TAB G

✦✦✦DRAFT ✦ FOR DISCUSSION PURPOSES ONLY✦✦✦

MEMORANDUM

TO: Members of the Advisory Committee on Human Radiation Experiments

FROM: Advisory Committee Staff

DATE: December 12, 1994

RE: Discussion Memo on Proposed Remedies Guidelines

[This memo was prepared by the staff in order to help facilitate a Committee discussion on how to address the issue of what remedial guidelines may be appropriate where wrongs or harms have occurred. This draft is not intended to represent the views of the Committee or any Committee Member. Rather, it provides one possible approach for determining potential remedies for harms caused by government sponsored human radiation experiments conducted in the past.[1]]

I. INTRODUCTION

In proposing remedies for victims of radiation experiments, the Advisory Committee is both guided and circumscribed by its Charter, which directs the Committee to make recommendations regarding "human radiation experiments." The Charter defines "human radiation experiments" as (1) "Experiments on individuals involving intentional exposure to ionizing radiation," and (2) "Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation." The Charter also directs the Committee to provide information and recommendations on thirteen specific atmospheric releases of radiation that do not appear to meet the definition of "human radiation experiments" provided by the Charter. The Committee recognizes that many individuals may have been exposed to radiation outside of these contexts; however, the Committee must limit its recommendations to the matters under its purview.

Several challenges exist in proposing remedies for those individuals within the Committee's mandate. For example, the passage of time has, in many cases, made reconstructing

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[1] Prospective preventive measures that may be implemented to prevent similar harms in the future -- including heightened penalties for violations of current regulations and greater openness in government -- will be addressed separately.

a detailed record of events difficult. In addition, many of the victims have long since died. Moreover, in recommending remedies for the many experiments which were conducted, the Committee must assess the government's behavior in light of both contemporary mores and the ethical and scientific standards that prevailed at the time they were conducted. (The conduct of the government includes all of the agents and contractors that acted on the government's behalf.) Thus, the Committee must determine whether an experiment that complied with prevailing standards would be less susceptible of a remedy than one that did not, even if neither experiment would meet today's ethical criteria. The need to make retrospective moral judgments necessarily complicates any remedies analysis. Finally, in making recommendations concerning available remedies, the Committee is aware of the need to carefully distinguish between the various types of experiments.

II. JUDGING THE PAST: POSSIBLE CRITERIA FOR RETROSPECTIVE MORAL JUDGMENT

Before making specific recommendations regarding appropriate remedies, the Committee must make a foundational decision regarding the criteria it will use in making retrospective moral judgments about past experiments. It must be noted that the Charter grants wide latitude in this regard, directing the Committee to evaluate whether "the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today." There are several approaches that could be used in evaluating past experiments, which are discussed in separate manuscripts and memorandum. However, given the language of the Charter, any conclusion regarding ethics should take into account both past and present ethical standards. The ethical model adopted by the Committee may have implications for its decisions regarding the application of guidelines for remedies.

III. LESSONS FROM THE PAST

In order to best evaluate appropriate remedies for the victims of experiments that the Committee has been studying, it is useful to review how Congress, the courts, and previous Commissions have approached the issues of both compensating injured research subjects, and compensating victims of exposure to ionizing radiation. These sources can inform the Committee of the degree to which remedies may already be available and also of types of remedies that may be particularly appropriate. The Committee will review the statutory schemes available for veterans and others who have been exposed to ionizing radiation from nuclear weapons tests, as well as statutory, legal, and analytical conclusions that have been reached concerning the compensation of research subjects, such as the findings and recommendations of the 1982 President's Commission for the Study of Ethical Problems in Biomedical and Behavioral Research regarding the need for and means of establishing a program to compensate injured research subjects.

IV. GUIDELINES FOR REMEDIAL MEASURES

The following guidelines are meant to assist policymakers in determining appropriate remedies for individuals exposed to ionizing radiation in the context of an experiment. The guidelines attempt to address several major themes. The first concerns the overall policy considerations and limitations facing the Committee. The Advisory Committee is guided by its Charter, which limits its purview to "human radiation experiments" as defined therein. Accordingly, the Committee's guidelines for remedial measures are addressed to deal only with the types of experiments outlined in the Charter. These guidelines do not address every situation in which the government has caused persons to be exposed to ionizing radiation. The Committee notes that Congress has enacted legislation to provide compensation to certain groups of individuals exposed to radiation in the course of production, testing, and deployment of atomic weapons -- e.g., uranium miners, persons living downwind of the Nevada Test Site, and civilians and veterans who participated in atomic bomb tests. However, most of these individuals do not fall within the Committee's Charter. To the extent that there is a subset of individuals within those groups who may also have been involved in human radiation experiments, the Committee's guidelines may suggest that additional remedial measures are appropriate. Nor does the Charter include most workers at government owned atomic weapons production facilities, who may have been exposed to radiation, by accident or otherwise, in the course of their work. Some of these individuals may be entitled to remedies established by statute (e.g., occupational requirements) or imposed by the courts.

The Committee will then offer a set of "methodological guidelines" for assessing the type of remedy that would be most appropriate for a given type of experiment, based on the type of harm, the extent of government culpability (including subject selection and informed consent), and considerations of causation.

Finally, the Committee will address the need for effective implementation of any type of remedy scheme that is put in place. The ultimate responsibility for providing remedies of any form lies with the policymakers in Congress and the Executive branch. The Committee is aware of the dissatisfaction that has been expressed with respect to some of the existing compensation statutes, and believes, accordingly, that any program that is responsive to the harms engendered by government sponsored human radiation experiments must be clearly crafted and objectively administered so that all persons who are entitled to a remedy can receive it with the minimum of difficulty.

Guideline 1: The Committee's Remedial Guidelines are Designed to Address Remedies only for those Subjects Covered by Its Charter.

The Committee's Charter articulates two general categories of human radiation experiments: (1) "Experiments on individuals involving intentional exposure to ionizing radiation"; and (2) "Experiments involving intentional environmental releases of radiation that (A)

were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation."

Guideline 2: Possible Remedies that could be Considered under the Committee's Guidelines include Access to Information, Health Insurance, Life Insurance, Medical Evaluation, Medical Monitoring, Monetary Compensation, and Official Apology.

The kind of remedial measure available to individuals who may have been harmed by human radiation experiments (or their survivors, where applicable) will depend largely on the nature of the harm and the recognition of some degree of government culpability. (Although, as a general proposition, the government should not be liable where it is not culpable, the Committee will consider whether a form of strict liability is appropriate for persons who are injured in the course of serving as a research subject. The question of ensuring that remedies are available to research subjects who are harmed in the course of such research, regardless of fault, has been debated and contemplated for many years, with no firm policy currently in place.) The remedy should be molded to fit the specific harm. In some cases, more than one remedy may be appropriate.

- *Access to Information*. In many situations, experimental subjects have difficulty obtaining information pertaining to the particular event and their role in it. Such existing information could serve to answer questions and alleviate concerns about what took place. Thus, an important remedy, particularly for individuals who fear that they are at risk of developing a disease at some time in the future, will be the ability to gain access to records that bear on their experience.

- *Health Insurance*. Guaranteed health care is an appropriate remedy for persons who have permanent health problems as a result of their being the subject of an experiment. Such care is provided, for example, to veterans who are injured in the course of their military service. Although many medical institutions provide medical treatment for research subjects who are injured, such treatment is often only short term and is not guaranteed to all such subjects, nor does it necessarily extend to persons who move away from the hospital at which they were injured.

  One uncertainty concerning health insurance (and life insurance as well) is how broadly it should apply--i.e., would it cover all medical conditions of the recipient, or only those that are the result of the experiment? The VA, for example, generally provides health care only for service connected disorders.

- *Life Insurance*. A life insurance guarantee would serve to provide a death benefit to the survivors of an experimental subject. This form of remedy would be appropriate for people who are still alive but might die "prematurely" because of their involvement in

research. Life insurance could also be an additional benefit for injured persons in cases when the government's conduct is more culpable.

As with health insurance, the question arises as to whether such coverage applies only to any cause of death, or only to death attributable to the radiation exposure.

- *Medical Evaluation.* Oftentimes, persons who know that they were the subject of an experiment do not know whether they have been injured or are at greater risk of developing a disease. This is particularly true where the dose was low, and the probability of developing a disease is low. For such persons, the most appropriate remedy may be the opportunity to receive an independent, expert medical evaluation to determine what, if any, risks they face. Such a one-time evaluation would be based on an assessment of the experiment, which includes all available information on the experiment, most importantly the dose, along with a medical examination. This type of remedy will often serve to alleviate fears that persons may have by assuring them that the chance of disease is minimal, if it exists at all. It could also include some form of counseling for emotional distress and anxiety.

  This remedy is not without its risks. Many of the problems associated with medical monitoring could also apply to medical assessments -- e.g., false positives and negatives, diagnosis of unrelated, non-radiogenic disease, etc. (See discussion below.)

- ***Medical Monitoring.*** Medical monitoring may be an appropriate remedy for persons who have been exposed to doses for which there is a reasonable probability of developing a radiogenic disorder. This remedy would include period "check-ups" in order to detect disease at an early stage for more effective treatment, and should also include health insurance in the event that the subject does develop a disease. (The Committee's Charter explicitly charges the Committee to consider whether "medical follow-up" is "required to protect the health of individuals who were subjects of a human radiation experiment.")

