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

MEMORANDUM

TO: Members of the Advisory Committee on Human Radiation Experiments

FROM: Advisory Committee Staff

DATE: December 13, 1994

RE: Department of Energy / Atomic Energy Commission Ethics Policy History

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[Please note that this is a working draft. As the Advisory Committee receives further relevant information in the coming months it will be factored into the analysis.]

EXECUTIVE SUMMARY

At its 1947 creation, high officials in the Atomic Energy Commission (AEC) considered the need for rules regarding human experimentation. Documentation shows that in November 1947 the AEC's General Manager stated the requirement for "informed consent in writing."

In the search to date, we have found little evidence that the November 1947 statement was put into practice. For example, we have not found evidence of a rule for grant recipients that cites the requirement. Similarly, there is no evidence that the requirement was enacted by the AEC Isotopes Division, which, through its Subcommittee on Human Applications, was involved in the vigorous promotion of research involving radioisotopes. We note, however, that this Subcommittee did mention consent in 1949.

Questions surrounding the origins and lack of implementation of the 1947 policy may be examined in terms of the motivation for rules dealing with human subject research. That is, in order to know why policies may not have been implemented, it is useful to know what may have caused them to be stated in the first place.

Documentation shows that concern for what might be called the ethics of human subject research practices was often driven by "medical legal" concerns. The term "medical legal" was, at the least, plainly used in relation to strong concern about potential legal liability or public embarrassment that might stem from research. Of course, to some extent "medical legal" concerns and policies overlapped with what might be called "ethical concerns" and policies; but the terms do not seem to apply interchangeably. Thus, from the bureaucratic standpoint, the choice of the policy to be followed could depend on whether or not the concern stated was "medical legal" or ethical, and whether or not the "medical legal" solution required, for example,

written consent.

Documentation also shows that the term "medical legal" was not employed in place of the term "ethics." On some occasions the term "ethics" was employed to express "ethical" concerns (which, again, could overlap with "medical legal" concerns). Finally, documentation indicates that even where the term "ethics" was not used, policy and practice may well have also been driven by what might be called "ethical concerns".

Some AEC (now DOE) laboratories have provided documentation indicating that, from the 1950's, they possessed consent policies. When compared with policies stated by other research institutions at the time, these policies may prove to be at the forefront. However, they fall short of the consent policy stated in 1947 by the AEC General Manager, and restated in 1951, to at least one AEC laboratory. Here, too, there is potential disconnect between early and high level policy statement and implementation. Documentation of this story has been slim, however, and staff anticipates developing this section further as more information becomes available.

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The memorandum is organized in the following way:

I. BACKGROUND

A. Committee on Medical Research

During World War II the Department of Defense's Committee on Medical Research (CMR) coordinated wartime biomedical research efforts. Its contracts and organizational framework were later inherited by the National Institutes of Health (NIH). However, CMR's research ethics policies are also relevant to an understanding of the attitudes and policies of the day in the post-War AEC.

In 1942, 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 with the CMR, its director, Dr. A. N. Richards, formulated statements in a document dated October 31, 1942. According to the statements, human subject research involving risk requires that only fully informed volunteers are to be used, with consent forms signed that waive rights to damages. CMR wished to know in detail from its contractors what human experiments were planned, but attempted to place legal responsibility for any claim of damages upon the investigator and his or her institution.

B. Origins of the AEC Medical Program

With the 1946 decision to move control of the atomic energy program, the Manhattan Engineering District (MED), from the military to the new civilian-controlled AEC looming, the military began to analyze the scope of its work on the program. In February 1946, a proposal for the future of the atomic energy medical research program was discussed in a memorandum to Brigadier General K. D. Nichols, the District Engineer. Lt. Col. Hymer Friedell, from the Executive Office of the Medical Section, noted that data obtained from the program was used for establishing tolerance levels and, as Stafford Warren had indicated to him, it was proving useful "from a medical legal point of view."[1] In September 1946 a Medical Advisory Committee to the MED was formed and began an assessment of the status of health protection, medical care, and standards previously and currently existent in the project. This Committee concluded these were "satisfactory," but requested that the Medical Division submit a general survey of "all operating areas and units." This survey may have been intended to aid in the transition from military to civilian control of the medical programs.

After the AEC took over the responsibilities of the MED on January 1, 1947, the functions of the Medical Advisory Committee were assumed by the Interim Medical Advisory

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[1] February 26, 1946. Memorandum from H. L. Friedell to K. D. Nichols on the "Future Medical Research Program."

Committee. Following the recommendation of its Medical Board of Review,[2] in the fall of 1947 the AEC established the Advisory Committee on Biology and Medicine (**ACBM**) and the Division of Biology and Medicine (**DBM**). Shields Warren became the Director of the DBM, which was charged to work with the ACBM to coordinate the AEC's many medical and biological research programs.

II. ETHICS POLICY STATED AT THE BEGINNING OF THE AEC: 1946-1947

A. Concerns About Human Plutonium Injections

Memoranda from 1946-1947 established the terms of early discussion within the AEC about standards for use of human subjects in clinical research. These discussions may have been stimulated by concerns related to the plutonium injections in California that ended early in 1947.[3] Concerns might have stemmed partly from a lack of consent processes in the plutonium injections series, or perceived contractual/bureaucratic limits.

Shortly before the AEC was to assume the responsibilities of the MED, on December 24, 1946, K. D. Nichols sent a memorandum to the Area Engineer at Berkeley, California, regarding the preparations to administer radioisotopes to humans.[4] Nichols wrote:

> After discussion with Col. James P. Cooney, Medical Director, Manhattan Project, it is felt that such work does not come under the scope of the Manhattan District Program . . . You will take immediate action to stop this work under this contract, and report to this office upon compliance.[5]

In a memorandum dated December 30, 1946 from T. S. Chapman, Chief of the Oak Ridge Research Division's Operations Branch, to "the Area Engineer" at Berkeley, Chapman states:

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[2] June 20, 1947. Report of the Medical Board of Review to the Atomic Energy Commission.

[3] November 26, 1946. Progress Report for the Month of November 1946, Contract #W-7405-eng-48-A, by Joseph G. Hamilton, M.D., Director. This report describes the intention to prepare U^{232}, Pu^{238}, and Am^{241} for human injection.

[4] Nichols refers specifically to work done as part of the MED contract W-7405-Eng-48-A.

[5] December 24, 1946. Memorandum from K. D. Nichols, Colonel, Corps of Engineers, MED, to the Area Engineer, California Area, Berkeley.

1. With the concurrence of Lt. Col. Meals this office discussed a proposal in a 48A progress report with Drs. Stone and Miller. It was stated that preparations were being made for injection in humans by Drs. Stone and Miller.

2. These doctors state that the injections would probably be made without the knowledge of the patient and that the physicians assumed full responsibility. Such injections were not divergent from the normal experimental method in the hospital and the patient signed no release. A release was held to be invalid.

