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

MEMORANDUM

TO: **Members of the Advisory Committee on Human Radiation Experiments**

FROM: **Ruth Macklin, Chair of Ethics Subcommittee**

DATE: **July 1, 1994**

RE: **Ethics Subcommittee Data Gathering Projects**

As chair of the Ethics Subcommittee, I submit the attached summary of its data gathering project plans to the Advisory Committee for its information. The projects were discussed and approved by the Subcommittee for submission to the full Committee in a June 30, 1994 conference call. Since I will be unable to attend the next Advisory Committee meeting, I ask that Ruth Faden present the project plans to the Committee.

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

MEMORANDUM

TO: **Members of the Advisory Committee on Human Radiation Experiments**

FROM: **Ethics Subcommittee**

DATE: **July 1, 1994**

RE: **Data Gathering Projects**

The Ethics Subcommittee has approved three projects as part of its data gathering efforts, as briefly summarized below: oral histories, patient interviews, and research protocol review. These projects are intended to implement Part 3 of the Subcommittee's data gathering plan submitted to the Committee at the June meeting, regarding investigation of past and present practices in human subjects research. More extensive project descriptions are attached for the oral history and patient interview projects; the basic plan for the protocol review project is still under development.

1. Oral Histories: The oral history project is intended to investigate the evolution of ethical standards and research practices from the early 1940s onward. Oral histories are to be obtained from approximately 15 investigators involved in either ionizing radiation research or other research during that time period. An expert panel of both ethicists and historians will be convened to assist both in the initial project development and its implementation. Three persons will conduct the oral histories, after extensive preparation. See Attachment A for a lengthier project description. .

2. Patient Interviews: Oncology patients currently undergoing treatment will be interviewed in order to assess the nature and extent of their understanding of, and attitudes concerning, their participation in research protocols. One hundred radiation oncology patients, and one hundred medical oncology patients, will be interviewed at ten leading research institutions, both academic and governmental. Interviews will be semi-structured and transcribed. Resulting data will be analyzed by the project interviewers. See Attachment B for a lengthier description.

3. Research Protocol Review: The research protocol review project, still in its preliminary planning stages, is intended to evaluate written protocols of contemporary ionizing radiation research and other research involving human subjects. Samples of research protocols sponsored by various federal agencies will be examined, focusing specifically on risk-benefit analysis, level of risk to which patients are subjected, and informed consent procedures. The Subcommittee is in the process of determining who exactly would conduct the protocol review and evaluation. Jay Katz is interested in leading the project.

The Subcommittee welcomes any questions and comments from the Advisory Committee concerning these projects. Plans are underway to begin the projects as soon as possible, in light of obvious time pressures.

ATTACHMENT A

Oral History Project

Purpose: The purpose of the project is to obtain oral histories from clinical investigators who have been involved in both radiation and non-radiation research, in order to understand the evolution of ethical standards and research practices in human experimentation from World War II onward. Oral histories are an essential element to piecing together the evolution of both policies and practices, since information from both primary and secondary sources will be incomplete.

Expert Panel: Preparation is critical for the success of an oral history project. Prior to taking the oral histories, it would be advisable to convene a panel of experts composed of both ethicists and oral historians, who will advise us both at the initial phase of project formulation and also during its implementation. Suggestions for potential advisors include: Charles McCarthy, Al Jonsen, John Fletcher, Ed Pellegrino, Bob Levine, Saul Benison, Allan Brandt, F.L. Holmes, Elizabeth Etheridge, and Charles Weiner.

Process: It has been suggested that ten investigators who have engaged in radiation-related research on human subjects be interviewed, and five who have been involved in non-radiation research. Ideally, these investigators would have lengthy careers that span the years under review by the Advisory Committee, and would represent a broad spectrum of institutional affiliations. (We are currently checking out an oral history project on medical aspects of nuclear medicine that was conducted at UC-Berkeley, for background and possible lists of researchers.)

No more than three persons will conduct the oral histories. These persons will need extensive preparation in order to be able to both elicit new information from the researcher and stimulate recollection. The interviewers must be familiar not only with relevant information in the public record, but also with unpublished information from any relevant archival sources. A search of relevant archival sources, as well as other pertinent research, thus must be conducted before the histories may be taken.