  The Committee recognizes that there are potential hazards associated with medical monitoring (as well as medical assessment). For example, there are only a limited number of conditions for which there is scientific evidence that early diagnosis prolongs life -- e.g., cervical and breast cancer, but not lung cancer.[2] If early detection does not in fact prolong life or contribute to one's quality of life, then its value may be outweighed by other problems. For example, it can increase the personal anxiety of the patient if they are told at an early stage that they are likely to develop a disease for which there is no cure. In addition, such information could result in burdens imposed by others, such as

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[2] Although screen-detected cases do tend to live longer than clinically-diagnosed cases, this apparent improvement is often the result of "lead-time" bias (advancing the date of diagnosis rather than delaying the date of death) and "length" bias (the tendency for screening to preferentially detect the less aggressive tumors).

stigmatization by family and friends. Medical and life insurance may be cancelled or premiums raised to allow for a pre-existing condition. It may be difficult to get or keep a job because the employer is concerned about their health insurance or workers compensation premiums. On the other hand, people might welcome the opportunity to plan their life in accordance with their medical condition and might prefer that they be given the choice to know, regardless of the consequences.

Medical monitoring could also produce false negatives, which can have serious ramifications. Monitoring must be recurrent if it is to be effective. However, there are great debates about the optimal frequency of screening. A single cross-sectional survey of an exposed population is unlikely to be of much use, either scientifically or for the benefit of the individuals. Parallel to the problem of false negatives is the problem of false positives, which any screening method can also be expected to produce. Eventually, these cases should be weeded out, but usually not without further unnecessary and possibly risky tests, diagnostic radiation, biopsies, or other procedures, and not without considerable anxiety to the patients.

The second problem is that in any population, some diseases are bound to be detected, which may have nothing to do with exposure to radiation. This might argue for a tightly focused screen for diseases that have a plausible causal connection with exposure, but even there, the radiogenic cases may be only a small proportion of those detected. The inclusion of diseases in a medical monitoring program is likely to be seen as conferring legitimacy to the public's belief that their conditions are causally related to their exposures. Certainly, most exposed populations tend to ascribe a wide range of conditions to their exposure, without recognizing the high frequency of many of these conditions in the general population. Poorly designed epidemiologic studies can feed this perception by overestimating the true prevalence of various subjective complaints, some of which may not represent any real pathology.

- *Monetary Compensation.* Monetary compensation, alone or as an adjunct to other remedies, is appropriate usually for the most egregious harms, or when the government's conduct is most culpable. In the legal context, such compensation generally occurs in cases involving death, bodily injury, or the loss of earning potential. In addition, punitive awards can serve as a form of retribution. Monetary compensation can be disbursed in a lump sum payment or through regularly scheduled (disability-type) payments.

- *Official Apology*. In certain situations, experimental subjects (or their survivors) may be entitled to official recognition of their involvement, and sacrifice, in the experiment. Whether or not some other form of remedy has already been or should now be provided, it may be vitally appropriate that the government formally apologize to the subjects or provide some other significant symbol of national regret.

Guideline 3: Remedial Measures Must be Based on an Analysis of the Government's Culpability and the Nature of the Harm to the Individual.

Consideration of possible remedial measures for subjects of human radiation experiments should be based on a number of key factors. The two foremost are the degree of government culpability (Guideline 4) and the nature of the harm to the individual (Guideline 5). Different combinations of these two elements may result in different forms of redress. The interrelationship between the two can be illustrated in the form of a grid, with a vertical axis representing increasing degrees of government culpability and a horizontal axis representing various types of harm to the individual. (See proposed grid at **Attachment A**.)

Several additional factors must be considered in order to properly determine appropriate remedies. The first is causation, of which there must be some element connecting the government's conduct to the resulting harm: i.e., in the case of all harms except lack of adequate consent, there must be a recognized causal relationship (even if presumptively established) between the radiation exposure and the resulting injury (Guideline 6). Another factor is informed consent. While a potential harm in itself, whether or not adequate consent was obtained will often inform upon the nature and degree of government culpability (Guideline 4). Similarly, the process by which subjects were selected for a particular experiment may also be a factor in assessing government culpability; this issue will generally arise in connection with the consent issue (Guideline 4).

Guideline 4: Culpability Varies on a Scale from None to Knowing.

The Committee may recognize five degrees of government culpability -- ***knowing***, ***reckless***, ***negligent***, ***strict liability***, and ***none***. Although these categories are rooted in legal terminology, they are not intended to have an exclusively legal meaning.[3] Rather, they are an attempt to delineate gradations of culpability through their common sense meanings. As noted above, final determinations regarding culpability will depend on the Committee's consideration of "retrospective moral judgments" -- e.g., the Committee could decide that conduct that it considers to be in accordance with standard practices of its time should be presumed not to be highly culpable, and thus probably not warranting remedies involving monetary compensation. (This issue will be discussed in an accompanying memo linking remedies and ethics.)

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[3] *See* section 2.02 of the Model Penal Code for descriptions of the various terms employed here; *see generally* Paul H. Robinson and Jane A. Grall, "Element Analysis in Defining Criminal Liability: The Model Penal Code and Beyond," 35 *Stanford Law Review* 681 (1983). Note however, that in the civil law context, the distinctions between negligence, recklessness, and inadvertence are themselves unclear, and appear to refer more to quality than kind. The distinction seems to have been generally rejected under the common law due to "the extreme difficulty in of classification [and] the almost complete impossibility of drawing any satisfactory lines of demarcation," although it is still used in certain statutes. William L. Prosser, *Law of Torts* 182 (1971).

Assessing culpability will generally require analyzing the various components of the government's conduct. In particular, the extent to which the government adequately informed the subject and obtained his or her consent may be a significant factor -- e.g., did the government negligently, or knowingly, fail to get consent? Or, if consent was properly obtained, does it mitigate the government's liability, especially if it contains a liability waiver? Moreover, the government's expectations and obligations regarding consent may differ depending on the nature of the experiment -- i.e., a one-time intentional releases over a large population raises different issues than in a biomedical experiment. Existence or absence of consent can also factor into how one judges the severity of other harms -- e.g., injury to someone who gave consent may result in a different remedy than if the same injury occurred in the absence of consent.)

An additional component of the government's conduct is the extent to which abuses in the subject selection process may be indicative of culpability. Selection of certain subject populations for particular experiments -- e.g., mentally retarded students, prisoners, indigent hospital patients -- raises the issue of whether these groups were deliberately exploited by the government because of their perceived vulnerabilities. For example, an exploited group may be less cognizant of the informed consent process and therefore less able to respond in a meaningful manner. The Committee must determine whether this issue constitutes a form of remediable harm that should be included in the current calculus, or whether the issue should be given separate consideration.

- ***Knowing***. "Knowing" applies to situations in which the government acts with full knowledge that its action is wrong and will almost certainly cause damage, but it nonetheless believes that such action is required. An example might be if the government deliberately administered a harmful dose of a toxin to someone for the sole purpose of seeing what biological effect it would have, without telling the subject what it was doing or why it was doing so. (The same example could be considered reckless if the dose was not considered to be harmful.)

- ***Reckless***. Recklessness applies in situations in which the government is aware that its conduct might be wrong and might cause injury, but it nonetheless acts without taking necessary precautions. Whereas knowing means "wilful" conduct, reckless means "careless" conduct. However, for both knowing and reckless, the government is aware of the harmful consequences that may result, and is therefore presumably both blameworthy and deterrable for its actions. An example of reckless conduct might be where a government agency continues to fund a research protocol unchanged after learning that subjects were suffering unanticipated injuries.

- ***Negligent***. The government can be considered negligent when it fails to recognize injurious conduct that it should have recognized. The Model Penal Code, for example, states that negligence applies when the actor's failure to recognize a risk "involves a gross deviation from the standard of care that a reasonable person would observe in the actor's situation." An example might be where the government funded a research program

without thoroughly reviewing available information that would have shown injurious deficiencies in the design of the program.

- *Strict Liability.* Finally, it may be appropriate to hold the government responsible even when it has not done anything wrong. Even if the government took every precaution and followed all established requirements, a judgment could be made that the subjects should nonetheless be compensated in light of the harm suffered, particularly if the government's conduct would not meet current standards. (Such a no-fault approach to injury has been advocated in the biomedical community for treating research subjects who are injured in the course of medical research.)

Guideline 5: The Types of Harms that could result from Human Radiation Experiments Range from None to Death.

The harms associated with radiation experiments fall into three general categories. The first involve physical injuries, such as acute injury from which there is full recovery (including radiation sickness -- nausea, vomiting, anorexia, infection -- skin burns), serious disease that does not result in death (including flash blindness, cataracts, mental radiation from in-utero exposure, and various non-lethal cancers), and premature death (fatal cancer or infection). The second involves emotional distress that may result when a person believes that he or she is at an increased risk of developing a disease or passing on a genetically transmissible injury to his or her offspring from a radiation experiment. The third are so-called "dignitary" injuries, which involve the violation of a person's autonomy by failing to obtain consent or to inform the person adequately of the risks. (This category includes the outcome where the only "harm" is the wrong of failing to obtain consent the absence of any material harm or risk of harm.) These harms are presented as general categories. Their location on the axis is not necessarily an indication of rank order; nor does physical injury necessarily mean greater harm. Rather, individual harm must be assessed on a continuum where there are no clear distinctions or there are several different harms of varying severity.