Nichols' orders to stop the research were repeated by the AEC. The Acting Manager, AEC Field Operations, Col. E. E. Kirkpatrick, on January 8, 1947 advised the Area Engineer of the California Area that Stone and Miller's proposed plan for human injection was not approved. Referring to a Progress Report for this project, Kirkpatrick advised the Area Engineer that "authorization cannot be given for the use of radioactive materials in human subjects under this contract." However, Kirkpatrick suggested:

> if the physicians at the University of California wish to administer radioactive isotopes [to humans] they may make application to the isotope branch of the Research Division of the AEC for the purchase of such isotopes.[6]

B. March-April, 1947 Policy Discussion

On or about March 7, 1947 there was a meeting of Edwin Huddleson, Jr., AEC Deputy General Counsel, Stafford Warren, chair of the AEC's Interim Medical Advisory Committee, Major B. M. Brundage, Chief of the Medical Division, and AEC lawyer John L. Burling. Burling wrote a memorandum for the record to Huddleson dated March 7 in which he summarized the results of the meeting; the subject of the memorandum was identified as "clinical testing."

> Dr. Warren and Major Brundage stated that under Manhattan Engineer District a program of employing radioisotopes in clinical testing had been commenced but that in January 1947 . . . the distribution of the material for this purpose was [to be] suspended.

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[6] January 8, 1947. Memorandum from E. E. Kirkpatrick, Acting Manager, Field Operations, AEC, to the Area Engineer, California Area, Berkeley.

> . . . the suspension of the distribution of radioisotopes, which was put into effect to await the decision of the Committee [Interim Medical Advisory Committee], is continuing, although the Committee has formally recommended a program of clinical testing[7] . . . .You [Deputy General Counsel Huddleson] consulted with Mr. Wilson [AEC General Manager Carroll L. Wilson] on the telephone and you gave legal approval to the recommendation, and Mr. Wilson accepted it.
>
> The Legal Division expressed the view that in all clinical testing it would be necessary to make sure that the testing was being carried on in relation to a research program properly approved. We [Huddleson and Burling] further expressed the view that it was most important that it be susceptible of proof that any individual patient, prior to treatment, was in an understanding state of mind and that the nature of the treatment and possible risk involved be explained very clearly and that the patient express his willingness to receive the treatment. On Dr. [Stafford] Warren's recommendation, you [Huddleson] authorized omission to obtain a written release but urged that in every case at least two doctors certify in writing to the patient's state of mind to the explanation furnished him and to his acceptance of the treatment.[8]

This memorandum appears first to describe a jurisdictional dispute about control over the distribution of radioisotopes following the human injection episode. The Oak Ridge Isotopes Division suspended the distribution program until the Interim Medical Advisory Committee could review it, but the suspension continued in spite of the [Interim Medical Advisory Committee] Committee's recommendation that it be lifted. At the March 7 meeting a decision was made to keep providing isotopes to approved programs pending acceptance of a plan for a formal clinical research program.

The second topic is the AEC counsel's recommendations concerning patient consent, that the patient be in "an understanding state of mind, and that the nature of the treatment and possible risk involved be explained very clearly and that the patient express his willingness to receive the treatment." There is some suggestion that counsel also recommended a written release form signed by the patient, but that this was dropped due to Stafford Warren's objection:

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[7] February 13, 1947. Memorandum from R.C. Armstrong to E.H. Marsden regarding comments on report referring to the January 23-24 1947 meeting of the Interim Medical Committee, AEC. This memorandum describes the human medical research recommended for funding by the committee.

[8] March 7, 1947. Memorandum from John L. Burling, of the AEC Deputy General Counsel's Office, to Edwin Huddleson, Jr., Deputy General Counsel of the AEC, regarding "Clinical Testing."

"On Dr. Warren's recommendation, you [Huddleson] authorized omission to obtain a written release. . . ." This March 7 memorandum was conveyed to General Manager Wilson by Deputy General Counsel Huddleson in a memo dated March 10, 1947.[9]

C. The April 1947 AEC General Manager Wilson Letter

Further meetings on the subject of clinical research were apparently held April 3 to 5, 1947, meetings at which General Manager Wilson himself seems to have been present. A few weeks later, on April 30, 1947, General Manager Wilson wrote to Stafford Warren in his capacity as Chairman of the AEC's Interim Medical Advisory Committee. At that time Warren was also Dean of the medical school at the University of California, Los Angeles. The letter establishes what appears to be the first AEC policy on the use of human research subjects. Included in the letter are the following passages:

> It is understood that your [Interim Medical Advisory Committee] Committee has recommended a program for obtaining medical data of interest to the [AEC] Commission in the course of treatment of patients, which may involve clinical testing. The Commission wishes to make clear to your Committee its understanding of the program which is being approved. The Commission understands that in the course of the approved program:
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> > a. treatment (which may involve clinical testing) will be administered to a patient only when there is expectation that it may have therapeutic effect;
> >
> > b. the decision as to the advisability of the treatment will be made by the doctor concerned.
>
> The Commission does not intend to influence in any way the exercise of judgment by the doctor as to the administration of any particular treatment authorized under the approved program. Indeed, from the discussion at the meetings of April 3-5, it seemed evident to me that doctors would not allow their judgment on this matter to be influenced by anyone.
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> In any such clinical testing, the Commission continues to request that the same procedure be followed which was agreed upon early

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[9] March 10, 1947. Memorandum from Edwin E. Huddleson, Deputy General Counsel of the AEC, to Carroll L. Wilson., General Manager of the AEC, on the subject of "Clinical Testing."

> in March. That procedure contemplated that it should be susceptible of proof from official records that, prior to treatment, each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment and its possible effects, and expressed his willingness to receive the treatment. In view of your recommendation, the Commission does not request that written releases be obtained in such cases, but it does request that in every case at least two doctors should certify in writing (made part of an official record) to the patient's understanding state of mind, to the explanation furnished him, and to his willingness to accept the treatment.[10]

A number of elements of this letter bear further analysis. First, the AEC at this time established a standard for clinical testing such that experimental interventions with patients must be intended to be for their benefit. Normal, healthy volunteers are not covered under such a policy, though other sources indicate wide acceptance of the principle that at least as strict a standard of voluntariness was recognized at that time for normal volunteers. It is worth noting, however, that by making no reference to permitting research on healthy volunteers or non-therapeutic research on patients, General Manager Wilson may have believed those kinds of research to be prohibited or irrelevant to the work proposed. This may have been a deviation from the policy recommend by the Interim Medical Advisory Committee, which appears to have supported "clinical testing" without qualification.

Second, the AEC did not in this letter create a system for the oversight of implementation of the therapeutic benefit standard it had adopted. Instead, it explicitly turns authority for the determination that the standard has been satisfied over to "the doctor concerned." General Manager Wilson's letter refers clearly to the physicians' opposition to the suggestion that the judgment of anyone but the doctor administering the "treatment" should even influence this sort of determination.