ATTACHMENT B

Interview Study of Contemporary Oncology Patients

Overview: The purpose of this investigation is to determine the nature and the extent to which patients receiving their medical care at leading research institutions appreciate that they are participants in research studies, and to ascertain their attitudes toward such participation. To this end, the proposed investigation centers on semi-structured interviews of oncology patients since they are likely to be receiving radiation and/or chemotherapy as well as likely to be enrolled in clinical trials. Those patients who think that they are actually enrolled in research trials will be asked about 1) the degree to which they feel that their involvement in the research study is voluntary, 2) their decision making process regarding becoming a research subject (e.g., did they feel that their care might be improved if they enrolled in a trial), 3) their understanding of the study that they are enrolled in (including research practices and experimental therapies), and 4) their perceptions of the informed consent process.

Patients will be recruited for enrollment in the interview study from oncology patients receiving medical care at ten leading research institutions - five academic and five governmental (3 Veterans Affairs Medical Centers and 2 federal agency hospitals) facilities. The particular institutions will be selected among the top recipients of federal research funding within their category (i.e., academic, VA, or federal agency) over the past five years.

Once institutions have been selected as a site for this interview study, two local physicians (a medical oncologist and a radiation oncologist) at each site will be identified to serve as co-investigators for this interview study. These local co-investigators will assist in adherence to institutional research policies, arrange for an appropriate location in which to conduct structured interviews, and facilitate access to patients, records and charts.

Process: Three trained interviewers will conduct all of the interviews for this project. Interviews at each site will be completed over a period of a two to three day visit. After a local staff member informs patients of the existence of the study, patients waiting for appointments in medical oncology and radiation therapy clinics will be approached by a member of the research team and asked to participate in the interview study. Patients willing to participate in the study then will be scheduled for an interview. Prior to the interview, trained interviewers will obtain written informed consent for participation in the proposed study. Consent will be obtained for the interview itself, review of medical and research records, and discussions with primary caregivers. [The Subcommittee has not yet determined the exact timing of the informed consent process, but will do so as the study is further developed.]

Twenty one-hour interviews will be conducted with patients (10 medical oncology and 10 radiation oncology patients) at each of the ten institutions participating in this study. Interviewers will follow an outline guide to assure that pertinent topics are covered during the interview. Interviews will be tape recorded and subsequently transcribed. Following the interview, the

interviewer will review the patient's chart to obtain accurate information regarding the patient's medical diagnoses and actual participation in clinical trials. Each patient's primary caregiver at the research institution will then be asked to review the abstracted medical information to verify its accuracy and to confirm whether the patient is a research subject.

Interview transcripts will be coded to identify passages of text that are of interest (e.g., matters related to consent procedures, voluntariness, or radiation) and entered into ethnographic research software (e.g., TALLY or Ethnograph). Data will be analyzed by the research staff interviewers.

Methods for Safeguarding Confidentiality: Patients who are interviewed will be assigned a unique number once they have granted consent to serve as subjects. The study number will be used on all tapes, data sheets, and materials to be analyzed. Once patients' charts have been reviewed, local co-investigators will keep a secure record of patients' assigned study number so that project staff will not have access to participants' names once they leave the interview site. Subject identifiers and names will not be used in any reports of these data.

The identity of institutions participating in this project will be disclosed. However, every effort will be made to prevent linking the names of participating institutions with particular statements or findings emanating from this research.

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

August 23, 1994

BY FAX
James B. MacRae
Deputy Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
Room 3236
Washington, D.C. 20503

Dear Mr. MacRae:

Thank you for taking the time to meet with us on Friday to discuss the Advisory Committee's projects. You and your staff were quite helpful, and we appreciate your input and your assistance in expediting the OMB review process.

As we now understand, the Subject Interview and the Research Proposal Review projects must receive OMB approval under the Paperwork Reduction Act, but the Oral History project does not. As you suggested, we met with John Gross at the Department of Energy to assist us in filling out the necessary forms and filing the Federal Register Notice. We hope to have the forms filed with OMB sometime this week, and the Federal Register Notice filed soon thereafter.

