

September 25, 1981

TO: Bio-Med Scientific Staff *[Signature]*

RE: Research Involving Human Subjects

It is time to remind all investigators that any project at LBL, whether DOE, NIH, or other source, which will in any way involve human subjects must be approved by the LBL Human Use Committee and the Campus Committee for Protection of Human Subjects prior to initiation of research. The following questions and answers address some of the more frequent misunderstandings in complying with Federal Regulations on Human Use.

1. What constitutes human subject involvement?:

In addition to the obvious use of human subjects in a research study, human subject involvement extends to include the use of questionnaires, and the use of fluids, tissues, cells, or other material of human origin (even if the material is residual and even if only one drop of fluid is used). Under the new regulations, the use of some existing data, pathological specimens, or diagnostic specimens may be exempt -- but contact Jan DeMoor to find out if your project would qualify.

2. Is human use approval required for a "pilot study" involving only a few subjects?:

Yes. Human subject approval is required prior to initiating any study or performing a single experimental procedure which involves human subjects. This is set forth by Federal Regulations and we must comply.

3. Can I use Donner Laboratory employees in my study?:

The policy of the Biology and Medicine Division is that all members of the subgroup must be excluded from participation. This includes all supporting members of the group (clerical and technical personnel, and so forth) but does not include the investigators. Investigators may take part in their own study if they follow the conditions of item 5. below. This policy was set to avoid any possible coercion of subjects.

4. What if the investigator is the only subject to be used?:

LBL Policy and Procedure (Vol. II, No. 4, 4/26/76) states that "Investigators must understand that projects in which the investigator is the only subject require review and approval."

DOCUMENT SOURCE	
Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<i>R & D Administrative Files Biology & Medicine Division 1976-86</i>
Accession No.	<i>434-89-0070</i>
File Code No.	<i>16-5-034</i>
Carton No.	<i>(5) of (6)</i>
Folder No.	<i>Human Use Comm., LBL</i>
Notes	<i>Policy & Procedure for Human Use</i>
Found By	<i>Karen Holmes</i>
Dates	

COPY

3004173

TO: Biomed Scientific Staff

5. Do investigator-subjects need to sign a consent form?:

Yes. Investigator-subjects must follow the same procedures as any other volunteer **when** taking part in a research study. Experience has demonstrated that **investigators** tend to be less rigorous in providing themselves with the **precautionary techniques** they use with their subjects. Also, an investigator who **utilizes** himself/herself repeatedly may, by the sum of the investigations, do harm that a single study would not do.

Investigators may take part in a study under the following conditions:

- 1) The research protocol has HUC and CPHS approval;
- 2) The investigator meets the same standards of eligibility as other volunteers;
- 3) The investigator signs a consent form.

6. Can I make a change in the procedure of an approved protocol?:

Changes in the protocol must be reported to the LBL Human Use Committee. If it is a modification that results in no increase in risk to the subjects involved, it may be handled administratively (and the document reporting the change would become a part of your human use file).

Modifications which increase the risk (you need to take more blood, or an additional test or procedure is required) will be submitted as a protocol addendum, and review and approval of the HUC and CPHS is required before the change can be initiated.

If you have questions about this, talk to Jan DeMoor and she will help you work it out expeditiously. Also, the HUC often helps the investigator in wording his/her protocol initially to allow sufficient range in setting the approved limits so that such problems can be avoided.

7. Do collaborative studies have to be approved too?

Yes. It is very important that we have appropriate documentation in each research file showing that all studies involving human subjects have been properly reviewed and approved for human use.

For collaborative studies you should obtain a copy of the protocol, consent form(s) used, and human use approval letter from the responsible institution. You then submit a transmittal letter (brief statement concerning your involvement in the collaboration) along with the documents to the HUC for review and approval.

8. What is the procedure when an untoward event occurs during a research study?:

All untoward events must be reported promptly to the LBL Human Use Committee (who in turn will see that CPHS is properly notified). Federal regulations require that review committees be aware of such events, and this is a condition stated in the approval letter you receive from CPHS for all studies.

3004174

DOCUMENT SOURCE	
Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<i>R & D Administrative Files Biology & Medicine Div. 1976-86</i>
Accession No.	<i>434-89-0070</i>
File Code No.	<i>16-5-034</i>
Carton No.	<i>5 of 6</i>
Folder No.	<i>HUMAN USE COMM. LBL</i>
Notes	<i>Policy & Procedure for Human Use</i>
Found By	<i>Karen Holmes</i>
Date	

COPY

September 25, 1981

-3-

TO: Biomed Scientific Staff

Please note that this is an advisory procedure to keep the review committee up to date on problems encountered in your study. The investigator reports that "such-and-such" occurred, how the situation was handled, and, when necessary, what procedural changes were made in your protocol to prevent a recurrence.