Guideline 6: Determination of Harm will Require some Consideration of Causation; Presumptive Causation will be Appropriate for Certain Types of Experiments.

Perhaps the most difficult aspect of determining injury, particularly for latent illnesses, is establishing a causal link between the exposure to radiation and the subsequent disease. This link must be considered at both the population level and at the individual level. At the population level, there must be at least some acceptable scientific evidence or biological plausibility that the disease could have been caused by the exposure. For many diseases, there is controversy as to the strength of this evidence, and this uncertainty needs to be factored into the recommendations for

remedies. If a causal association is not recognized at the population level, then there is no need to proceed with consideration of individuals' claims for that disease.

At the individual level, criteria are needed for judging whether it is likely that the disease was caused by the claimant's exposure rather than by other factors. In civil litigation, this judgment is traditionally made on the "balance of probabilities," i.e., a probability of causation (PC) of greater than 50% (but most legislative remedies have adopted a lower threshold). Others, including the Presidential Commission on Catastrophic Nuclear Accidents, have advocated that the magnitude of the award be proportional to the PC (perhaps with some minimal threshold to discourage frivolous claims and minimize administrative costs). One of the key factors entering into the PC calculation is the individual's radiation dose. (Other factors vary from disease to disease, but might include age, latency, and other exposures.)

The requirement to provide a "dose reconstruction" has proved to be cumbersome at best and a serious barrier to many legitimate claims at worst. Determining the dose can be a difficult task, especially when the records of the original exposure either were not maintained or no longer exist. Accordingly, the Committee recommends that remedies not require dose reconstruction to prove the cause of the disease. Rather, for certain types of experiments, causation should be presumed based on what is known about the conditions of the experiment as a whole and epidemiologic evidence about the likely effects of that exposure. Thus, judgements about causality would be rolled into the criteria for evaluating outcomes in relation to particular experiments. This is not to say, however, that any degree of exposure would constitute an acceptable presumption. For example, everyone in the world was exposed to fallout from nuclear weapons testing and is at slightly elevated risk of cancer as a result. However, the excess risk for most people is minuscule in comparison with the background risk from other causes. Thus, the Radiation Exposure Compensation Act recognizes only those persons who have certain minimal lengths of residence at particular times in particular downwind counties as having been presumed to have a sufficiently elevated risk to merit compensation. (The accompanying table at **Attachment B** attempts to illustrate the causality issue.)

Guideline 7: The Government's Relationship with a Contracting Party May Affect Government Culpability.

Government culpability may depend on the interrelationship between the government and the contracting party actually conducting the experiment. In many cases, the government was the sponsoring entity, while an independent contractor performed the experiments. In general, the government is responsible for the actions of its agents (to the extent that the agent is acting on the government's behalf), such that the government is culpable to the same extent that the agent is culpable.

However, with respect to past actions, the Committee may want to consider whether government culpability could be mitigated in situations where an agent has acted in a way that the

government could not have reasonably expected and protected against. If, for example, the government required that its contractor obtain informed consent and take all reasonable precautions, but the contractor nonetheless violated these requirements and injured a research subject, the government might not be culpable to the same degree as the agent, but might be culpable to a lesser degree. The Committee may also want to consider the reverse situation, where the agent is not deemed culpable because he or she acted with the standards of the time, but the government is still held accountable because the conduct is deemed to violate current standards (e.g., strict liability).

Guideline 8: Absent Evidence of Lost Earnings or Premature Death, Remedies will generally Inure only to the Subject, and not to the Relatives or Estate of Deceased.

The Committee must consider whether the remedies it proposes will be available only to experimental subjects or whether they should pass on to their relatives if the subjects are dead. Survivorship is generally not an issue when the remedy itself involves any form of medical support, which can only be of use to persons who may themselves be injured or at risk (except in the case of in-utero or genetically transmissible diseases). However, more difficult questions arise as to whether monetary remedies should survive the death of an experimental subject. Such remedies may survive where the experiment itself caused the death or lost earning potential of a subject and the government was culpable, which is a common measure in tort law for such damages. Where the experiment did not have these effects, but the subject has since died, monetary compensation would generally not seem to be indicated, except perhaps in situations where the government sought to keep experiments secret precisely in order to avoid legal liability.[4] Official apologies could apply to relatives as well as subjects, and would most likely apply to dignitary harms -- i.e., lack of informed consent or risk of latent disease.

Guideline 9: Measures Must be Taken to Insure that Remedies Proposed by Government Policymakers are Properly Implemented.

As noted above, the purpose of this chapter is to provide guidelines that the government policymakers in Congress and the Executive branch can use to determine what, if any, remedies should be available to the various experimental subjects covered by the Committee's Charter. The Committee believes that the government must ensure that any remedy it offers is properly and effectively implemented, so that eligible recipients are not unduly burdened in obtaining that to which they are entitled. Although the Committee will not make definitive findings regarding how the government should implement the proposed remedies, it will review potential methods of effective implementation. To do so, the Committee will examine current compensation schemes

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[4] Another option might be to distribute awards for these types of harms to relatives of the entire class of subjects or some other appropriate repository.

for both radiation, non-radiation, and research-related injuries, and may make findings regarding which schemes serve as the best models for effective administration of the Committee's proposed remedies.

ATTACHMENT A
(TAB G)

CULPABILITY/HARM GRID

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CULPABILITY/HARM GRID

Culpability

Knowing					
Reckless					
Negligent					
Strict Liability					
None					
	None	Failure to obtain Adequate Informed Consent in the Absence of Material Harm or Risk of Harm	Fear of Latent Disease --- Acute Side Effects With Full Recovery	Long Term or Permanent Disease or Disability, not Resulting in Death	Death

Harm

ATTACHMENT B
(TAB G)

CAUSALITY TABLE

✦✦✦DRAFT ✦ FOR DISCUSSION PURPOSES ONLY✦✦✦

CAUSALITY TABLE

Status of Individual	Causal Relationship in Population: Unlikely	Controversial	Accepted
Exposure and disease present; Other explanations unlikely; PC high	N.R.	??	Yes
Exposure and disease present; Other explanations possible; or PC low	No	??	??
Exposure undocumented or absent, or disease undocumented or absent	No	No	No

PC = Probability of Causation
N.R. = Not Relevant (PC could not be high if the population relationship is nonexistent)

This table summarizes the thought process involved in considering the causality issue. The relationship between exposure and disease in the population must be considered first. (This does not necessarily need to be assessed in the particular population of experimental subjects, however, only in properly designed epidemiologic studies that would be generalizable to the particular experiment.) Remedies should only be considered in situations where there is a relationship between exposure and disease that is generally accepted as causal, or at least reasonably plausible. Obviously the individual must also have both exposure and the particular disease under consideration for a remedy to be contemplated. The key questions are how much exposure is needed and how confounding and modifying factors are to be allowed for. This is where the presumptions fit in to resolve the "??"s in the table.

FIRST DRAFT

TAB H

✦✦✦DRAFT✦FOR DISCUSSION PURPOSE ONLY✦✦✦

MEMORANDUM

TO: Members of the Advisory Committee on Human Radiation Experiments

FROM: Advisory Committee Staff

DATE: December 12, 1994

RE: For Discussion: Ethical Standards and Government Culpability

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[This memorandum was prepared by the staff in order to help facilitate a Committee discussion. This draft is not intended to represent the views of the Committee or any Committee member. Rather it is to provide one possible approach for the Committee's consideration.]

I. INTRODUCTION

The purpose of this memo is to move from consideration of a general framework for ethics criteria, retrospective judgment, and guidelines for remedies, to an assessment of the government's culpability in light of available historical evidence. The position put forth in this memo for consideration by the Committee is that there is sufficient evidence of at least some government culpability where morally wrong actions occurred in the conduct of government-sponsored human radiation research.

II. GOVERNMENT CULPABILITY

Specifically, we contend:

1. The government acted with full knowledge that the use of citizens to serve the ends of government raises basic ethical questions. In 1947, on behalf of his nomination to become the first chairman of the newly created Atomic Energy Commission, David Lilienthal told the United States Senate that:

> . . . all Government and all private institutions must be designed to promote and protect and defend the integrity and the dignity of the individual. . . . Any forms of government. . . which make men means rather than ends in themselves. . . are contrary to this conception: and therefore I am deeply opposed to them. . . . The

> fundamental tenet of communism is that the state is an end in itself, and that therefore the powers which the state exercises over the individual are without any ethical standards to limit them. That I deeply disbelieve. [1]

2. The government had ethical standards to govern human radiation research. These standards date back at least to the 1930's (Department of the Navy), World War II (the Committee on Medical Research), and the post-War era (the Atomic Energy Commission). In the early and mid-1950's the Department of Defense adopted the Nuremberg Code and the Clinical Center of the National Institutes of Health created a system of prior peer review. There was also at least one relevant professional code, that of the American Medical Association in 1946.

3. Even compared to current rules, these standards were respectable. They included the notion that subjects must give consent and that they should not be exposed to serious harm. Although these ideas were perhaps vaguely understood and minimal from a modern standpoint, they were surely better than no standards at all. The Nuremberg Code-based policy adopted by the Department of Defense in 1953 might be said to be more protective than today's standard.

4. Though one may quarrel with the adequacy of the standards as written, it appears that even those standards were not followed by the government in at least some cases.

5. The government is culpable for its failure to ensure that human radiation experiments conducted with Federal support followed its own ethical standards.