It is my understanding that the Federal Register Notice will provide for a fifteen day comment period, at the end of which the OMB will approve the Committee's projects. We understand that the approval must take into consideration any comments filed with the Committee during the comment period, and that the entire process is anticipated be completed by about mid-September.

As to substantive concerns, the OMB staff's specific questions about the Subject Interview Project appeared to have been addressed by Jeremy Sugarman during the August 19 meeting, and OMB has not raised any specific concerns about the Research Proposal Review Project. We therefore are assuming that any substantive concerns about these projects now have been satisfactorily addressed.

Thank you again for your help. Please let me know if you have any further comments or questions about this matter.

Sincerely,

Anna Mastroianni
Associate Director

cc: Phil Caplan, White House Cabinet Affairs
John Gross, Department of Energy
Ruth Faden, Advisory Committee Chair
Dan Guttman, Advisory Committee Executive Director

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

AUG 12 1994

NOTE FOR PHIL CAPLAN

FROM: Katherine K. Wallman

SUBJECT: Data Gathering Projects for OMB Review

Jim MacRae has asked me to share with you the comments that follow on the Advisory Committee projects. Several of our staff members who have experience with these types of projects have taken a look at the materials you provided.

We know that you are anxious to complete the necessary reviews, and we certainly are willing to discuss the attached comments with you at your convenience. We see no problem in expediting the OMB clearances for the projects. Please give Jim a call.

c: Gary Rowe
Jim MacRae

ACHRE Data Collection Proposals (3 projects)

General questions and comments:

- What hypotheses underlie each of the projects?
- Are the results of all three projects going to be brought together in any way?
- Comparisons across research protocols of the 40s and 50s with protocols of research conducted after the 70s may be inaccurate and not particularly useful. Recall may be a particular problem for characterization of early research activities. Were validation requirements, e.g., records, considered?
- Why was it decided to go to the 10 biggest grantee universities? Findings for such entities may not be representative of the majority of radiation research.
- The patient interview proposal may trigger some Privacy Act requirements concerning notification and systems of records. In any event, patients should be clearly informed about what the information will (and will not) be used for, and how it will be protected.

Specific Methodological comments:

(Note that these comments relate to the stated objectives and do not address other potential problems related to the general comments).

A -- Research Proposal Review Project, and
B -- Oral History Project

- The methods proposed appear to be useful as far as they go (but see general questions above).

C -- Patient Interview Project (three phases)

Phase I: Focus Groups

- The methods proposed are useful for gaining insight within the usual limitations of focus groups (i.e., they are not representative and are unlikely to reflect all issues and viewpoints).

Phase II: Short Survey

- o The subject matter should be highly salient to the target respondents. This usually produces high response rates unless other problems intervene. Thus self-selection need not be a significant factor if the survey is well-designed and executed. Several items need attention:

  -- The participating organizations should not assume a neutral posture. They should encourage patients to participate and provide a brief written description of the survey to motivate participation. Another option is a short-answer "example" questionnaire (to be kept by the respondent) followed by an in-person contact to get and clarify answers. If not all patients can be interviewed on a given day, a random selection procedure is needed to avoid interviewer selection bias.

  -- There is no need for a separate informed consent statement for the interview (participation <u>is</u> consent in this case) -- the only effect of such statements is to reduce response.

  -- A separate written consent statement for limited access to medical records should be requested at the end of the interview. Opening medical records to the researchers is likely to be more sensitive than the specific information being sought -- some effort must be made to assure respondents that other information will not be searched. Perhaps the best approach for the "medical records" information would be to give the respondent several options, e.g.,

     "We would like to get some additional information (some of it technical) from you or from your medical records" [identify specific items and accept items volunteered] "If you do not know the technical details, would you be willing to 1) give your doctor permission to answer these questions from your medical records, or 2) give us permission to get the answers directly from your medical records. (two different consent statements)

  -- The sample questionnaire is at several points leading, ambiguous, or difficult to answer. We assume that this instrument will be thoroughly scrubbed and tested, e.g.: move #2 to end; add multiple choice short answers for #6, #7, and parts of #9; rework #9a and #9b; add "other" or "don't know" choices as appropriate; and develop (with testing) a non-threatening script for addressing the medical records items as suggested above.