Third, the AEC adds a "request" that "it should be susceptible of proof from official records" that the patient understood the treatment being offered, that he or she was informed of its nature and possible effects, and that he or she expressed "willingness" to receive the treatment. These were the recommendations of the AEC legal counsel. It is interesting that this "request" was not part of the conditions for an approved research program outlined earlier in the letter.

Finally, the request that two doctors give written certification instead of signed patient consent is consistent with the insistence on physician discretion that the AEC encountered among

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[10] April 30, 1947. Letter from Carroll L. Wilson, General Manager of the AEC, to Stafford Warren, at the University of California, Los Angeles.

its medical advisors.

D. The November 1947 AEC General Manager Wilson Letter

AEC General Manager Wilson appears to have altered the content of his own policy not long after he wrote the April letter to Stafford Warren. On January 22, 1951 Leslie Redman of AEC Los Alamos Laboratory "D" Division sent the AEC headquarters an inquiry regarding human experimentation policy.[11] In a March 5, 1951 response, Shields Warren quoted a November 5, 1947 letter from General Manager Wilson to Dr. Robert Stone, of the University of California, which stated that the Interim Medical Advisory Committee had made a statement that "substances known to be, or suspected of being, poisonous or harmful" should not be used in humans:

> unless the following conditions [are] fully met:
>
> (a) that a reasonable hope exists that the administration of such a substance will improve the condition of the patient, (b) that the patient give his complete and informed consent in writing, and (c) that the responsible next of kin give in writing a similarly complete and informed consent, revocable at any time during the course of such treatment.[12]

Thus the policy referred to in the November 1947 letter retained a reference to therapeutic benefit, required written patient consent (rather than the investigators' certification) and also required written consent by next of kin. This constituted a formidable consent standard. Certainly it was far stricter than the policy expressed in the April 30, 1947 letter from General Manager Wilson to Stafford Warren. As discussed below, that exchange did not require written consent. It does not appear that the 1951 letter resulted in implementation of the policy at Los Alamos. Los Alamos documents indicate that the policy adhered to by Los Alamos, to the extent policy was enacted, was that stated in a 1956 Los Alamos-AEC exchange, as will be discussed in Section VI, part B. The conflict between the policy expressed in the General Manager Wilson letter to Stafford Warren and that expressed in the General Manager Wilson letter to Stone a few

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[11] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory. The basis for the Los Alamos inquiry remains a mystery. At Los Alamos, the "H" division was responsible for most biomedical research. The "D" division was involved in legal and declassification matters. The relationship of the "D" and "H" divisions is unclear. Los Alamos has not been able to locate further documentation and reports that Mr. Redman has no recollection of particulars.

[12] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory.

months later remains unexplained.[13]

IV. AEC IMPLEMENTING BUREAUCRACY: AN APPARENT DISCONNECT

Evidence suggests that both the policies described by General Manager Wilson in April 1947 and November 1947, (as described in section II) were more strict than any which were understood or enforced by those working in the field.

From the onset, the AEC had a vigorous program of promoting research with AEC-produced radioisotopes. Thousands of orders were filled in the early years, many of these for human experimentation at AEC facilities, private institutions, and other government research entities. Thus, it is not a question of whether human experiments were being conducted. The question is the relationship of grand statements to practices. Curiously, Shields Warren's 1951 letter to Leslie Redman,[14] which recited General Manager Wilson's November 1947 consent statement, does not simply identify a policy document (e.g., rule or grant manual), but instead "urges" compliance with the "guiding principles" described in that letter –this is an odd direction from the person who directed the program.

The DBM and the ACBM were the central Washington, D.C.-based, biomedical policy entities, and were responsible for grants, but a separate Isotopes Division existed at the Oak Ridge Laboratory, which was responsible for producing and distributing radioisotopes. In mid-1946 the MED created a Committee on Isotope Distribution Policy, with subcommittees on Allocation and Distribution and on Human Applications. The minutes of the initial meeting show the delegation of distribution administration to research institutions, who would form local committees "to pass upon all isotope requests originating from their institutions."[15] The Committee on Isotope Distribution Policy created by the Army became the Advisory Committee on Isotope Distribution under the AEC and remained a part of the Isotopes Division at Oak Ridge.

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[13] In an interview with Joseph Volpe, who served in the AEC Counsel's Office at its onset, staff was told that based on the Office of the General Counsel's recommendation, written consent was required by the AEC at a very early time in its history. Mr. Volpe expressed confidence that this policy should be recited in AEC minutes. Some of these minutes remain classified, and should be reviewed by staff shortly.

[14] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory.

[15] June 28, 1946. Minutes of the Subcommittee on Human Applications, of the Advisory Committee on Isotope Distribution, Isotopes Division, Oak Ridge.

Because of limited documentation, the scope of the isotope regulation remains unclear. For example, did it include institutions with the capability to produce their own isotopes? An October 5, 1949 memorandum from Paul C. Aebersold, Chef of the AEC Isotopes Division to A. H. Holland, Director of Research and Medicine on "Use of Radioisotopes in Human Subjects" records:

> Dr. Warren instructed that such allocation would be made by the Isotopes Division only after review and approval by the Subcommittee on Human Applications of the Committee on Isotope Distribution. *It should be emphasized that the instruction applies even though the radiomaterial is produced in the laboratory where it is to be used.*" (Emphasis added.)

There appears to have been a "disconnect" between the statements on high by General Manager Wilson and the DBM and ACBM officials, and the requirements of AEC officials involved in the Isotopes Division. Whether this disconnect represents fragmentary data, since much Isotope Division materials remain to be located, or reality, remains to be seen. In either case, the question is complex because Isotope Distribution officials worked closely with the DBM, as did the Subcommittee on Human Applications members who themselves, as in the case of Friedell and Hamilton, were engaged in research with human subjects. Staff is continuing to examine the role of the Isotopes Division.

The available data on the Subcommittee on Human Applications (**Subcommittee**) indicates that, on at least one occasion, it took a position on the basis of ethical concerns. For example, the July 19, 1949 minutes of the March, 1949 Subcommittee meeting record that "in general the use of radioisotopes in normal children should be discouraged."[16] This policy comes out of an analysis of safety concerns and is reached from a balancing of risks and benefits. In terms of a risk/benefit calculation, the Subcommittee qualified that research on children would be considered: "for use in important researches, provided the problem cannot be studied properly by other methods and provided the radiation dosage level in any tissue is low enough to be considered harmless."[17] The Subcommittee also made reference to "consent" in the case of unusually high doses for sick patients. The minutes state that in "instances in which the disease from which a patient is suffering permits the administration of larger doses for investigative

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[16] July 19, 1949, Letter from S. Allan Lough, Chief, Radioisotopes Branch, Isotopes Division, Oak Ridge Operations, to Dr. Hymer Friedell, Dr. G. Failla. Dr. G. Hamilton, and Dr. A. H. Holland, and "Revised Tentative Minutes of March 13, 1949 Meeting of the Subcommittee on Human Applications of the Committee on Isotope Distribution of the AEC.