6. Neither of two obvious defenses for this failure of government is persuasive. The first defense is that the norms of the day permitted the use of human research subjects in ways that would not be permitted today. But the government need not be judged by present day norms. For the purpose of this memorandum it may be judged only by those represented in its own past ethical standards. The second defense is that national security considerations "trumped" research ethics. But there is little or no evidence that the government's own ethics policies either contemplated national security or identified national security considerations as justified exceptions, to ethical standards for human experiments. To the contrary, the 1953 Defense Department Nuremberg Code policy was clearly effected in the immediate context of national security concerns, and did not include any recognized national security exception. We will return to the subject of national security later.

This argument goes to government culpability and the need for remedies, but not to the degree of government culpability or the nature or extent of remedies. Those issues require a more refined evaluation according to specific fact situations. A framework for those questions is found in the staff memorandum on "Remedies."

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[1] McCullough, David, Truman, (Simon & Schuster: NY, 1992), pp 537-538.

III. TWO SCENARIOS

In light of what the Advisory Committee has learned so far, two scenarios may be relevant characterizations of the past. We believe that Scenario 1 best represents the situation during the period of interest to the Advisory Committee:

Scenario 1. *There were officially sanctioned ethical standards, but these standards were not widely disseminated, implemented or practiced. (Note this interpretation of the historical state of affairs corresponds to positions 3-4 on Ruth Faden's proposed schema for assessing degree of culpability.)*

Some may not be prepared to adopt Scenario 1 as an accurate description of the past research environment. But the following more modest construction also has important implications for remedies:

Scenario 2. *There were articulated but not widely accepted standards at the time. (Note: This corresponds to positions 2-3 on Ruth Faden's proposed schema.)*

Each of these states of affairs can be "unpacked" in terms of its implications for remedies.

Scenario 1. The Advisory Committee's work suggests that there were officially sanctioned ethical standards for research involving human subjects, but that these standards were not widely disseminated, implemented or practiced.

By "officially sanctioned" is meant that persons in authority adopted or enacted ethical standards on behalf of an institution (e.g., in a policy directive). Failure of dissemination or recognition is a partial explanation for the failure of subordinates to implement these standards. Specific reasons for these kinds of failures will depend on the case at hand but could include the level of classification of the document, different ways of interpreting the standards, or ambiguity about the assignment of responsibility for ensuring that the standards are enforced.

Those who have the authority to promulgate ethical standards have a correlative responsibility to make a good faith effort to see that they are implemented. Individuals and institutions are therefore culpable for the failure to implement such standards. Those who were wronged as a result of failed implementation of standards that should, by the terms of those standards, have applied to them, are entitled to the full panoply of remedies.

Subordinates who failed to operate according to standards about which they were not given reasonable notice cannot be held blameworthy (e.g., obtaining a subject's consent in writing), unless the standards spoke to moral norms of which they should have been aware from other contexts (e.g., the arbitrary use of vulnerable people in dangerous medical experiments

against their will). Then they are culpable on other grounds.

Scenario 2. Instead of Scenario 1, perhaps it should be said that standards were articulated but not widely accepted. Under this interpretation, standards were expressed by some individuals but did not receive official sanction. Although we do not subscribe to this description of the relevant period, it still has implications for culpability and remedies.

If acts were performed in violation of articulated standards then remedies should be provided to those who were harmed or wronged but the agent may not be morally culpable. Judgments about agents' culpability for a violation of articulated but not widely accepted ethical standards depend on a number of considerations. In particular, in order to be held to the highest level of culpability the agent must have been in a position not only to evaluate, but also to implement the articulated ethical standard. In other words, agents may be criticized for failing to appreciate the ethical standard, but the degree of their culpability for failing to act in accord with that standard is limited unless they were demonstrably in a position to have considered and acted on a standard that was not yet widely accepted, and the wrongs that resulted were significant by today's standards.

This scenario also goes to institutions that could be held to collective responsibility for failure to accept a superior ethical standard. Arguably, it is the burden of institutions--and especially *governmental* institutions--to submit their current policies to constant review in light of the continual societal conversation about normative questions. In some cases, including instances that are relevant to the work of the Advisory Committee, it may be transparent that articulated ethical standards that were not widely accepted were relevant to the institutions' functions.

IV. CONCEPTIONS OF THE GOVERNMENT

How one understands what "the government" is may be crucial to one's interpretation of the arguments in this memorandum. There are at least two ways of conceptualizing "the government."

On one, the government is a unified corporate person, a singular entity. There are discrete units within government and administrations may come and go, but "the government" persists. On the other view, what we call "the government" is simply the grossest manifestation of the aggregate, though often inharmonious, actions of its individual entities (e.g., the Department of Defense, the Department of Energy, the Department of Veterans Affairs, etc.) or of individual human agents who are in some official capacity with regard to the government.

But most Americans do not think of government in this atomized way. Rather, we are mainly accustomed to thinking of government in the first sense, as itself an agent, and as one that is indivisible. We adopt this way of thinking of government for the remainder of this

memorandum.

V. NATIONAL SECURITY CONSIDERATIONS

Again, there is no evidence that the government's own ethical standards created an exception for national security considerations. Yet the Advisory Committee has documented instances of non-disclosure that an experiment was being conducted, or of limited disclosure of its details.

For example, a plain example of complete non-disclosure in the Advisory Committee's purview seems to be the plutonium injections conducted under the auspices of the Manhattan Project. In those cases there is generally no evidence of disclosure to the subject of what was being done, and some evidence that what was being done was deliberately not disclosed.

Examples of limited disclosure (concerning why some experiments were being done) likely abound in the cases within the Advisory Committee's mission. In these instances certain information that might have been relevant to the subjects was not provided.

But even if not all of the purposes of an experiment could be disclosed to a patient on national security grounds, at least the general nature of the experiment, its potential harms and the funding source may be disclosed without generating national security concerns.

Of course, difficult questions could be raised, e.g., the extent in which no disclosure at all would be acceptable (and the need for special protections, if any, in such case). However, these questions, while critical as prospective issues, do not appear to be addressed by the policies we have found in the past, which do not, on their face, provide for "national security" exceptions to the rules of consent they state.

VI. REMEDIES FOR HARMS WITHOUT WRONGS

Perhaps some past actions that resulted in harms will not be judged as wrong in the present. Even though they were not wronged, if some individuals were harmed in the past they may be considered as due remedial action. None of the positions on judging the ethics of past actions reviewed in this memorandum applies to such cases, nor do any of them place limits on remedies that may be judged as due to individuals who were harmed but not wronged.

Although the philosophical bases of remedies for harms without wrongs differ from those discussed in this memorandum, they are familiar from other contexts. These contexts include the military (benefits for those widowed or orphaned by a service-related death), and certain dangerous industries (compensation for work-related injury).

One important rationale for such remedial action is that these individuals have shouldered especially weighty burdens in activities that benefit the rest of society, and they or their loved ones should not be penalized for this service. Another rationale is forward-looking: society's future needs in these relatively high-risk areas may not be served unless candidates for such jobs believe that their interests are going to be cared for.

In any case, remedies for past wrongs should not be hostage to doubts about the specific grounds for the wrongfulness of an historic incident.

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

June 17, 1994

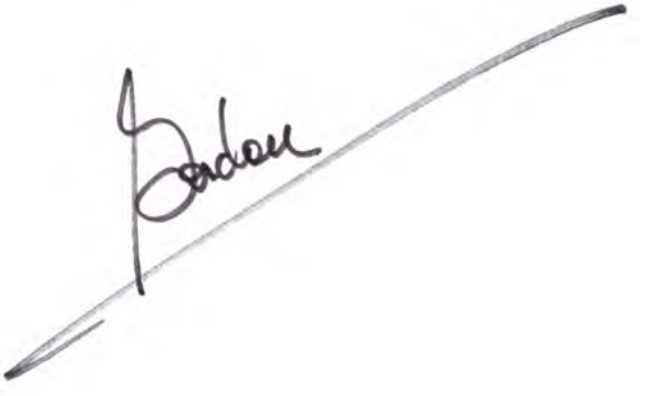
MEMO FOR: Phil Caplan

SUBJECT: Transmittal of Document

Phil:

Attached you will find a copy of the minutes from the 18-19 May Advisory Committee on Human Radiation Experiments meeting. I'm sorry you didn't get a copy sooner. I'll get you a copy of the minutes from the last meeting as soon as they "come of the press."

Isn't this fun?



Department of Defense
Radiation Experiments Command Center
6801 Telegraph Road
Alexandria, Virginia 22310-3398

MAY 2 6 1994

RECC

MEMORANDUM FOR DR. GORDON K. SOPER, PRINCIPAL DEPUTY, ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC ENERGY)

SUBJECT: Advisory Committee on Human Radiation Experiments Meeting, 18-19 May 1994

Attached is a report that summarizes the meetings conducted by the Advisory Committee on Human Radiation Experiments on 18-19 May 1994. For your information and review.

FOR THE DIRECTOR:

CLAUD BAILEY, JR.
Colonel, AG, USA
Deputy Director,
Command Center

Attachments
as stated

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

1.0 GENERAL.

The Advisory Committee on Human Radiation Experiments conducted its second set of meetings on 18-19 May 1994 at the Ramada Plaza Hotel, 10 Thomas Circle, Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 18-19 MAY 1994.

