June 6, 1975

724861

Committee for Protection of Human Subjects
Mll Wheeler Hall
Berkeley campus

To the Committee:

I have been requested as Lawrence Berkeley Laboratory Consulting Pathologist for NCI Grants CA15184 and CB-74-41 and proposed NCI Grant, TREATMENT OF CANCER WITH HELIUM AND HEAVY IONS, to outline for you the processing of breast specimens for heavy-ion radiology, in order that you may understand why a special permit from the patient would not be considered necessary.

Normal procedure for a breast specimen consists of obtaining a frozen section at the time of operation. This specimen is read by a member of the Pathology Department, UCSF (often by me) and, if the diagnosis is cancer, the breast is removed. The type of operation ("lumpectomy"; radical mastectomy; modified radical mastectomy) is determined by the surgeon, and the specimen is delivered in fresh state to the Pathology Department to be handled in the best fashion for diagnosis.

At this point, the specimen often is loaned for a short time to the Radiotherapy Department for xenography and/or mammography. This aids them in refining their techniques; in addition, it aids us in locating suspicious diagnostic areas, since the radiotherapists often inject potentially cancerous areas with Evans blue. When the specimen returns to our department, we often photograph the gross specimen for our files and for teaching. A small portion is removed for organ culture, scanning, and transmission electron microscopy. This latter procedure is part of an experimental study by Dr. Elias at UCSF but does not require a special permit, since it may add to our diagnostic information and in no way compromises the routine processing of the specimen.

The specimen is next fixed in formalin for one to two days and sectioned according to standard techniques; a diagnostic surgical pathology report is then formulated.

For heavy-ion radiology, the only modification of our standard technique would be to bring the specimen to Berkeley for several hours for radiography. It is important that this additional procedure would in no way alter the tissue so that it would be unsuitable for diagnosis; nor would this procedure delay the surgical pathology diagnostic report. In fact, the additional information provided by the heavy-ion radiographs may aid the pathologists in localizing the breast lesions, in a fashion similar to xenography and mammography.

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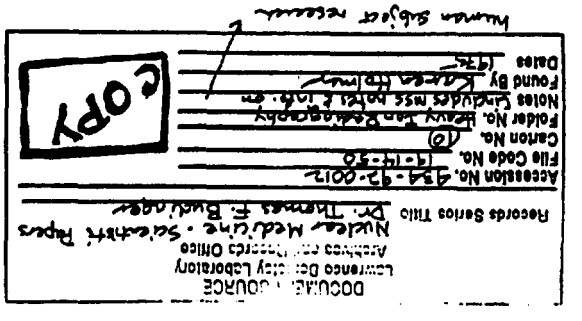

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I have discussed with M. Cruty, H. Genant, MD, and C. Tobias, of the heavy-ion radiography project, the care of the breast specimens, and I anticipate supervising initial transportation and handling of the specimens myself. I have discussed this matter with Dr. Oscar Rambo, Professor and Acting Chm of Pathology at UCSF, and he has given his permission that the heavy-ion radiographs be made. Again, the important points to be considered are that there will be no delay in diagnostic procedure or alteration in the diagnostic material.

Sincerely,

K.H. Woodruff, MD
Asst. Clinical Professor
Pathology Dept, UCSF
Consulting Pathologist, LBL

KHW/dm

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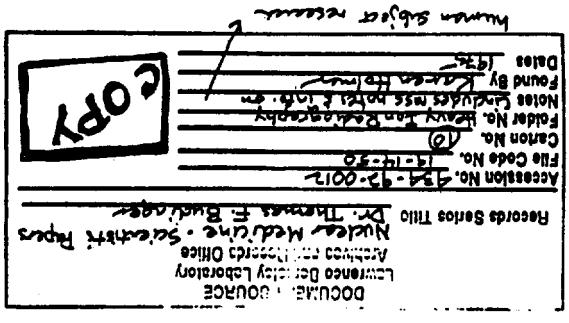

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CONSENT TO ACT AS SUBJECT
FOR RESEARCH AND INVESTIGATIONS
UNDER INTERAGENCY AGREEMT YO1-CB-40302

Your physician suspects that you have a problem involving localization of a probable soft-tissue abnormality.

Patient's name _____ Date _____

Physician's name _____

Patient's diagnosis _____

1. I hereby authorize _____

(name of person(s) who will perform diagnostic procedures & investigations)

and/or associates who may be selected by him to perform the following diagnostic studies using heavy-ion radiography at the Berkeley BEVALAC.

Heavy particles can detect small differences in tissue density with a sensitivity that is greater than the sensitivity of most X-ray procedures. At the medical wing of the accelerator, the procedure will be as follows:

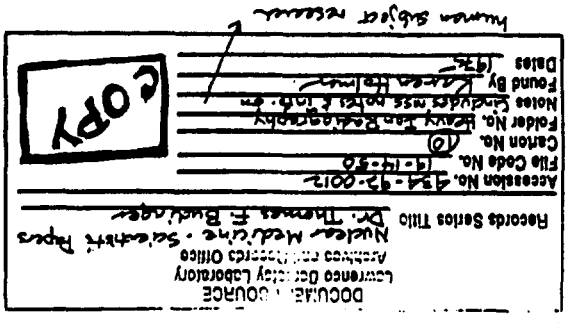
a. Areas of the body that are to be exposed to a diagnostic stream of particles will be prepared. This may involve local cleansing of the skin; application of a neutral paste containing glycerol or a similar agent to remove air bubbles; smoothing of hair; and, in some cases, shaving of a local area. One or more packets containing gelatin or water may be attached externally to the outside contour of the body. These will remain attached during the diagnostic process. In an alternative procedure, the part of the body to be studied may be immersed in water solution while the picture is being taken.

b. Positioning will be similar to routine X-ray diagnostic shots and will require holding the appropriate position for a short period of time.

c. One to three diagnostic pictures will be taken using _____* particles (actual exposure is only a fraction of a second). After a special development process that might take one or two hours, the procedure may be repeated from another exposure angle. There will be no spcial sensation or discomfort from the particles.

d. The packets are removed at the end of the procedure, and processing and interpretation of the radiographs will take some time. Results will be transmitted by the patient's physician.

*carbon or helium



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2. The procedures and investigations listed above have been explained to me by _____. He will be present during the procedure, and I may ask further questions and clarification from him at any time.

3. I understand that the procedures and investigations described above involve the following possible risks and discomforts:

a. The combined dose of irradiation from the particles that will be used will result in a radiation dose less than that received in X-ray diagnostic tests for my condition. Together with the previous X rays I have received at the hospital, total dose will be less than that received in two X-ray procedures.

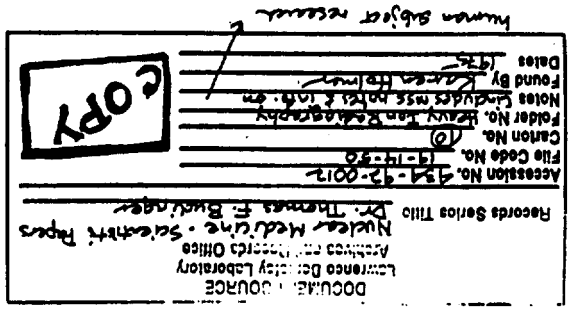
b. Any discomfort I may experience would be similar to that in routine X-ray diagnostic procedures and would be due to the necessity of remaining still for short periods of time while in a somewhat restrained position.

These studies will result in information leading to a better understanding of my disease and may help in planning treatment.

I understand that I may terminate my participation in the study at any time.

Patient's signature _____

Witness _____



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