[17] July 19, 1949, Letter from S. Allan Lough, Chief, Radioisotopes Branch, Isotopes Division, Oak Ridge Operations, to Dr. Hymer Friedell, Dr. G. Failla. Dr. G. Hamilton, and Dr. A. H. Holland, and "Revised Tentative Minutes of March 13, 1949 Meeting of the Subcommittee on Human Applications of the Committee on Isotope Distribution of the AEC.

purposes," applications will be considered so long as "[t]he subject has given consent to the procedure."[18]

In addition to the confusion about consent policy, it also appears that the Isotope Division did not implement a broad policy against non-therapeutic experiments, as suggested in the April 1947 General Manager Wilson memorandum. Recall also the memorandum dated January 8, 1947 from Col. Kirkpatrick regarding the proposed plan for human research in San Francisco.[19] Kirkpatrick indicated that the research was not permitted under the AEC research contract but that a proposal could be made by the University of California investigators to the Isotopes Division for purchase of the necessary research material. In a memorandum to Paul Aebersold of the Isotopes Branch of the AEC, Earl Miller, M.D. made a request to administer iodine in:

> fairly large doses of I^{131} to patients in order to determine their uptake, distribution, and excretion of the Iodine. Patients with diseases are used in order that high doses may be administered. The fact that they have disease is incidental and the medical aspects of these patients are cared for outside of the project.[20]

Miller sent a similar request the next year, on April 16, 1948, in which he explained that the iodine would be used

> for the purpose of administering relatively large doses of this material to the thyroid. The fact that these patients have carcinoma of the thyroid makes the administration of such large doses permissible.[21]

The apparent inconsistency between both the policies stated by General Manager Wilson in

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[18] July 19, 1949. Letter from S. Allan Lough, Chief, Radioisotopes Branch, Isotopes Division, Oak Ridge Operations, to Dr. Hymer Friedell, Dr. G. Failla. Dr. G. Hamilton, and Dr. A. H. Holland, and "Revised Tentative Minutes of March 13, 1949 Meeting of the Subcommittee on Human Applications of the Committee on Isotope Distribution of the AEC.

[19] January 8, 1947. Memorandum from E. E. Kirkpatrick, Acting Manager, Field Operations, AEC, to the Area Engineer, California Area, Berkeley.

[20] April 14, 1947. Memorandum from Dr. Earl R. Miller, University of California, to Paul Aebersold, Isotopes Division, AEC.

[21] April 16, 1948. Memorandum from Dr. Earl R. Miller, University of California, to Paul Aebersold, Isotopes Division, AEC.

1947,[22] which indicated that research should be conducted on humans only when there is some likelihood that it may have some benefit, and the distribution of isotopes to Miller implies that the policies developed by the AEC headquarters staff were either not communicated to or not enforced by the Isotopes Division staff. We do note, however, as will be discussed later, that in 1949, the Subcommittee on Human Applications of the Isotopes Division, makes special reference to the need for consent in cases where high doses of radioisotopes are to be administered to very sick people.

Documents show the apparent lack of communication between the DBM/ACBM, and the Isotopes Division. For example, in a letter dated April 8, 1948, a researcher, Everett Evans, M.D., of the Medical College of Virginia, asked John Bowers, M.D., the Assistant to the Director of the DBM, three questions that point directly to the policies discussed by the DBM and the ACBM.[23] Following approval from the Isotopes Division to use P^{32} for "experimental procedures in the human . . .simply for investigational purpose and not for treatment of disease," Evans asked about "medical-legal aspects" and "permission forms".[24] One might have thought that this inquiry would have yielded, among other things, some form of General Manager Wilson's consent policy. However, Bowers simply referred Evans to the Isotopes Division.[25]

Nathan H. Woodruff, the Chief of the Technical Branch of the Isotopes Division responded to Evans' inquiry to Bowers on May 14, 1948, but offered no real advice. Without suggesting that Evans obtain patient consent, Woodruff nevertheless wrote:

> I regret to say, however, that we can be of little assistance. . .the answers to these questions would involve legal opinions on matters concerning the activities of the College and its relationships with other private parties. Under these circumstances we feel that it would not be appropriate for us to furnish legal advice to either party of a private business relationship. . .we understand that most hospitals do require patients to sign general releases before

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[22] April 30, 1947, Letter from AEC General Manger Carroll Wilson to Stafford Warren, and November 1947, as restated by Shields Warren to Leslie Redman in March 1951.

[23] April 8, 1948. Letter from Everett Idris Evans, M.D., Medical College of Virginia, to John Z. Bowers, M.D., Division of Biology and Medicine, AEC.

[24] April 8, 1948. Letter from Everett Idris Evans, M.D., Medical College of Virginia, to John Z. Bowers, M.D., Division of Biology and Medicine, AEC.

[25] April 27, 1948. Letter from John Z. Bowers, M.D., Division of Biology and Medicine, AEC, to Everett Idris Evans, M.D., Medical College of Virginia.

entering into treatment."[26]

In sum, the AEC had several groups with some role in shaping and implementing policy for oversight and regulation of human experimentation but the policies did not seem to mesh. The seeming failure of implementation raises obvious questions about how consent policies came into being, but yet did not come to be applied (i.e., what made things happen)?

IV. DRIVERS FOR ETHICS POLICY: "MEDICAL-LEGAL"

As discussed in Section V, the term "ethics" (or its equivalent) does not predominate in the early documents. The operative term in discussion about policies that might today seem to be "ethics" discussions, is "medical legal."

Recall that in 1946, Stafford Warren supported further biomedical research in part because the research already done under the MED was "proving valuable from a *medical legal* point of view."[27] (Emphasis added.)

The meaning of "medical legal" and its relation to consent is highlighted by documents surrounding the declassification of biomedical research. As discussed above, they indicate that consent policy was driven in large part by legal liability and public relations concerns.

An early report on plutonium injections, entitled "CH-3607--The Distribution and Excretion of Plutonium in Two Human Subjects," indicates that the report was declassified on January 3, 1947, but, reclassified as "Restricted" on March 31, 1947.[28] Prior to declassification, in December 1946, Dr. Hymer Friedell, approved the declassification because, in his opinion, doing so would "not . . . result in the release of information beyond that authorized for disclosure by the current Declassification Guide." The decision to reclassify the document seems based primarily on concerns for public relations and legal liability for medical/insurance claims.

On February 28, 1947, C. L. Marshall, the Deputy Declassification Officer, AEC Technical Information Branch, expressed substantial concerns about the declassification of the document. He wrote:

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[26] May 14, 1948. Letter from Nathan H. Woodruff, Chief, Technical Branch, Isotopes Division, to Everett Idris Evans, M.D., Medical College of Virginia.

[27] February 26, 1946. Memorandum from Hymer L. Friedell, Manhattan District, to Brigadier General K. D. Nichols, District Manager, Manhattan District, on the subject of "Future Medical Research Programs."