The first day's session included opening remarks by Dr. Ruth Faden, Committee Chair, briefings by three Committee members on their areas of expertise, staff reports on their case studies of three experiments (Cincinnati, plutonium injections, and Green Run), and a public comment period. The second day's sessions included staff briefings on visits to the Departments of Energy and Health and Human Services, a briefing from the White House Counsel's Office on conflicts of interest (not discussed in this paper), and a discussion of Committee operational and organizational matters.

3.0 DR. FADEN'S OPENING REMARKS.

3.1 GENERAL.

After Mr. Phil Caplan of the White House officially opened the meeting Dr. Faden made her opening remarks. She stated that the Committee had a packed and important agenda and then reviewed the agenda. Dr. Faden announced that Committee member Frank Press, Ph.D, resigned from the Committee for personal reasons. A short discussion then ensued about whether Dr. Press could and would be replaced. Dr. Faden was checking with the Administration on this point. The Chair also announced that Committee member Dr. Philip K. Russell, M.D., who is listed as the Committee's military medicine specialist, was absent because of travel conflicts. Dr. Russell has missed both sets of scheduled meetings.

3.2 OBJECTIVES.

Dr. Faden then stated her three main objectives for the meeting.

3.2.1 First Objective. The first objective was for the Committee to begin its self education process by hearing presentations from three Committee members on their areas of expertise. The three Committee members who would make presentations, and their topics, were Dr. Ruth Macklin on the ethical principles of human experimentation; Dr. Henry Royal on the

health effects of radiation; and Dr. Susan Lederer on the history of human experimentation in the United States.

3.2.2 Second Objective. Dr. Faden's next objective was that after the two days of meetings she wanted the Committee to have provided the staff with detailed and specific guidance for their work during the period between this meeting and the next. Dr. Faden also stated that over the next two days the Committee would hear reports on the tasks assigned to the staff at the end of the first meeting. These tasks were to begin identifying and evaluating the ethical policies of Federal agencies; to prepare individual methodological case studies on three experiments (See paragraph 2.0 above); to start evaluating agency research and record search efforts; and, as a result of their agency evaluations, to provide the Committee recommendations on the guidance to be provided the agencies. Two Federal agencies were evaluated--the Departments of Energy and Health and Human Services.

3.2.3 Third Objective. The final objective was to receive comments from the public during the public comment period scheduled for the afternoon of 18 May 1994. Dr. Faden stated that the Committee was notified that four members of the public to speak during the public comment period.

3.3 CONCLUSION.

Dr. Faden concluded remarks by having old and new staff members introduce themselves.(See Tab B for staff information.) She then stated that, as the staff has expanded and evolved, it started to informally organize itself around two "stories" that Dr. Faden believes that the Committee is responsible for relating to the public. The first is the "Cold War Story." The theme of this story is how the Cold War caused the Government to use research, in general, and human subjects specifically, to attain scientific objectives other than those that would advance medicine and be of benefit to mankind. The second story involves "ethics in science." This will address the evolving standards, policies, and practices of human experimentation. For the near future these "stories" and associated themes will guide the staff's data collection effort and, by extension, agency information requirements.

4.0 COMMITTEE MEMBER BRIEFINGS.

4.1 GENERAL.

Three Committee members presented briefings during the morning session. Dr. Ruth Macklin discussed ethics and human experimentation. Dr. Henry Royal described the health effects of radiation. Dr. Royal was followed by Dr. Susan Lederer, who presented a paper on human experimentation in the United States.

4.2 ETHICS AND HUMAN EXPERIMENTATION.

The presentation referenced the Belmont Report which was issued by a national commission in 1979. The report was described as a succinct statement of principles and, as such, it leaves room for interpretation and nonstandard application. Three principles were identified and their philosophical underpinnings were discussed, as well as their practical application. The principles were respect for persons, the obligation to maximize possible benefits and to minimize possible harm, and the validity of the of retrospective application of ethical standards. When discussing the principle of respect for persons an interesting parallel was drawn. The Belmont Report identified the use of prisoners in research as wrong because prisoners are in coercive environment, which limits their freedom to choose whether or not to participate in research. A parallel between the coercive prison environment was drawn with the environment in the military.

4.3 EFFECTS OF RADIATION.

This was a technical presentation which provided the Committee members with an overview of radiation and its health effects. Topics included types of radiation (ionizing and nonionizing), background radiation, units of radiation, doses, and deterministic and stochastic effects. Aside from the technical points, the presenter made two interesting observations. He stated that society's culturally conditioned perception of radiation was essentially negative. Also, that radiation is carcinogenic but it is a relatively weak carcinogen.

4.4 HUMAN EXPERIMENTATION IN THE UNITED STATES.

The focus of this presentation was on the first forty years of the 20th century. This period was selected because it was during these years that the scientists and doctors who conducted experiments in the late 1940's, 1950's, and 1960's were trained. The general historical evolution of human experimentation was first traced, followed by an analysis of the 19th century roots of 20th century practices. The work of two Army doctors, William Beaumont's study of the human digestive system and Walter Reed's yellow fever research, were cited as early examples of studies that incorporated elements of informed consent. Another point presented was that early efforts to protect humans in research grew out of the anti-vivisectionist (animal protection) movement of the late 19th/early 20th centuries. In response, the briefer asserted, influential segments of the American medical community monitored research involving human subjects as a means to protect researchers and research, thus providing some sort of oversight and self regulation. The presenter concluded that in the early part of the 20th century the moral problems involved with human experimentation were acknowledged and that there were generally understood, but uncodified, rules for human experimentation. However, there were no formally adopted and promulgated standards or mechanisms to enforce compliance with these standards.

4.5 DISCUSSION.

After each presentation there was a short question and answer period. The points raised included

4.5.1 Did the concept of distributive justice--as applied to the Cincinnati experiments--preclude a physician or institution that serves a minority population from doing research using such a population or in such an environment? The general answer was that it did not, if the subjects of the research benefitted from the research.

4.5.2 Again, in reference to the Cincinnati experiments, in which one of the criticisms is that it exploited a vulnerable population, was an adequate defense presented by the fact that the experiment's demographics generally matched the hospital's demographics? Ethically, the question of justice involves the issue whether the patients at Cincinnati had access to other health care.

4.5.3 A question was asked of the ethical implications of the concept of added disadvantage(i.e., not only was person poor, but the person was also sick, in an environment [a hospital] in which they had diminished autonomy). There was not a simple answer to this question the briefer stated.

4.5.4 A Committee member asked whether the test(s) to apply to evaluate whether or not an ethical principle was violated were objective, subjective, or a hybrid. The general answer was any test would combine both objective and subjective criteria.

4.5.5 After the radiation presentation, the question was asked how a received dose of radiation was reconstructed. The presenter said that there was no good way to do this and that it was a complex process. Another Committee member noted that this was an important question and that the subject (dose reconstruction) should be incorporated into the Committee's self-education program.

5.0 ADVISORY COMMITTEE STAFF BRIEFINGS.

5.1 GENERAL.

Over the two days of meetings six sessions were devoted to briefings by the Committee's staff who prepared written and oral presentations. The written and verbal reports were generally similar. The general format included a description of what the staff found, followed by an analysis of what was discovered, and concluded with recommendations from the staff for further guidance and/or research. The briefing subjects were(Tabs identified contain the text of the reports presented to the Committee.)

5.1.1 A review of agency documents related to ethical standards.(Tab C)

5.1.2 Methodological case studies of the Cincinnati (Tab D), plutonium injection (Tab E), and Green Run (Tab F) experiments.

5.1.3 Reports on staff visits to the Department of Energy (Tab G) and the Department of Health and Human Services (Tab H).

5.2 Agency Ethical Standards.

The Committee's staff presented its review of documents provided by the Departments of Energy, Health and Human Services, Defense, and Veteran's Affairs. DoD documents were forwarded to the Committee on 9 May 1994 attached to a letter from Dr. Soper to Dr. Faden.(See enclosure to Tab C.) The letter was written in response to a 26 April 1994 letter from Dr. Faden in which she asked for, on the Committee's behalf, "any ethical standards and regulations that may have been relevant to the human experimentation conducted or sponsored by your agency and its predecessors since, at least, 1940." Documents related to ethical standards included in the DoD's packet were the 1953 Memorandum from Secretary of Defense Wilson, information papers from the Army and Air Force on the evolution of their regulations pertaining to informed consent, and a description of the Navy's regulatory history. The focus of the Committee's review was the 1953 Memorandum and the points presented from their written report (subsequently cited in other venues)were

5.2.1 The Memorandum was a classified, verbatim recapitulation of the Nuremberg Code. In the report's text, the word classified was underlined. This, and subsequent discussions over the next day and a half indicate that classified documents (real and presumed) and projects are of extreme interest to the Committee and its staff.

5.2.2 Why was it classified and how could a classified document be of use since its distribution would be controlled and limited?

5.2.3 What led to the Memorandum's development and adoption? Did any specific event or project "trigger" its adoption?

5.2.4 Did the Memorandum apply to only internal DoD projects, or did it also apply to contractors?

5.2.5 Did DoD-sponsored researchers need and have security clearances?

5.2.6 Before concluding the review of DoD policy the staff briefer did note a 1975 DAIG report on LSD experiments which revealed, at least to the staff, that the tenets of the Nuremberg code did exist within the military in an unclassified form.