Phase III: In-depth Interviews

-- It is not clear what purpose is served by the longer interview. Self-selection and judgmental selection are major problems here, so that the information is similar in kind and limitations to the information from focus groups. The selection process does not support statistical inference. Thus if there is some analytical purpose to be served, the recruitment process must overhauled to assure random selection from an appropriate target population and to assure a high level of participation. Otherwise this component does not appear to be useful.

-- If you can justify a redesign, your incentive strategy also needs to be reconsidered. The Heberlein - Baumgartner experiment reported in 1986 found that general (dissonance/compensation) cash incentives have little effect on participation when the subject matter is highly salient to respondents, but we have observed that payments to offset actual costs imposed by the protocol (an allowance to cover carfare, childcare, etc. for an special trip to the instrumented interview site) may be useful.

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

FAX TRANSMITTAL

NUMBER OF PAGES (including cover): 10

TO: PHIL CAPLAN

FROM: ANNA MASTROIANNI

DATE: AUGUST 5 1994

RE: OMB REVIEW

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

MESSAGE:

PLEASE CALL ME TO DISCUSS

THANKS!

Jeff Kahn 414/456-8498

Cathy Taylor

MEMORANDUM

TO: **Phil Caplan**

FROM: **Anna Mastroianni**

DATE: **August 5, 1994**

RE: **Description of Data Gathering Projects for OMB Review**

As you requested, attached are short descriptions of the three projects approved by the Advisory Committee as part of its data gathering efforts, which include sample topics/questions where appropriate:

Attachment A: Research Proposal Review Project

Attachment B: Oral History Project (with sample topics)

Attachment C: Patient Interview Project (with sample short survey)

While the basic methodology of these projects will remain unchanged, some specific details remain open (e.g., the exact number of oral histories or patient interviews conducted, and the exact number of protocols to be reviewed).

As you know, the Committee must begin these projects as soon as possible in light of obvious time constraints. Again, there are certain threshold questions which OMB must consider, such as whether the patient interview and oral history projects even require OMB review under the Paperwork Reduction Act. Thanks again for your assistance.

ATTACHMENT A

RESEARCH PROPOSAL REVIEW PROJECT

PURPOSE: The project will evaluate the extent to which the rights and interests of persons currently involved as subjects of research conducted or supported by the federal government appear to be adequately protected, and to compare the subjects of radiation research with those in non-radiation research.

Objective I. To determine for a sample of contemporary research projects, based on research proposal and IRB materials, whether risks and benefits, informed consent procedures, and the selection of subjects appear to be appropriate.

Objective II. To determine whether research proposals and IRB materials provide sufficient information to make judgements about the protection of human subjects.

PROJECT UTILITY: The project will collect data from agencies and grantee institutions that is necessary to assist the Committee in its overall review of contemporary practices and policies regarding human subjects research. The data to be obtained is not currently available in useful form from other sources.

METHOD: Listings of pertinent research protocols will be obtained from the Departments of Defense, Energy, Health and Human Services, Veterans Affairs, NASA, and possibly the CIA, including:

(1) Research proposals involving ionizing radiation that were approved and funded by the agency in FY '93 (excluding those studies which involve only incidental uses of such radiation)

(2) A comparison group of research proposals not involving ionizing radiation that were approved and funded during the same period as category (1).

Both intramural and extramural proposals in each category will be considered for review.

From these lists, a sample of research proposals will be selected. The individual institutions performing the research will then be contacted to supply information regarding selected projects. Supporting material may include the full research proposals IRB file, IRB minutes from when the proposal was reviewed, the consent form, and when applicable, information from Radiation Committee review of the grant application.

In addition, major medical journals that publish clinical research involving radiation may be reviewed to identify research studies of interest to ACHRE's charge. If such studies are identified, investigators and institutions will be contacted to provide the research proposals and relevant IRB materials.

A subset of Committee members and staff will review and evaluate the proposal materials. This team of evaluators will include persons with technical radiation risk and medical expertise, knowledge of the appropriate standards for informed consent and selection of human subjects, and any additional expertise necessary to address the objectives listed above. For proposals outside of radiation research, consultants will be added as needed.