[28] July, 29, 1947. List of comments from reviewers regarding "CH-3607 -- The Distribution and Excretion of Plutonium in Two Human Subjects."

> This document appears to be the most dangerous since it describes experiments performed on human subjects, including the actual injection of the metal plutonium into the body . . . . It is unlikely that these tests were made without the consent of the subjects, but no statement is made to that effect . . . . Unless, of course, the legal aspects were covered by the necessary documents the experimenters and the employing agencies, including the U.S., have been laid open to a devastating lawsuit which would, through its attendant publicity, have far reaching results.[29]

The need for consent is evidently tied into the need for documentation for legal purposes.

The decision to reclassify the document was supported by the Medical Division. In a memorandum, dated March 19, 1947, Major Brundage, Chief of the Medical Division, stated:

> The Medical Division also agrees with Public Relations that it would be unwise to release the paper "Distribution and Excretion of Plutonium" [MUC-ERR-209] primarily because of *medical legal* aspects in the use of plutonium in human beings and secondarily because of the objections of Dr. Warren and Colonel Cooney that plutonium is not available for extra Commission experimental work, and thus the paper's distribution is not essential to off Project experimental procedures.[30] (Emphasis added.)

In short, "medical legal" concerns were strongly felt. While they appear to be a driver of consent requirements, however, consent was not necessarily the answer to "medical legal" concerns. The potential divergence of the two appears evident in the previously noted exchange between Woodruff and Evans.

The relationship between medical legal and ethical concerns is also revealed in memoranda surrounding Oak Ridge efforts to expand its research program. On September 26, 1947, J. C. Franklin, Manager, Oak Ridge Operations, sent a memorandum to General Manager Wilson that outlined the policy concerns of the Medical Advisor's Office at Oak Ridge, of which

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[29] July 29, 1947. List of comments from reviewers entitled "CH-3607 -- The Distribution and Excretion of Plutonium in Two Human Subjects."

[30] March 19, 1947. Memorandum from Major B. M. Brundage, Chief, Medical Division, to Declassification Section, on the subject of "Clearance of Technical Documents." Warren and Cooney's comment about "off Project" work seems to refer to work that is done outside the AEC's purview.

Albert H. Holland, Jr., M.D. was the Acting Medical Director.[31] This memorandum stated basic concerns about the organizational structure and related legal obligations:

> (2) What responsibilities does the AEC bear for human administration of isotopes (a) by private physicians and medical institutions outside the Project, and (b) by physicians within the Project? This latter category includes contractors personnel employing AEC funds (indirectly) to perform tracer research, some of which is of no immediate therapeutic value to the patient. What are the criteria for future human use?[32]

Franklin requested that his questions be forwarded to the ACBM, and accordingly, a memorandum was drafted, dated October 8, 1947.[33] This memorandum repeats almost verbatim the concerns raised by Franklin and adds sections of background and proposed solutions in a way that is supportive of physicians' independence but careful to avoid giving medical researchers complete freedom. The author of this memorandum is not identified. It's style suggests that it was drafted by an attorney or someone in General Manager Wilson's office. For two reasons, that the unique role a federal agency is invoked and that the language employed is unlikely to be used by a physician, this memorandum appears to have been written by someone less interested than Holland. The questions the memorandum raises, however, are in many parts verbatim from Franklin's September 26, 1947 memorandum and Holland is in it referred to as "available for subsequent meetings of your Board." We note, however, that the minutes of the October 11, 1947 ACBM meeting indicate that the memorandum was "from Dr. Albert Holland."[34]

The October 8, 1947 memorandum vividly portrays the basis for some concerns about organizational structure and legal responsibility. On the question about the responsibility for the human use of isotopes, the memorandum suggests that the AEC is not "responsible" for isotopes distributed to privately-funded researchers and leaves open the question of whether it is responsible for AEC-funded research. With respect to privately-funded research, the memorandum states:

> Careful consideration of this problem seems to indicate that once a

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[31] September 26, 1947. Memorandum from J.C. Franklin, Manager, Oak Ridge Operations, to Carroll L. Wilson, General Manger AEC, regarding "Medical Policy."

[32] September 26, 1947. Memorandum from J.C. Franklin, Manager, Oak Ridge Operations, to Carroll L. Wilson, General Manger AEC, regarding "Medical Policy."

[33] October 8, 1947. Memorandum addressed to the ACBM, based on a memorandum from Oak Ridge.

[34] October 11, 1947. Draft Minutes of the AEC Advisory Committee on Biology and Medicine.

> recipient has been deemed "qualified" by the Isotope Branch and their advisory committees to receive and use radioisotopes, the Commission bears little if any responsibility for human administration. Past medico-legal experience provides numerous instances of claims and suits against medical institutions for the use of experimental drugs. In practically every case the physician involved has taken sole responsibility and therefore may or may not be guilty of malpractice, but the institution is exonerated. This analogy might well apply to our present problem.

This response indicates that the author of the section considers "medico-legal" concerns and insurance claims to be the primary factors to consider in assessing responsibility for this research.

On the second question, about AEC funded human research, the memorandum enumerates several considerations. The memorandum states:

> If the expressed opinion of the Medical Board of Review, which convened last June, is accepted in establishing criteria for human administration, then obviously a great deal of our present human tracer studies must be discontinued. The pertinent facts of the case, pro and con, seem to be these:
>
> Pro-
>
> (1) Tracer research is fundamental to toxicity studies.
> (2) The adequacy of the health protection which we afford our present employees may in a large measure depend upon information obtained using tracer techniques.
> (3) New and improved medical applications can only be developed through careful experimentation and clinical trial.
> (4) Tracer techniques are inherent in the radioisotope distribution program.
>
> Con -
> (1) Moral, ethical and medico-legal objections to the administration of radioactive material without the patient's knowledge or consent.
> (2) There is perhaps a greater responsibility if a federal agency condones human guinea pig

experimentation.
(3) Publication of such researches in some instances will compromise the best interests of the Atomic Energy Commission.
(4) Publication of experiments done by Atomic Energy Commission contractor's personnel may frequently be the source of litigation and be prejudicial to the proper functioning of the Atomic Energy Commission Insurance Branch.

This list demonstrates that legal and public relations concerns were primary factors in discussions to limit human studies research.

In sum, in the context of public relations and liability concerns, the institutional logic behind the experimental regulatory bureaucracy begins to make sense. A policy requiring that "legal safeguards" be met and consent obtained, which seems, in fact, to be at odds with the practices of the research community, could be maintained so long as an alternative mechanism for promoting research existed.