5.2.7 The DoD portion of the report concluded with a statement that this was all that was provided to the Committee, which left the question of policy origins and implementation unanswered. Not stated was that, in his letter, Dr. Soper had stated that the DoD has been

implementing the January 1994 guidance promulgated by the Interagency Working Group. This guidance did not include policy-related documents. Dr. Soper also stated that the Department would incorporate the Committee's requests into its research protocol. Furthermore, there was no acknowledgement by the Committee's staff of the information provided with Dr. Soper's letter on DoD component regulations related to human use. This was possibly done because the information provided was not primary source material, i.e., not the regulations referenced in the information papers.

5.2.8 The staff report also noted that they discovered 1942 documents that discussed human experimentation. The documents were from the World War II Committee on Medical Research which was later incorporated into the National Institutes of Health. In the staff's view, this document, along with the 1953 Memorandum and a 1947 Atomic Energy Commission (AEC) document referenced in their report, call "into question usual assumptions [unstated] about this topic [agency ethical standards]."

5.3 CASE STUDY, CINCINNATI EXPERIMENTS.

The staff presented a briefing on the results of their review of material related to the research conducted by Dr. Saenger in Cincinnati, Ohio. The Committee report at Tab D provides the details of their analysis. However, during the extensive discussion after the presentation several points arose that are of potential interest to DoD.

5.3.1 A Committee member asked if the documents provided the Committee included any DoD documents that summarized the work and its military application. The staff member responded that the initial application and Defense Atomic Support Agency (DASA) reports were provided. These documents described the work's military application and the reports summarized the research.

5.3.2 In line with the staff's recommendation to research the question of why psychological and psychiatric tests were added to the research protocol a Committee member asked what the nature of the expanded protocol was and what the type of tests conducted were. The staff member answered that this was a question worthy of study because psychological/psychiatric testing was not mentioned in Dr. Saenger's 1958 application, but some time between 1963 and 1964 they were added. What was not clear from the available documents was why the tests were added and who suggested the expansion--the DoD or Dr. Saenger? He also said that the size of the expansion deserved study. While this discussion was going on, another Committee member asked when the LSD and other behavior control experiments were being conducted with the implication possibly being that there may be a possible connection between the addition of psychological and psychiatric tests and a larger Government sponsored program.

5.3.3 A question was asked if a patient list was available. It was noted that each report contained patient case histories, but the staff researcher was not aware of any patient list.

5.3.4 The issue was raised of what can be learned from this specific case that would have a general application to the Committee's work. The reply highlighted the fact that this case study revealed the strength of reviewing documents, but the document search technique does not tell the full story. The Committee or staff had not conducted any interviews nor gone to any of the sites. Also the staff did not have a sense if anything associated with this research was classified. Another benefit this case study identified that may have general applicability was that a possible thread or theme for the Committee to follow was the military's interest in this type of research.

5.3.5 The staff researcher made the point that the military-funded research was "piggybacked" on Saenger's other radiation research and that the military aspect of the experiment needed to be evaluated separately from the other research. Another aspect of this issue, and similar to the theme identified above, is the question of the military's motivation and need to fund these and similar experiments.

5.3.6 A general discussion was conducted of the research's mortality rates and research design. It became apparent from the discussion that research design and medical practices of the 1960's needed to be studied by the Committee.

5.3.7 The Committee accepted all of the staff's recommendations for additional documentation that are listed on the last two pages of their report at Tab D.

5.4 CASE STUDY, PLUTONIUM INJECTIONS.

A detailed description of the staff's report on the plutonium experiments is at Tab E. Salient points from the briefing and ensuing discussion include

5.4.1 The 18 plutonium injection experiments appear to be part of a larger program to ascertain the effects of radioactive substances on humans. The staff researcher stated that there appeared to be plans for expansion of the program after December 1946 but it was not clear if that expansion was ever implemented.

5.4.2 In the spring of 1947 the Atomic Energy Commission (AEC) and its university contractors discussed informed consent. It appeared to the staff that the contractors demanded a great deal of autonomy in the areas of informed consent. The primary contractors for this early era in the AEC's history were the Universities of Chicago and Rochester.

5.4.3 To build a better data base the Committee's staff wants the documentation that was referenced in a 1974 DOE Inspector General's report on the plutonium experiments. They also want access to documents in the possession of the University of Chicago and the University of Rochester. The Committee decided to pursue these documents as a test of how much cooperation it will get from Government contractors. Later in its discussions the Committee decided to ask DOE to write letters to these institutions seeking their cooperation.

5.4.4 On pages 4 and 5 of the staff report they note a possible connection, through one of the researchers (Dr. J. J. Mickson, M.D.), between the plutonium injections and Dr. Saenger's research.

5.4.5 The Committee approved all of the staff's recommendations.

5.5 CASE STUDY, GREEN RUN EXPERIMENTS.

The Committee staff's report of the Green Run experiments is at Tab E. Several issues emerged from the discussion of the Green Run. From the staff's perspective a major part of the Green Run story is why did the experiment take place and how was it planned? In the staff's view, to answer these questions, fully or in part, they will require access to classified information. Access to classified information became a major discussion topic. (Although it had been a subtheme of previous discussions.)

5.5.1 As the Committee discussed access to classified information, an interesting part of the discussions related to the issue of whether the Committee had subpoena power so that the Committee could call people to testify and put the witnesses under oath. This issue was raised in the context of getting, or not getting, classified information with the implication appearing to be that if classified information was not provided then the Committee had a tool to find out why it was not provided.

5.5.2 The Committee does not have subpoena power, but will go back to the White House and ask for it if desired. A Committee member noted that if the Committee was provided this power a new Executive Order would have to drafted.

5.5.3 A complementary point raised was that the Advisory Committee is working with Government agencies and assumes that when it asks for cooperation it will get that cooperation. Dr. Faden pointed out that if the Committee does not get the cooperation it expects, then the Committee will have to address that issue when it occurs.

5.5.4 It appears, however, that in line with recommendations from the staff, the Committee is going to ask for some documents to be declassified as a possible test of agency cooperation. One of the possible classified documents the staff identified as wanting declassified was either an Air Force operational history identified at the bottom of page 2 of their report or one concerning the Air Force organization responsible for aerial monitoring. The Committee approved the staff's recommendations contained in its report.

5.6 STAFF VISITS, DEPARTMENT OF ENERGY AND DEPARTMETN OF HEALTH AND HUMAN SERVICES.

The Committee staff reports on visits to these agencies are Tabs F and G, respectively. The reports on visits to agencies generated much discussion between the Committee members and staff on a variety of issues. Some of the issues discussed included

5.6.1 The search efforts up until now have employed a "dragnet" approach to discovering information and documents. The Committee staff is trying another tack which is more like "connecting the dots." For example, one piece of information is discovered, like the 1953 Wilson Memorandum, and that piece leads into other areas and other document requirements. The Committee and its staff can assist the agencies in their document collection efforts by directing agency efforts along lines identified by their (the staff's) research.

5.6.2 The mechanisms and methods to conduct quality assurance checks of the document search effort. It appears that a primary method will be to develop a strategy (or strategies) to frame questions, requests, and issues in specific ways and then make the agencies responsible for being responsive to these questions, requests, and issues.

5.6.3 Declassification of documents and the need for personal security clearances were extensively discussed by the Committee. As mentioned previously, the Committee will ask for access to classified documents and expects agencies to comply with their requests for either access to and/or declassification of classified information. Dr. Faden will send a memorandum to each agency asking that the agency expedite the declassification of specific classified documents that the Committee identifies as being useful to its deliberations.

5.6.4 A complementary issue was the need for Committee members and staff to have security clearances to have access to, and to be able to discuss, classified information. There was much discussion on this point and it revolved around two issues. The first was that some Committee members did not want a clearance because they fear that it would constrain them and their activities. The second was the effect that having access would have on the Committee's proceedings and its report. No resolution on either point was reached.

5.6.5 In the course of the discussion it was revealed that if and when Committee personnel submit their paperwork for a clearance, DOE is going to give them Top Secret access. The DOE representative, and others, noted that there were reciprocity problems with other Federal agencies. The DOE security office was trying or will try to address this issue with other agencies.

6.0 PUBLIC COMMENT PERIOD.

During the hour set aside for public comment on the afternoon of 18 May 1994 representatives from four public groups with interest in radiation issues appeared before the Committee. Groups represented were The National Committee for Radiation Victims, The Radiation Effects Public Interest Law Group, The National Association of Radiation Survivors, and The Physicians for Social Responsibility. Issues that these representatives presented to the Committee included

6.0.1 The Marshall Islanders and Navajo uranium miners should be included in the Committee's charter. Several Committee members supported their inclusion and this issue

will be examined on the Committee subcommittee tasked to evaluate the scope of its charter (See paragraph 7.0 below).

6.0.2 There was concern expressed that there was a conflict of interest in agency record searches because the people who were doing the searches may also have an interest in suppressing the information. To preclude this possibility three suggestions were offered. The first was to get independent verification (quality assurance checks) of agency search efforts. Second was to issue guidelines that made it clear that tampering with documents was unlawful. Third was for the Committee to consider issuing its own directive on document searches.

6.0.3 A suggestion was made to add a radiation survivor to the Committee.

6.0.4 The Committee had to consider the issues of compensation, medical care, and accountability.

6.0.5 A morbidity study should be funded.

6.0.6 The Committee was urged to work through groups such as these to receive input from radiation victims and survivors. The representative of The Physicians for Social Responsibility stated that one of the Committee's fundamental responsibilities was to reach out to the public. Not only was this a fundamental responsibility but it was fundamental to the Committee's credibility.