In order to safeguard confidentiality, the identity of the investigators associated with the research proposals under review and their affiliated institutions will not be reported or otherwise made public by ACHRE. Whether sponsoring agencies may request access to ACHRE reviews of identifiable proposals has not been determined. This project raises no privacy concerns for persons involved as research subjects with the protocols under consideration as the identities of subjects will not be requested.

ATTACHMENT B

ORAL HISTORIES PROJECT

PURPOSE: To obtain oral histories from clinical investigators who have been involved in both radiation and non-radiation research, in order to understand the evolution of ethical standards and research practices in human experimentation from World War II onward.

PROJECT UTILITY: Oral histories are an essential element to piecing together the evolution of ethical standards and practices in human research, since information from both primary and secondary sources will be incomplete.

METHOD: Approximately ten to twenty-five senior research scientists active in the research community from 1942 to present, in both radiation and non-radiation research, will be interviewed by experienced interviewers on the Committee and staff. These scientists will come from two age cohorts: one consisting of clinical researchers who began their careers in the 1940s or 1950s, and the other of those whose careers began in the early 1970s, when the federal government became extensively involved in the regulation of human experimentation.

Prior to taking the oral histories, the Committee will consult with approximately six experts (ethicists and historians) concerning both whom to interview and the proposed methodologies.

SAMPLE TOPICS: Specific standardized questions will not be used when taking the oral histories, since each history must be tailored to the experiences of the individual scientist. However, certain topics will be addressed in each interview. While these topics are currently under development, sample topics may include:

- To what extent were researchers aware of the Nuremberg Code, and how did this influence their work?
- How were malpractice suits a concern in designing and implementing lab protocols?
- How were clinical research standards communicated to junior researchers?
- How were research subjects selected, and how explicitly were the risks and procedures of the experiments communicated to them?
- Were approaches to therapeutic and non-therapeutic research clearly distinct?
- What was the impact of federal regulation on the formulation of research protocols, and research practices?

ATTACHMENT C

SUBJECT INTERVIEW STUDY

PURPOSE: To collect data concerning (1) whether oncology patients seeking medical care at major research institutions believe they are participants in research; (2) the perceived voluntariness of this participation; and (3) patients' reasons for agreeing to participate.

PROJECT UTILITY: The project would enrich the deliberations of the Committee with direct information about the contemporary experiences of some research subjects. Although some level of self-selection bias is unavoidable, these options would provide less biased information than any other (non-research) approach that has been suggested for "hearing from current subjects." To date, no national committee or commission charged with addressing research ethics has obtained systematic information from persons most affected by governmental policies concerning research subjects.

METHOD: The project will proceed in three phases. (1) Focus groups will be conducted to assist in development of (2) a short survey, which will be administered to approximately 1000 patients drawn from 10 different institutions, followed by (3) a semi-structured interview to be administered to approximately 150 patients who are a subsample of those completing the short survey.

Phase I: Focus groups. Focus groups comprised of patients from at least two different institutions will be conducted by a professional facilitator. A "convenience sample" of the two institutions will be selected for this component.

Liaison staff at each of the institutions will ask patients whom they **know** to be participants in experimental protocols if they are willing to participate in a focus group related to participation in experimental protocols. Participants will be paid for their participation.

Issues to be covered in focus groups include:

- Voluntariness: did they feel as if they had a choice about whether to participate in an experimental protocol; were others involved in the decision?
- Reasons for participating, including whether it had been recommended and, if so, by whom
- Understanding of what it means to participate, such as what it means for a drug or treatment to be experimental, and how being a patient in a research protocol differs from getting regular medical care.

Phase II: Short Survey. Based on the focus group responses, a short survey, anticipated to take
5-10 minutes to complete, will be designed by ACHRE staff in conjunction with survey research consultants.

Sample: The five academic and five governmental institutions that receive the most federal research funding will be included in this study. IRB approval from each of these institutions will be obtained. Approximately 100 patients will be interviewed at each institution, for a total of 1000 patients. Patients will be recruited from the waiting rooms of medical oncology and radiation oncology departments.

Recruitment: Local staff will inform all patients that the facility is cooperating with an interview study of patients' experiences, that the patient may be approached by someone from the study, and that it is entirely up to the patient whether he/she wants to participate. Project staff will briefly describe the project to prospective participants and seek written informed consent, both for the interview and for access to the patients' medical records.