V. "ETHICS" AS AN ALTERNATIVE OR COMPLEMENTARY DRIVER

A. The Use of the Term "Ethics"

Notwithstanding the "medical legal" concerns, documents indicate concerns, that while perhaps subsumed under the medical legal context, also may stand as the impetus for what may be understood as a concern over ethical issues. An early reference to ethics appears in a 1945 MED memorandum, dated July 26, 1945[35], on the subject of "Determination of Policy on Cases of Exposure to Occupational Disease." The memorandum raises "ethical considerations" in light of civilian physicians' obligations to disclose to MED workers that they have developed nephritis or tuberculosis. The memorandum states:

e. Ethical Considerations

Are they [the medical officers] in accordance with their canons of ethics to be permitted to advise the patient of his true condition, its cause, effect and probable prognosis? If not on ethical grounds, are they to be permitted to fulfill their moral obligation to the individual employee in so advising him? If not on moral grounds,

[35] July 26, 1945. Letter from Philip J. Close, 2nd Lt., JAGD, to Major C. A. Yaney, on the "Determination of Policy on Cases of Exposure to Occupational Disease."

> are those civilian medical doctors employed here bound to make full disclosure to the patients under penalty of liability for malpractice or proceeding for revocation of their license for their failure to do so?[36]

Similarly, in the just-discussed October 8, 1947 memorandum to the ACBM (Section IV), "ethics" is raised as one reason not to conduct certain kinds of human experiments. Again, with respect to the conduct of human tracer studies, the memorandum lists as the first reason against such research the "[m]oral, ethical, and medico-legal objections to the administration of radioactive materials without the patient's consent."[37] This passage suggests that moral and ethical concerns about using humans in radiation research are distinct from "medico-legal" concerns that otherwise seem to dominate discussion. It is interesting that such a distinction was not drawn in this context in related memoranda by either Franklin[38] or Holland[39] in their discussions of the topic. Franklin explained the existence of human tracer research and Holland pointed to the importance of "moral" responsibilities, but neither directly connected moral responsibility to the practice of clinical testing and patient consent.

In a November 7, 1947 memorandum, which appears to be a follow-up to the memorandum Franklin sent to General Manager Wilson in September, Holland asks first about the AEC's legal responsibility for the application of isotopes to humans and then asks: "How far can *moral* responsibility be presumed to extend in this program?"[40] (Emphasis added.) Additionally, Holland seems to argue that biomedical research is necessary on moral, as distinct from legal, grounds. He argued that those working in the field of atomic energy "have *both a legal and a moral responsibility* . . . to undertake adequate statistical surveys and interpret them in light of our medical and biological research information." It is unclear why Holland limited his point to statistical surveys, given that he justified the work as "mandatory if we are to maintain the efficiency and success of our personnel protection program." That Holland

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[36] July 26, 1945. Letter from Philip J. Close, 2nd Lt., JAGD, to Major C. A. Yaney, on the "Determination of Policy on Cases of Exposure to Occupational Disease."

[37] October 8, 1947. Memorandum addressed to the ACBM, based on a memorandum from Oak Ridge.

[38] September 26, 1947. Memorandum from J. C. Franklin, Manager, Oak Ridge Operations, to Caroll Wilson, General Manager, AEC, on the subject of "Medical Policy."

[39] November 7, 1947, Memorandum from Albert H. Holland, M.D., Acting Medical Advisor, Oak Ridge, to J. C. Franklin, Manager, Oak Ridge, on the subject of "Medical and Operational Policy Decisions."

[40] November 7, 1947. Memorandum from Albert H. Holland, M.D., Acting Medical Advisor, Oak Ridge, to J. C. Franklin, Manager, Oak Ridge, on the subject of "Medical and Operational Policy Decisions."

distinguishes moral and legal responsibility suggests that he held some understanding of a difference between these ideas and a sense that they may have placed different demands on human experimentation standards and policies, at least for those setting policy at the headquarters level.

B. Concern for Specific Types or Aspects of Research

Where the policy makers struggled with the control of human experimentation, there is evidence of specific concerns that, while perhaps "medical legal," may also be viewed as "ethical". The objects of their concerns are not always the same, and not clearly consistent (perhaps, of course, we lack the full picture).

In particular, there were concerns about research involving non-therapeutic purposes, vulnerable populations, and secret research. Initial concerns to protect researcher's scientific freedom, as illustrated by Stafford Warren's early 1947 opposition to a requirement for written patient consent, seem to give way to a more troubling concern about certain types of research.[41]

1. Non-Therapeutic Research

As the concern for the MED human experiments, notably the plutonium injections, illustrates, a key concern was the non-therapeutic experiment. The policy articulated by General Manager Wilson in his memorandum of April 30, 1947 specifically allows for human experimentation to be done "in the course of treatment of patients." To clarify the experimentation being permitted, Wilson goes on to specify that such testing will be conducted "only when there is expectation that it may have therapeutic effect."

Similar evidence of this concern about non-therapeutic research is seen in discussions about document classification and ACBM medical policy. In an April 17, 1947, memorandum concerning secret research entitled "Medical Experiments on Humans," Colonel C. G. Haywood, Jr., of the AEC Corps of Engineers, indicated that research which involves "experiments with humans and might have adverse effects on public opinion or result in legal suits. . . has been prohibited by the General Manager." But went on to say "These instructions do not pertain to documents regarding clinical or therapeutic uses of radioisotopes and similar materials beneficial to human disorders and diseases."[42]

Haywood allows for research done on patients who are already within the clinical setting or who may derive medical benefit from research but indicates that other kinds of research are

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[41] March 7, 1947. Memorandum from John L. Burling, of the AEC Deputy General Counsel's Office, to Edwin Huddleson, Jr., Deputy General Counsel of the AEC, regarding "Clinical Testing."

[42] April 17, 1947. Memorandum from C. G. Haywood, Jr., to Dr. Fidler, Oak Ridge, on the subject of "Medical Experiments on Humans."

unacceptable.

Additionally, early provisions for consent at the Isotopes Division appear to apply only in cases where non-therapeutic and potentially harmful research is conducted. The Subcommittee on Human Applications provision for consent, as discussed in Section III, seems to apply only in cases of research , probably non-therapeutic, where "larger doses for investigative purposes" are justified because the patient is suffering from severe disease.[43]

2. Vulnerable Populations

The Isotopes Division's Subcommittee on Human Applications also showed concerns for experimentation on certain vulnerable populations. It drew distinctions about research on pregnant women and children. For pregnant women, the Subcommittee concluded ". . . the use of radioactive materials in all normal pregnancies should be strongly discouraged where no therapeutic benefit is to be derived."

With respect to "normal" children, as discussed in Section III, the Subcommittee on Human Applications indicated:

> In general, the use of radioisotopes in normal children should be discouraged. However, the Subcommittee will consider proposals for use in important researches, provided the problem cannot be studied properly by other methods and provided the radiation dosage level in any tissue is low enough to be considered harmless.[44]

3. - Secrecy

The sporadic concern for human experimentation policy makes more sense in the context of experiments that were not only non-therapeutic, but also were rooted in secrecy. In light of the 1947-48 AEC internal declassification discussion, high AEC officials had reason to be concerned about the mixture of secrecy and non-therapeutic human experimentation. At the meeting of the ACBM on September 8 and 9, 1950, there was this reaction to the military

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[43] July 19, 1949. Letter from S. Allan Lough, Chief, Radioisotopes Branch, Isotopes Division, Oak Ridge Operations, to Dr. Hymer Friedell, Dr. G. Failla. Dr. G. Hamilton, and Dr. A. H. Holland, and "Revised Tentative Minutes of March 13, 1949 Meeting of the Subcommittee on Human Applications of the Committee on Isotope Distribution of the AEC, pp. 5-6.