6.0.7 As part of its outreach responsibilities, the Committee should compile a list of interested nongovernment groups and notify them of the meetings; provide more timely notification of its meetings to the public; and hold meetings at various places around the country.

6.0.8 The Committee was asked how it was going to make the documents that it procures available to the public.

7.0 DISCUSSION, COMMITTEE AND STAFF WORKING RELATIONSHIPS.

The meeting's final session was a two hour discussion of Committee organizational and operational matters. The focus of the discussion was on the formation of subcommittees to better focus the Committee's work. The Committee formed four subcommittees to examine public outreach, the scope of the Committee's charter, the Cold War story, and the ethics story.

8.0 OBSERVATIONS.

Observations from the two day meeting include

8.0.1 As a way to focus its efforts the Committee believes that it has two stories to tell the public. One is identified as "the Cold War story." The second is the story of ethics in science. The information requirements to tell these "stories" will guide the Committee and its staff research effort for the near future as they are still in the data collection phase of their work.

8.0.2 The historical aspect appears to be increasingly important to their work. Historical research that may be of interest to the DoD may include the evolution of research and development policies, the development of policies that address DoD support of research at universities, Cold War military requirements, organizational relationships within the Department (in the late 1950's and 1960's the Army was tasked to provide DASA with administrative and procurement support), and the evolution of policies and regulations related to human use.

8.0.3 The Committee endorsed most, if not all, of the staff recommendations that were developed as a result of their meetings with DOE and HHS, and their analysis of the case studies (Cincinnati, plutonium injection, and Green Run experiments, and the review of agency ethical policies). Along with the subcommittees, these recommendations focus the staff's efforts and provide a guide for the agencies on what type of specific information the staff will be requesting from the agencies.

8.0.4 A developing area of interest for the staff is interagency coordination and support of research/experiments. They appear to be interested in policies, processes, and mechanisms. DoD and HEW support of Saenger's research was used several times as an example of research that was funded by several agencies.

8.0.5 The Committee attained the three objectives outlined by Dr. Faden in her opening remarks on the first day. Of immediate interest to the DoD is the Committee's endorsement of the staff recommendations that will guide their effort and be reported on at the next meeting. Also, to ensure that the Committee and staff gain a better understanding of the historical evolution of DoD ethical and human use policies it is incumbent on the Department to provide the Committee with the information requested in Dr. Faden's 26 April 1994 letter and DoD RECC's 9 May 1994 Memorandum, Subject: White House Advisory Committee on Human Radiation Experiments Request for Information.

8.0.6 Another subject that will be reported on at the next meeting will be the Committee's staff perception of its meeting with the DoD officials on 20 May 1994. The staff will render an oral and written report on the meeting. Department officials may want to attend. The next meeting is scheduled for 13-14 June 1994.

Thomas A. Popa
DoD RECC

Clinton Presidential Records
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A

Divider Title: _____

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

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

FINAL AGENDA

Wednesday, May 18

9:00 AM	Call to Order *Philip Caplan, Special Assistant to the President for Cabinet Affairs*
9:05	Welcome and Orientation to Second Meeting *Ruth Faden, Chair*
9:10	Staff Introductions *Ruth Faden*
9:15	Briefing: Health Effects of Radiation **(Tab D)** *Henry Royal*
(9:50)	Committee Question and Answer Period *Moderator: Ruth Faden*
10:10	Briefing: Ethical Principles of Human Experimentation **(Tab E)** *Ruth Macklin*
(10:35)	Committee Question and Answer Period *Moderator: Ruth Faden*
10:50	Break
11:05	Briefing: History of Human Experimentation in the United States **(Tab F)** *Susan Lederer*
(11:35)	Committee Question and Answer Period *Moderator: Ruth Faden*
11:50	Review of Agency Ethical Standards: Progress Report **(Tab I)** *Staff Presentation: Jeffrey Kahn, Jeremy Sugarman*
(11:55)	Committee Discussion *Moderator: Ruth Faden*
12:30PM	Lunch

1:45 Methodological Case Study: "Cincinnati Experiments" **(Tab L)**
Staff Presentation: Ron Neumann, Jonathan Engel

(1:50) Committee Discussion
Moderator: Ruth Faden

2:25 Methodological Case Study: "Plutonium Injection Experiments" **(Tab M)**
Staff Presentation: Gregg Herken, Ron Neumann

(2:30) Committee Discussion
Moderator: Ruth Faden

3:00 Break

3:15 Public Comment Period **(Tab K)**
Moderator: Ruth Faden

4:15 Methodological Case Study: "Green Run" **(Tab N)**
Staff Presentation: Gil Whittemore, Gregg Herken

Committee Discussion
Moderator: Ruth Faden

5:00 Meeting Adjourned

Thursday, May 19

9:00 AM Opening Remarks
Ruth Faden

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

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

9:35 Methodological Review of Agency Data Collection Efforts: Department of Energy **(Tab G)**
Staff Presentation: Dan Guttman, Faith Bulger, Jim David, Gregg Herken, Ron Neumann

Committee Discussion
Moderator: Dan Guttman

10:40 Break

10:55	Methodological Review of Agency Data Collection Efforts: Department of Health and Human Services **(Tab H)** *Staff Presentation: Dan Guttman, Faith Bulger, Jim David, Gil Whittemore*
	Committee Discussion *Moderator: Dan Guttman*
12:00 PM	Lunch
1:00	Committee Discussion--Committee/Staff Working Relationships: Subcommittee on Public Outreach **(Tab J)** and Formation of Other Subcommittees *Moderator: Ruth Faden*
2:55	Closing Remarks *Ruth Faden*
3:00	Meeting Adjournment

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B

Divider Title: _____

Advisory Committee on Human Radiation Experiments
1726 M Street, N.W.
Suite 600
Washington, DC 20036

May 17, 1994

Biographical Sketches

(including full-time and part-time staff)

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 KEPPER
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. XII* (1988). pp. 431-462. Dr. Whittemore also devotes some time to teaching middle-school science at the Boston Archdiocesan Choir School in Cambridge.

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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.

[redacted]

W. Warren

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.

[redacted]

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, overreaching, 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

COPY

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.

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 informin 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

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J.C.S. 1865/39

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.

DoD (1-1-48) 5.11

Sept 11/14 Ltr 75

[redacted] COMMISSION
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

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.

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

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Joint Chiefs of Staff
Research and Development Board

7 October 1975

COPY NO. ______

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

COPY

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.

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

COPY

(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.

Enclosure--Documents/Information Provided to the Advisory Committee on Human Radiation Experiments

1. Ethical Standards and Regulations

Memorandum for the Secretaries of the Military Departments from the Secretary of Defense, dated 26 February 1953, Subject: Use of Human Volunteers in Experimental Research. The Memorandum established DoD policy for the use of DoD volunteer personnel in experimental research in the fields of atomic, biological, and/or chemical warfare.

Department of the Army Memorandum, dated 7 January 1994, Subject: Historical Perspective on Informed Consent, with attached information paper. The information paper traces the evolution of the Army's policy on informed consent and human use review. A chronology is also included.

Department of the Air Force Memorandum, dated 10 January 1994, Subject: History and Current Practice of Informed Consent in Clinical Practice and Clinical Research - INFORMATION MEMORANDUM. The memorandum is a chronology that traces the evolution of consent standards for human subjects from the 1940's to the present. It also incorporates the development of Air Force regulations relative to the subject.

The Department of the Navy also researched its regulatory history for instructions governing human use. In a report on its review of human radiation experiments dated 28 February 1994 the Navy stated, "The Navy Manual of the Medical Department in 1951 provided formal guidance for conducting experiments using human use test subjects. Further guidance was issued in DoD and BUMED [Bureau of Medicine] instructions in 1964, 1982, 1983, 1984, 1988 and 1989."

2. Plutonium Injection, Green Run and Cincinnati Experiments.

The available information was provided to the Committee staff on 29 April 1994. Our office has no information on plutonium injections (these experiments fall under the purview of the Department of Energy). Also, the material received from the University of Cincinnati contained duplicate copies of the same documents. To ensure the integrity of our search and that the Advisory Committee received a complete set, the documents were reproduced as is, with no attempt to remove duplicates.

Additional information on the Green Run experiments received after 29 April 1994.

3. Document Search

Secretary of Defense Memorandum, dated 7 January 1994, Subject: DoD Human Radiation Research Review. The memorandum published general record retention and search guidance.

Department of Defense Memorandum, dated January 31, 1994, Subject: Locating Records of DoD Human Radiation Experiments. This memorandum provides the Department's components and agencies detailed guidance by which to conduct their document search. It also established reporting suspenses and formats in which the reports were to be rendered.

Briefing vu-graphs, *Department of Defense Human Radiation Experiments Review*. The vu-graphs are copies of those that were used to brief the Committee on 22 April 1994 and contain information on the scope of the research effort and resources employed.

Additional information on search techniques and resources are in the Phase I and Phase II reports contained in the boxes provided to the Committee staff on 29 April 1994.

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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;

* 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

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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 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.

I. 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,

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."

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.

* 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

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.

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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

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[1] 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.

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[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

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

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[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

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[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

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[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 filed 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

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[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.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

H

Divider Title: _____

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, 1994[1] 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).