Data to be collected:

1. Interview: The interview instrument will be designed to capture the following topics, provided as potential examples only. The actual questions will be developed with focus group data to be refined with pilot testing. Questions may be tightly structured and close-ended or more open, but in either case they will require a total of no more than five to ten minutes to answer. **A sample survey instrument is attached.**

- Beliefs about being a research participant, such as whether the patient is currently receiving any treatments or drugs considered to be experimental, or participating in any research studies or protocols.

- Voluntariness (to be asked of patients who believe they are currently participants in research), such as whether the patient believes he/she had a choice about whether to participate in research or experimental therapies, and why or why not.

- Reasons for participating, e.g., to receive state-of-the-art treatment; to help advance science; to receive compensation; because someone recommended they should, whom, etc.

- Understanding of what it means to participate in research, such as whether the patient understands what it means for a drug to be experimental, the difference from regular medical care, whether everyone in their research protocol is getting the same drug or treatment.

2. Medical Record: From each patient's medical record, study investigators will review documentation as to whether the patient is receiving experimental therapy/participating in a research protocol, existence of signed informed consent form, and basic demographic

information.

Interview/Procedures: Staff will conduct approximately 10-15 pilot interviews, and a consulting firm or staff would then conduct the rest of the interviews.

Phase III: In-depth Interviews. Semi-structured in-depth personal interviews then will be conducted with 10-15 patients at each of the ten institutions.

Recruitment: Every patient interviewed in the short survey will be asked if he/she is willing to be interviewed more extensively at a later date, with the expectation that each interview will last approximately 30-45 minutes. From the pool of patien3ts who have expressed a willingness to participate in a personal interviews, a purposive sample will be contacted to assure that the interviews include participants who actually are research subjects. Interviews will be scheduled in advance, and patients paid for their participation to compensate for their time and expenses.

Development of the interview guide: The guide will be developed with the help of the focus groups, and the same issues covered in the closed-ended survey will be included in the guide, with questions posed to individuals in an open-ended fashion and follow-up questions asked based on the patient's response to previous questions. Through this process, considerably more attention can be given to the relevant topics such as the meaning of research participation for subjects.

Interview procedures: Staff will conduct ten to twenty of the semi-structured interviews. Outside consultants would conduct the remainder of the interviews. Interviews will be tape recorded and subsequently transcribed. Transcripts will be coded and analyzed using available software (e.g., TALLY or Ethnograph).

Oncology Patient Short Interview

SAMPLE

1. ID Number _____

2. Consent signed _____

3. Date of interview _____ Time _____

4. Location _____

5. Are you currently receiving any treatments or drugs considered to be experimental?

6. What does it mean for a drug or treatment to be experimental?

7. How is being a patient in a research project different from getting regular medical care?

8. Are you participating in any research studies or protocols now?

9. **[To be asked of patients who answer YES to question 8, otherwise skip to question 10]:**

   a. Did you believe that you had a choice about whether to participate in research or experimental therapies?

   b. Why or why not?

   c. For which of the following reasons did you choose to participate in this study?
      (1) to receive state-of-the-art treatment?
      (2) to help advance science?
      (3) to receive compensation?

   d. Was it recommended that you participate in this study?
      If so, by whom? _____

   e. Is everyone in your research project getting the same drug or treatment.

10. If we contact you, would you be willing to participate in a longer, about 1 hour, interview to talk about these issues in greater detail? _____
    If yes, give information about the semi-structured interview and scheduling.

Oncology Patient Short Interview-- Continued

SAMPLE

ID Number: _____

Medical Record Review:

1. Basic demographic information:

    a. Date of Birth

    b. Sex

    c. Race

2. Primary diagnoses:

3. Major therapeutic modalities:

    a. Radiation therapy

    b. Chemotherapy

    c. Other

4. Is there documentation as to whether this patient is receiving experimental therapy or are participants in a research protocol?

    a. Description of trial

    b. Existence of signed, informed consent form *for research*?