[44] July 19, 1949. Letter from S. Allan Lough, Chief, Radioisotopes Branch, Isotopes Division, Oak Ridge Operations, to Dr. Hymer Friedell, Dr. G. Failla. Dr. G. Hamilton, and Dr. A. H. Holland, and "Revised Tentative Minutes of March 13, 1949 Meeting of the Subcommittee on Human Applications of the Committee on Isotope Distribution of the AEC.

proposal for human experimentation in connection with the proposed nuclear airplane.[45]

> A full discussion was held once again on the problem of human experimentation. The Committee [ACBM] felt that human experimentation at the present time is not indicated, that it would have serious repercussions from a public relations standpoint if undertaken by an agency that has to do a portion of its *work in secret*; and that adequate data can be obtained from animal exper[iments], from the Los Alamos accidents, from certain observations which have been made by clinical radiologists, and from the studies at Hiroshima and Nagasaki.
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> The Committee endorsed the action of the Director of the Division of Biology and Medicine in not concurring in a program for human experimentation.[46] (Emphasis added.)

At its next meeting, on November 10, 1950, the ACBM again considered the issue of human experimentation and heard testimony from representatives of the Surgeons General of each service.[47] The ACBM again rejected proposals for human experimentation on a group of service volunteers because, according to Adm. F.C. Greaves of the Navy, "they felt that human experimentation was not justified and that sufficient information could be obtained from animal experimentation and interpolation from clinical data." [48]

Thus, concerns about human experimentation were mixed with worries about public relations and secrecy. The 1947-1948 declassification controversy and 1949-1950 NEPA debate may also explain why Shields Warren linked codes of human experimentation and secrecy in his March 5, 1951 letter to Leslie Redman.[49] Warren cited with apparent approval remarks by the

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[45] For further discussion of this topic, see the DOD Ethics Memorandum, this briefing book.

[46] September 8-9, 1950. Minutes from the Advisory Committee for Biology and Medicine of the Atomic Energy Commission.

[47] November 15, 1950. Resume of the November 10, 1950 meeting with the AEC "Advisory Board of the Division of Biology and Medicine," written by Adm. F.C. Greaves. This memorandum appears to describe part of the ACBM meeting of that date.

[48] November 15, 1950. Resume of the November 10, 1950 meeting with the AEC "Advisory Board of the Division of Biology and Medicine," written by Adm. F.C. Greaves.

[49] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory.

Medical Board of Review from June 20, 1947[50] that were critical of secrecy in research unless required by national security. Warren also quoted an observation made in September 1948 by Alan Gregg, his predecessor as Chairman of the Advisory Committee on Biology and Medicine, that the public's acceptance of the need for secrecy in the AEC creates "special conditions for the clinical aspects of its work."[51] Perhaps this is an oblique reference to an obligation to maintain high scientific and ethical standards under such conditions.

Similarly a letter dated September 25, 1952, from James G. Terrill, Jr., Acting Chief of the Radiological Health Branch of the Division of Engineering Resources of the NIH, to Charles V. Kidd, Chief of the NIH's Research and Planning Branch, shows that Shields Warren may have continued to push for the decoupling of human experimentation from secret agencies. The letter summarizes a September 8-12, 1952 meeting of the Joint Panel on the Medical Aspects of Atomic Warfare. Terrill wrote:

> After the Panel has [sic] reviewed the animal work which has been done in the laboratory and at atomic field tests, there was a general feeling that the question of human exposure under controlled conditions should be reconsidered. The need for such studies was emphasized by military as well as scientific considerations. After a brief discussion, it was reported that Dr. Shields Warren, former Chief of the Division of Biology and Medicine, had indicated that be believed studies of this type should be conducted by the Public Health Service or some Agency where security restrictions would not lead to public misunderstanding.[52]

VI. FIELD OFFICES

In light of the above, the policies and practices at the AEC field sites (including both the laboratories and related hospitals, and private research institutes and universities) raise interesting questions. Once again, in the smaller world of the time, the key personnel at these sites must have had knowledge of the views of individuals such as Shields Warren, certainly were privy to liability and public relations concerns. and may have had knowledge about the AEC/DOD discussions regarding research and secret agencies. There is no evidence to suggest that the AEC altered the policies discussed by Warren and others personnel at the AEC

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[50] June 20, 1947. Report of the Medical Board of Review to the Atomic Energy Commission.

[51] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory.

[52] September 25, 1952. Letter from J. Terrill, Jr., Acting Chief, Radiological Health Branch, Division of Engineering Resources to C. Kidd, Chief, Research Planning Branch, National Institutes of Health.

headquarters in the late 1940's and early 1950's.

Therefore, one might hypothesize that the field sites had well-run human use subcommittees, and employed the consent procedures stated by General Manager Wilson in November 1947 and restated to Leslie Redman by Shields Warren in 1951. But this does not appear to have been uniformly the case. While the policies and practices may have been sophisticated in comparison with those employed in non-AEC connected settings, they fell short of the highest standards stated by General Manager Wilson in 1947 and restated by Warren in 1951.

A. Oak Ridge National Laboratory

A review of the admissions materials for new patients at the AEC-sponsored Oak Ridge Institute for Nuclear Studies (**ORINS**) in 1950 shows that the forms for patient signature were designed primarily to protect the hospital from lawsuit and incidentally to explain to the patient the circumstances of the treatment. At the outset, the patient was advised that the procedures were experimental and "probable benefit, if any, cannot always be predicted in advance." In the application for admission, the applicant agreed to "such operations and biopsies as are deemed necessary and advisable by the hospital."[53] Upon admission, the applicant was required to sign a "Waiver and Release," that did not describe the treatment, but included a lengthy release from the patient, the patient's "heirs, executors, administrators, and assigns," for any "causes of action, claims, demands, damages, loss, costs, and expenses, whether direct or consequential," associated with or as a result of care in the hospital.[54] A 1954 "Authority to Operate," form indicates little improvement in the amount of information given to the patient. The form authorizes the hospital to administer "whatever anesthetics and [perform] whatever operation that] may be decided to be necessary."[55] While it is possible that the hospital staff nevertheless explained each intervention to each patient, the blanket release and consent forms suggest that this may not have been the case. We note, however, that this practice was probably standard among hospitals at the time.

In 1957, the release and admissions application forms seem to have been condensed into one form, the "Patient Admittance Agreement," that again makes legal liability the primary

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[53] 1950. The ORINS "Application for Admission to the Medical Division Hospital." Moreover, though perhaps not surprisingly given the time, the tone and style of the form place the patient in an entirely subordinate position whereby "The applicant is expected to fully cooperate at all times with the hospital," and "the hospital reserves the right to discharge the patient" at its discretion.

