of Medicine and founding Director of the Division of Humanities in Medicine at the SUNY Health Science Center at Brooklyn. Dr. Moreno has also held full-time academic appointments at George Washington University, the University of Texas at Austin, and Swarthmore College. He received a Doctorate in Philosophy from Washington University in St. Louis in 1977, and graduated from Hofstra University in 1973, with highest honors in philosophy and psychology. Dr. Moreno has been Associate for Social and Behavioral Studies at the Hastings Center, was the first Philosopher-in-Residence at Children's National Medical Center in Washington, D.C. and was an Andrew Mellon Post-Doctoral Fellow in association with the Aspen Institute for Humanistic Studies.

RONALD NEUMANN, M.D.

Senior Policy and Research Analyst

In addition to his staff duties, Dr. Neumann is Chief of the Nuclear Medicine Department, Clinical Center of National Institutes of Health, and is Clinical Professor of Nuclear Medicine at the George Washington University Medical School. He received his medical degree and residency training in Anatomic Pathology and Nuclear Medicine at Yale University. Dr. Neumann served as an Assistant and Associate Professor of

Radiology and Anatomic Pathology at the Yale School of Medicine before joining the NIH in 1985. His research interests focus on radionuclide techniques for identifying and treating cancers.

DAVID SAUMWEBER, M.A.

Director of Information Services

Before joining the Advisory Committee staff, Mr. Saumweber was Director of the Office of Archives and Information Services at the National Academy of Sciences' National Research Council. In that position, Mr. Saumweber directed the NRC Library and the NAS Archives. Mr. Saumweber's recent activities include managing development of computer applications for electronic information delivery, membership management and institutional policies, directing redevelopment of records management programs, and planning future service development. Mr. Saumweber received a Bachelor's degree with honors in Philosophy and a Masters in Philosophy of Science from the University of Virginia. His research interests include the nature of the document and the meaning of authenticity in electronic environments. Mr. Saumweber's most recent publications are a review of the NAS archival program for the AIP History Newsletter and contributions to *Preservation of Historical Records*, an NRC report to the National Archives.

GARY M. STERN, J.D.

Senior Policy and Research Analyst

From 1987 to 1994, Gary Stern was Legislative Counsel with the American Civil Liberties Union and its Center for National Security Studies. Mr. Stern's work concentrated on government secrecy, security clearances, counterintelligence, oversight of the intelligence community, the Freedom of Information Act, and information policy. Mr. Stern is editor of The U.S. Constitution and the Power to Go to War (Greenwood Press, 1994, with Morton H. Halperin), co-author of The Right to Protest: The Basic ACLU Guide to Free Expression (S. Illinois University Press, 1991), and an editor and contributor to the ACLU's annual Litigation Under the Federal Open Government Laws. He has published articles in the New York Times, Foreign Policy, The Christian Science Monitor, and The Nation. Mr. Stern graduated from Yale Law School in 1987, where he was Editor-in-Chief of the Yale Journal of International Law. He received his A.B. from Vassar College in 1983, where he majored in Ancient Greek and was Phi Beta Kappa.

JEREMY SUGARMAN, M.D., M.P.H., M.A.

Senior Policy and Research Analyst

In addition to his staff duties, Dr. Sugarman is an Assistant Professor and Co-Director of the Program in Medical Ethics in the Division of General Internal Medicine, Senior Fellow in the Center for the Study of Aging and Human Development, and Assistant Research Professor in the Center for Health Policy Research and Education at Duke University Medical Center. He received his medical degree and residency training at Duke and went on to pursue formal training in Medical Ethics at Georgetown University, where he received his Master of Arts in Philosophy. Dr. Sugarman also received training in Empirical Research at the Johns Hopkins University School of Hygiene and Public Health, where he received a Masters in Public Health. Dr. Sugarman is board-certified in Internal Medicine and is a practicing physician at the Duke Medical Center. He has consulted for the U.S. Congress' Office of Technology Assessment on its Defensive Medicine and Use

of Medical Technologies Project. His primary research interests relate to the moral issues associated with physician-patient communication, such as advance directives, informed consent, and shared medical decisionmaking.

DONALD WEIGHTMAN, J.D.

Senior Policy and Research Analyst

Before joining the Advisory Committee staff, Mr. Weightman was special counsel at the Office of Thrift Supervision, working in a special unit investigating departures from professional standards by lawyers and accountants in the savings and loan collapse. Previously, he was in private practice at Spiegel & McDiarmid, where he helped lead investigations into causes and consequences of cost overruns in nuclear construction programs. He received his J.D. from the University of Pennsylvania Law School. Before studying law, he did graduate work in philosophy at Boston University, and received a B.A. from Harvard College.

GILBERT WHITTEMORE, Ph.D.

Senior Policy and Research Analyst

Dr. Whittemore is a lawyer and Historian of Science from Cambridge, MA. He received a B.A. from Harvard College in 1972, a J.D. from Harvard Law School in 1975, and a Ph.D. in the History of Science from Harvard University in 1986. He has taught the History of Science at Harvard and in the Concourse Program for first year students at MIT. He currently serves in an "of counsel" capacity for the Boston law firm of Stalter and Kennedy, while completing a book on the history of radiation protection standards and beginning a book on attempts to build a nuclear- powered aircraft. Scholarly work relevant to the Advisory Committee's tanks includes his dissertation *The National Committee on Radiation Protection, 1928-1960: From Professional Guidelines to Government Regulation* (University Microfilms #8704465) and the article "A Crystal Ball in the Shadows of Nuremberg and Hiroshima: The Ethical Debate Over Human Experimentation to Develop a Nuclear-Powered Bomber, 1946-1951", published in E. Mendelsohn, M.R. Smith and P. Weingart (eds.), *Science, Technology and the Military: Sociology of Sciences Yearbook, Vol. XIII* (1988). pp. 431-462. Dr. Whittemore also devotes some time to teaching middle-school science at the Boston Archdiocesan Choir School in Cambridge.