Re-send

Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, D.C. 20036
202/254-9795
Fax: 202/265-9827

FAX TRANSMISSION COVER SHEET

Date: September 29, 1994

To: Philip Caplan

Fax: 456-~~[illegible]~~ 6704

Re: Materials relating to 9/29/94 Meeting at 4:00 pm at OEOB

Sender: Sara Chandros

YOU SHOULD RECEIVE 4 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.

Attached is a draft of the agenda that, with your approval, we will distribute to attendees at this meeting. I hope I listed you and Christine Varney under an appropriate heading ("Cabinet Affairs") in the attendees section at the beginning of the agenda. If you have any changes to suggest, please call me at 254-9852. Also attached are bios of the three staff members, including myself, who will attend this meeting (FYI).

Martin Michaelson can be reached at 617-969-6613 ~~tomorrow~~ today at 4:00 so that he can be "teleconferenced" in to the meeting. I hope that this can be arranged.

I know that this has been a big logistic nightmare, and I thank you for all of your help in setting up this important meeting.

[Draft]

AGENDA

Meeting with Government and University Counsels on Issues Relating to the Advisory Committee on Human Radiation Experiments ("ACHRE") Research Proposal Review Project

Thursday, September 29, 1994
4:00 p.m., EDT
Old Executive Office Building
[room to be determined]

Meeting Facilitator: Ruth Faden, Ph.D., MPH
Chair, Advisory Committee on Human Radiation Experiments

Attendees:

Advisory Committee on Human Radiation Experiments

Ruth Faden, Advisory Committee Chair
David Saumweber, Staff, Director of Information Services
Kathy Taylor, Staff, Research Analyst
Sara Chandros, Staff, Research Associate

University Counsel

Martin Michaelson, Hogan and Hartson (via teleconference)

Government Counsel

Robert Nordhaus, Department of Energy General Counsel
Steve Neuwirth, White House General Counsel

Cabinet Affairs

Christine A. Varney, Secretary to the Cabinet
Phil Caplan, Special Assistant to the President for Cabinet Affairs

I. Overview: Description of the Project

II. Description of Desired Materials

A. Grant Application submitted to IRB, including project proposal

B. Correspondence between the IRB and the project's principal investigator(s), such as that relating to any IRB-suggested changes to the proposal, and the IRB's final disposition of the proposal.

C. Consent form, as approved by the IRB

D. Final disposition letter.

E. Minutes from the IRB meetings where the proposal was discussed.

III. University Concerns

IV. Confidentiality Issues

A. What confidentiality assurances can ACHRE give to the universities/agencies concerning the requested materials?

V. Practical Issues

A. How and to whom ACHRE should submit the requests for the desired materials?

1. Requests for grant/project proposals?

2. Copies of requests to whom in university administration?

SARA CHANDROS
Research Associate

In addition to her Committee duties, Ms. Chandros is a Doctor of Science candidate in the Program in Law, Ethics, and Health at the Johns Hopkins University School of Hygiene and Public Health. Her primary research interests include research ethics and issues of genetic technology and reproductive rights. She has served as ethicist on the Johns Hopkins' School of Public Health Animal Care and Use Committee, and participated in several health policy research projects at the school. Prior to her graduate studies, Ms. Chandros earned a Bachelor of Arts in Biology from Brandeis University in Waltham, Massachusetts, where she conducted research for several years in the area of molecular genetics. In addition, she was a three-year member and chairperson of the Brandeis University Board on Student Conduct.

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 B.A. degree with honors in Philosophy and an M.A. 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.

KATHERINE A. TAYLOR, J.D.
Research Analyst

Ms. Taylor is currently pursuing a Ph.D. in Philosophy at Georgetown University, with a specialization in bioethics. Before returning to school, she practiced health law for six years, first with Fulbright & Jaworski in Houston and Washington, D.C., and then with Fox, Bennett and Turner, also in Washington. Her health practice included regulatory and lobbying work in the food and drug arena; medical malpractice defense; and counseling hospitals on issues such as medical staff matters, reimbursements, informed consent, and withholding of treatment. Ms. Taylor received her B.A. and J.D. degrees from the University of Texas at Austin.