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[1]Advisory Committee staff - designate (Dan Guttman, Faith Bulger, Jim David, Ron Neumann, and Gil Whittemore) 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

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[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.

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

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

[6]However, 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

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[7]In 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.

[8]NIH 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 minutes[9] 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?

[9]The 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

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[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

[13]The 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 feet 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 histocompatiblity 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."

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[14]The 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. *NEIM* 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 AI\AN 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; Athapascan 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 in 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 isotopes 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 cas 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 assi 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

Preliminary Report on HHS - May 12, 1994

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.

Attachment B

(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-93

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

(COPY)

UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

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.

"3. 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:"

3. 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 angiocardiography, 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

FEDERAL SECURITY AGENCY
PUBLIC HEALTH SERVICE

APPLICATION FOR GRANT-IN-AID
Rec. 6/2/50

C 396(C3)

No S.S.

Date May 1, 1950

(Extension Application for Grant C-396(C2))

Application is hereby made for a grant-in-aid in the amount of $ 117,207.43 (RA) for the period from January 1 1951 to December 31 1951 inclusive,

TITLE OF PROJECT

Physiology of patients with cancer and experimental therapy of cancer

TITLE OF PRINCIPAL INVESTIGATOR	NAME OF PRINCIPAL INVESTIGATOR
Dean of the Medical School and Professor of Pediatrics	Dr. Francis Scott Smyth

ADDRESS OF PRINCIPAL INVESTIGATOR
University of California School of Medicine
Medical Center, San Francisco 22, California

TITLE OF FINANCIAL OFFICER TO WHOM CHECK SHOULD BE MAILED	NAME OF FINANCIAL OFFICER
Vice-President - Business Affairs	Mr. James H. Corley

ADDRESS OF FINANCIAL OFFICER
250 Administration Building, University of California,
Berkeley 4, California

Name of institution University of California School of Medicine

(Name and title of official authorized to sign for institution) Robert G. Sproul
President of the University

Form No. 68 - 12953

COPIED: 4/19/94
RECORD GROUP: #330
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FILE: (in box #55)

NUMBER (Do not change or use another number) C 396(C3) No S.S.

(a) Budget proposed for the year 1/1/52 through 12/31/52 (This date to be the same as those given on page 1)

ITEM	FUNDS REQUESTED FROM THE PUBLIC HEALTH SERVICE	FUNDS FROM OTHER SOURCES
PERSONNEL (Itemize all positions, give names of persons employed, if available)		
See attached breakdown	$ 68,223.90	$ 8,940.00
PERMANENT EQUIPMENT NEEDED		
None	—	—
CONSUMABLE SUPPLIES NEEDED		
See attached breakdown	17,554.00	7,060.00
TRAVEL		
—	—	—
EXPENSE (Itemize)		
Contractual, for bed spaces: Reimburse Laguna Honda Home 15 patients @ $4.10 per day, 365 days	22,347.50	—
SUBTOTAL	108,525.40	(RQ) x x x x x x x x
OVERHEAD (Not to exceed 8% of subtotal)	8,682.03	(RQ) x x x x x x
TOTAL FOR THE YEAR	$ 117,207.43	(RQ) $ 16,000.00

(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

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APPLICATION FOR GRANT-IN-AID C-396(02)

NUMBER (Do not write in this space) C 396(C3)

No S.S.

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

PERSONNEL (1(a) cont.)

		Per Mo.	Per Annum	Total
Ward Nurses:				
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 personnal rolls. The per annum figure represents the entrance salary for a beginning employee. No professional (M.D. or Ph.D.) personnal are employed on these funds.

Allowance for yearly honor merit increase for personnal:

Nurses	1,800.00
Dietitian	120.00
Ward Helpers	720.00
Orderlies	840.00
Kitchen Helpers	720.00
Secretary	360.00
Janitor	240.00
	(4,800.00)

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

General Assistance:

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

Allowance for accumulated vacation leave for personnal 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..... $68,223.90

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APPLICATION FOR GRANT-IN-AID

C-396(C2)

C 396(C3)

No S.S.

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

NSUMABLE SUPPLIES NEEDED (1(a) cont.)

	Total
Supplemental food for dietary:	
15 patients @ $0.65 per day, 365 days	3,599.00
Drugs, including fluids, antibiotics, heparin	5,219.00
Surgical Dressings	1,272.00
Kitchen Equipment, expendable	230.00
Glassware, syringes, surgical supplies, catheters	1,526.00
Surgical Instruments, cutlery, replacement items for permanent equipment on hand	241.00
X-ray film, photographic supplies	552.00
Linen replacements	774.00
Household supplies (soap, paper towels, lysol, etc.)	627.00
Minor repairs and maintenance of equipment	248.00
Total.....	$13,894.00

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 2a

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APPLICATION FOR GRANT-IN-AID

C-396(C2)

C 396(C3)

No S.S.

BUDGET SUMMARY COMPARISON SINCE ESTABLISHMENT OF RESEARCH WARD

	C-396(1) 1948 1/	C-396(CHECK) 1949	C-396(C2) 1950	C-396(C3) 1951
Personnel.....	55,150.56	54,111.00	60,732.00	68,223.90
Permanent Equipment.....	14,196.00	2,577.50	—	—
Consumable Supplies.....	5,500.00	14,495.00	12,743.00	17,854.00
Contractural-Bed space..	15,246.50	15,490.65	20,422.00	22,447.50
Other Expenses.....	400.00	—	—	—
Overhead.....	5,579.44	7,194.73	7,511.76	8,682.03
Total.....	$79,372.50	$97,128.88	$101,406.76	$117,207.43 2/

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

2/ As seen from the budget, the increase of $15,798.67 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 sort of reimbursement for beds to Laguna Honda 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 2a

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C-396(03) No S.S.

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 (From ___ To ___)
VIOUS			
boratory	Univ. of California School of Medicine	$ 5,000.00	1/47 - 6/30/47
search Ward	Univ. of California State Funds	38,000.00	11/47 - 6/30/48
boratory	Univ. of California School of Medicine	3,000.00	7/1/47 - 6/30/48
search Ward - Isotope Unit	Univ. of California State Funds	7,000.00	11/47 - 6/30/48
search Ward - Pathology Unit	Univ. of California State Funds	20,000.00	11/47 - 6/30/48
search Ward	Univ. of California State Funds	12,500.00	7/1/48 - 6/30/49
boratory	Ditto	4,500.00	7/1/48 - 6/30/49
search Ward - Isotope Unit	Ditto	9,500.00	7/1/48 - 6/30/49
search Ward - Pathology Unit	Ditto	7,200.00	7/1/48 - 6/30/49
RRENT			
search Ward and Laboratory	Univ of California State Funds	15,000.00	7/1/49 - 6/30/50
search Ward - Isotope Unit	Ditto	7,400.00	7/1/49 - 6/30/50
search Ward - Pathology Unit	Ditto	11,000.00	7/1/49 - 6/30/50
search Ward	Damon Runyon Fellowship	500.00	7/1/49 - 6/30/50
DING			
search Ward and Laboratory	Univ. of California State Funds	15,000.00	7/1/50 - 6/30/51
search Ward - Isotope Unit	Ditto	5,000.00	7/1/50 - 6/30/51
search Ward - Pathology Unit	Ditto	11,000.00	7/1/50 - 6/30/51

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0-396(C3) No S.S.

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

GRANT NUMBER	TITLE OF PROJECT	AMOUNT	YEARS OF SUPPORT From – To
...OUS			
...l. Cancer Inst.	Direct Allocation - Laboratory	51,900.00	1/1/47 – 6/30/47
...l. Cancer Inst.	Direct Allocation - Laboratory	94,514.58	7/1/47 – 6/30/48
...396(2)	Research Ward	79,372.50	3/1/48 – 12/31/48
...l. Cancer Inst.	Direct Allocation - Laboratory	117,525.00	7/1/48 – 6/30/49
...396(C)	Research Ward	85,084.20	1/1/49 – 12/31/49
...396(C2)	Research Ward	12,084.66	1/1/49 – 12/31/49
...RENT			
...l. Cancer Inst.	Direct Allocation - Laboratory	114,000.00	7/1/49 – 6/30/50
...396(C2)	Research Ward	101,408.76	1/1/50 – 12/31/50
...amount shown includes 8% overhead			

...OPOSED 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(s).
- 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.

INSTRUCTIONS: Remove last copy and carbon only, and replace ... between carbon and paper plate before returning to Public Health Service.

APPLICATION FOR GRANT-IN-AID

4. PROPOSED PLAN (Continuation Sheet)

NUMBER: (Do not write in this space)
C 396(C3)
No S.S.

(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 biochemistry 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 Home. 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 2 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 (Aminco), preparatory ultracentrifuge (Spinco), microchemical assembly (Kirk), and a full clinical physiology complement of strain-gage indicators, recording cameters, oscillographs, electroencephalographs, etc.

PHS-396

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PLICATION FOR GRANT-IN-AID
PROPOSED PLAN (Continuation Sheet)

NUMBER: (Do not write in this space)
C 396(C3)
No S.S.

4). Previous Work Done on This (or closely related) Project. The Laboratory of perimental Oncology was initiated in January 1947 and the research ward, which supported by Grant C-396, was opened on July 6, 1948. The attached project eport indicates the lines of investigation being undertaken and the publications dicate 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.

6(a). Results Pending 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 Shimkin and Bierman (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.

6(b). Publications by Others on Related Work. Refer to 6(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.