[54] 1950. The ORINS "Waiver and Release." The form, which apparently became effective in May, 1950, simply states that the hospital has described the "character and kind of treatment ."

[55] 1954. The ORINS "Authority to Operate."

consideration.[56]

In 1966, ORINS instituted a Human Use Committee to monitor the proposals for new research with humans, which evolved into the Committee on Human Use in 1967. This Committee was established "to monitor the Medical Division program in relation to the ethics of research in human beings."[57]

In 1967 a revised "Patient Admittance Agreement," appeared to give more weight to the patient's informed consent by allowing that the patient may "reserve the right to a full explanation of any proposed examination, test, or treatment and the right to withdraw [my] consent."[58] Likewise, a significantly revised "Consent to Operation" form provides space where the patient describes the operation, and indicated that possible alternatives as well as the "risks . . . [and] possibility of complications," have been explained. Furthermore, in 1967, separate "Consent to Experimental Treatment," and "Authorization for Administration of Radioactive Substances" forms are provided.[59]

It seems probable that the improved consent forms provided in 1967 were the result of a changing climate towards research ethics. This change was described in 1966 by Gould Andrews, an experimenter at the Oak Ridge Laboratory since at least the early 1950's. In a paper given to the Annual Bio-Assay and Analytic Chemistry Meeting, Andrews spoke about "misleading and exaggerated statements" regarding the lack of ethics in human experimentation but acknowledged that "a serious problem does now exist."[60] At present, staff is unaware of overall AEC policy changes from 1967.

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[56] 1947. The ORINS, Medical Division, Patient Admittance Agreement.

[57] April 6, 1967. Report of the Meeting to Consider the Establishment of Committee on Human Use.

[58] 1967. The ORINS "Patient Admittance Form."

[59] 1967. The ORINS "Consent tot Experimental Treatment" and "Authorization for the Administration of Radioactive Substances."

[60] October 13-14, 1966, G. A. Andrews, "Ethical Considerations in Human Experimentation," from the *Proceedings of the Twelfth Annual Bio-Assay and Analytic Chemistry Meeting.* Gatlinburg, TN, October 13-14, 1966. jointly sponsored by the Oak Ridge Affiliated Universities, the Oak Ridge National Laboratory, the Oak Ridge Y-12, and the Oak Rdige EDP.

B. Los Alamos National Laboratory

As noted earlier, in 1951, Leslie Redman of the Los Alamos "D" Division queried AEC Headquarters on human experimentation policy.[61] In response, Shields Warren referred Los Alamos to AEC General Manager Wilson's November 1947 policy. However, there is no indication that this was adopted or adhered to. In 1956, coincident with Los Alamos' introduction of a human body counter and related human experiments, the Health Division Leader at the Los Alamos National Laboratory (LANL) forwarded an inquiry to the AEC on "the experimental use of human volunteer subjects."[62] In response, the Director of the Division of Biology and Medicine stated that tracer doses may be administered under four conditions, including that subjects be volunteers who are fully informed.[63] Strikingly absent is the reference to written consent described by Warren in 1951 and General Manager Wilson in November, 1947. These rules were then given to "staff distribution" by Thomas Shipman, M.D., the Health Division Leader at LANL.[64] Seven years later, in 1962, the Health Division Leader at LANL restated these 1956 rules.[65]

It is not yet clear from the documents available to the Advisory Committee whether the 1956 rules were consistently applied, or applied to those who were not LANL employees, such as patients at area hospitals.

C. General

A memorandum dated May 13, 1966 from Bertram H. Schur, AEC Associate General Counsel, to Dr. Charles L. Dunham, Director, Division of Biology and Medicine, characterized AEC policy on the use of human subjects at that time.[66] The letter was written in response to a contemplated new project involving

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[61] March 5, 1951. Letter from Shields Warren, Director, of the Division of Biology and Medicine, AEC, to Leslie Redman, "D" Division, Los Alamos National Laboratory.

[62] June 18, 1956. Letter from Thomas Shipman, M.D., Health Division Leader, to Dr. Charles Burnham, Division of Biology and Medicine.

[63] July 5, 1956, Letter from Charles Dunham, M.D., Director, Division of Biology and Medicine, to Dr. Thomas Shipman, LANL.

[64] July 12, 1956. Memorandum from T.L. Shipman, Health Division Leader, Los Alamos, to staff distribution regarding the administration of tracer doses to humans.

[65] March 13, 1962. Memorandum from Thomas L. Shipman, M.D., to C. C. Lushbaugh.

[66] May 13, 1966, Memorandum from Bertram Schur, Associate General Counsel, to Charles Dunham, Director, Division of Biology and Medicine, dated May 13, 1966.

> convicts, college students, and other individuals, twenty one years of age or older. . .will be invited to volunteer, and monetary compensation will be paid for their services. These individuals will ingest or be injected with promethium-147 or plutonium-237.[67]

The Associate General Counsel recommended that each volunteer sign a "written, witnessed agreement." The memorandum stated: "Assuming complete understanding and no unequal bargaining factors (e.g., pressure on prisoners to submit), such an agreement would protect against liability for unauthorized invasion of the person."

The staff has not found any evidence that the study, which was to have been conducted by the Hanford Occupational Health Program, was ever carried out. However, "Markey" experiment number 110, "Promethium administered in humans," was conducted in 1967 for the AEC by the Hanford Environmental Health Foundation. Fourteen subjects drank fluids containing promethium-143.

VII. CONCLUSION

From its creation in 1947, the AEC sponsored (and provided necessary isotopes for) human radiation experiments. From its creation in 1947, there were clear concerns for the policies regarding consent; indeed, at the highest level there was support for what might qualify today as "informed consent." Nonetheless, the "informed consent" policy did not percolate throughout the AEC bureaucracy (and contractors/grantees) into practice. The absence of clear implementation may relate to the fact that the research policy appears to have been driven as much by "medical legal" (and public relations) concerns as by "ethical" concerns. Thus, there was periodic hand-wringing about human experimentation policy and practice, but no integrated understanding of all the issues--ethical as well as medical legal--involved. Perhaps this failure to integrate the full reality of the human experimentation it sponsored explains how it came to be that the AEC felt the need to tell the public that it did not engage in human experimentation at all. For example, in 1951 a question from the press lead to the preposterous statement from Shelby Thompson, the Chief of the Atomic Energy Commission's Public Information Service, that "the AEC. . ..*has never sponsored a medical research project where human beings are used for experimental purposes.*" [68] (Emphasis added.)

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[67] May 13, 1966, Memorandum from Bertram Schur, Associate General Counsel, to Charles Dunham, Director, Division of Biology and Medicine, dated May 13, 1966.

[68] December 7, 1950. Letter to the Associated Press from Shelby Thompson, Public Information Service, AEC.