AGENDA

Meeting with Government and University Counsels on Issues Relating to the Advisory Committee on Human Radiation Experiments ("ACHRE") Research Proposal Review Project

Thursday, September 29, 1994
4:00 p.m., EDT
Old Executive Office Building

Meeting Facilitator: Ruth Faden, Ph.D., MPH
Chair, Advisory Committee on Human Radiation Experiments

Attendees:

Advisory Committee on Human Radiation Experiments

Ruth Faden, Advisory Committee Chair
David Saumweber, Staff, Director of Information Services
Kathy Taylor, Staff, Research Analyst
Sara Chandros, Staff, Research Associate

University Counsel

Martin Michaelson, Hogan and Hartson (via teleconference)

Government Counsel

Robert Nordhaus, Department of Energy General Counsel
Steve Neuwirth, White House General Counsel

Cabinet Affairs

Christine A. Varney, Secretary to the Cabinet
Phil Caplan, Special Assistant to the President for Cabinet Affairs

I. Overview: Description of the Project

II. Description of Desired Materials

A. Essential Documents

1. Grant Proposal submitted to IRB
2. Application to the IRB
3. Consent form, as approved by the IRB
4. Final disposition letter from the IRB

B. Desired Documents

1. Correspondence between the IRB and the project's principal investigator(s), such as that relating to any IRB-suggested changes to the proposal, and the IRB's final disposition of the proposal
2. Minutes from the IRB meetings where the proposal was discussed

C. Information not needed by ACHRE (assuming linkage purposes are satisfied)

1. Identifying information re: investigators
2. Budget information
3. Identifying information re: subjects

III. University Concerns

IV. Confidentiality and Exposure Issues

V. Practical Issues

A. How and to whom ACHRE should submit the requests for the desired materials?

1. Requests for grant/project proposals?

   a. FOIA or direct requests

2. Copies of requests to whom in university administration?

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

FAX TRANSMITTAL

NUMBER OF PAGES (including cover): 3

TO: MaryAnn Shebek

FROM: Sara Chandros

DATE: Aug. 30, 1994

RE: Confidentiality issues re. the Research Proposal Review Project

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

MESSAGE:

Sat # 586-8685

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

August 30, 1994

By FAX

Ms. Mary Ann Shebek
Deputy Assistant General Counel
for General Law
U.S. Department of Energy
1000 Independence Ave., S.W.
Washington, D.C. 20585

Dear Ms. Shebek:

The Advisory Committee on Human Radiation Experiments is undertaking a Research Proposal Review Project, which will entail reviewing a group of human subject research proposals involving ionizing radiation, and a comparison group not involving ionizing radiation. The Committee therefore plans to request the following documents from institutions performing federally-funded extramural research, for each research proposal to be reviewed:

1) The research grant application, and

2) Documents from the Institutional Review Board (IRB) that reviewed the proposal, including:

- The IRB application;
- Correspondence between the IRB and the proposal investigator(s), such as that relating to any IRB-suggested changes to the proposal, or the IRB's final disposition of the proposal;
- The final disposition letter;
- The consent form approved by the IRB; and
- Minutes from the IRB meetings where the proposal was discussed.

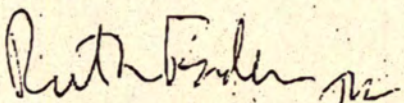
In order to uphold principles of confidentiality and to ensure that the research institutions will provide the requested documents, the Advisory Committee wishes to make assurances to the institutions that it will safeguard the confidentiality of all records requested by it. The Committee proposes that none of the documents described above would be subject to public review, but would be available only to Committee members and staff. Further, the identity of the investigators associated with the research proposals under review, as well as their affiliated

institutions and the members of the reviewing IRB, would not be reported or otherwise made public by the Committee. Any project findings would be reported only in the aggregate, with efforts made to minimize the possibility that any finding could be linked to the identity of any of these entities.

We therefore need the advice of senior counsel regarding whether the Committee may make these assurances of broad confidentiality. If so, the Committee would like practical guidance as to how it can best guard the confidentiality of these documents. If not, the committeee needs to know the extent to which it can keep these documents condifdential.

This matter is of great urgency to the Committee. We therefore request a response in writing by September 1. Thank you for your assistance in this matter. If you have any questions or comments, please speak with Anna Mastroianni or Jeff Kahn.

Sincerely,



Committee Chair

cc: Anna Mastroianni