9. Where are consent forms kept?:

The original signed consent forms are to be sent to Jan DeMoor (459 Donner) for permanent retention.

We hope this information will help you to comply with Federal Regulations for the protection of human subjects in research projects. If you have further questions concerning these regulations, or need help in preparing human use protocols and/or consent forms, please get in touch with Jan DeMoor who will be glad to help.

Edward L. Alpen

ELA:dls

DOCUMENT SOURCE	
Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	R & D Administrative Files Biology & Medicine Div. 1976-86
Accession No.	434-09-0070
File Code No.	16-5-034
Carton No.	⑤ of ⑥
Folder No.	Human Use Comm., LBL
Notes	Policy & Procedure for Human Use
Found By	Karen Holmes
Date	

COPY

3004175

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title Research Program and Project
Grant Files

Accession No. 1
File Code No. 15-11-86
Clinton No. 1/1 (Management)
Folder No. Pituitary Irradiation Program
Notes Consent Form
Found By John Stone
Date 1957-1972

COPY

TREATMENT PERMIT

fully aware of the serious nature of my illness and the fact that all conventional methods of treatment have been tried and at the present time there is nevertheless extension of the disease process. I, therefore, on the advice of my own physicians, have applied to the Donner Pavilion and Donner Laboratory of the University of California for consideration of pituitary irradiation. It is fully understood that the treatment proposed is new and that its effectiveness on the course of my disease cannot be predicted with accuracy. However its possible benefit is believed to outweigh the hazards of any untoward effects.

The treatment consists of repeated irradiation of the pituitary with the cyclotron beam, which is expected to cause some degree of ablation of the pituitary, either total or partial, and would, therefore, effect some metabolic changes which will require replacement therapy.

These possible endocrine changes may further result in loss of fertility. I have also been informed that since the pituitary is located in the center of the brain and is surrounded by the brain, brain stem and certain of the cranial nerves that there might be some injury to these closely adjacent structures as a result of irradiation. It is understood that such possible injury might affect the function of these organs and the risk of these hazards is hereby accepted. I hereby consent to treatment on the above understanding and with full knowledge of side effects.

I further authorize the release of any medical information regarding my illness from any physician who has or will be treating me.

copy

I also consent to the taking of such photographs as may be considered desirable or useful for the staff of Donner Laboratory and Pavilion for the purpose of evaluating my illness and the use of such photographs for teaching, research or reproduction in scientific publications.

I also agree that the period of receiving such treatments, the need for and length of hospitalisation, shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for follow-up studies. In the event of my death from any cause whatsoever

I hereby authorize and permit a post mortem examination and it is my express intent that such permission shall have the same effect and validity as a testamentary disposition. I further grant permission for the removal and use of such tissues as may be deemed necessary for the course of study and research purposes, if such removal is deemed desirable by my physicians for medical and research purposes.

Witness: _____

Date: _____

I further consent and authorize _____ relative to my _____ concerning _____

Signed: _____

I also agree that the period of hospitalisation, the need for and length of hospitalisation, shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for follow-up studies.

With _____

With _____

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title Research Program and Project
Grant files

Accession No. _____
File Code No. 13-11-26
Carton No. 1/1 (Marionne - 200)
Folder No. Primary Irradiation Program (Loose papers)
Note: Consent form
John Stone
1957-1978

copy

3004177

DECLASSIFIED BY: [redacted] DATE: [redacted]

Perhaps Laguna, of San Francisco, California, as fully aware of the nature of my present illness and the fact that all conventional methods of treatment have been tried and that at the present time there is nevertheless extension of the disease process. I therefore, on the advice of my own physicians, have applied to the Donner Pavilion and Donner Laboratory of the University of California for consideration of further treatment and have been informed that treatment will be tried. It is fully understood that the treatment proposed is new and that the results of treatment are uncertain and cannot be anticipated in advance. The treatment consists of repeated irradiation of the pituitary with the x-ray beam, which is expected to cause some degree of ablation of the pituitary, either total or partial, and would, therefore, effect some metabolic changes which will require replacement therapy. It is also fully understood that possible endocrine changes may result in the loss of fertility. While the effectiveness of such treatment on the course of my disease cannot be anticipated, the possible benefit is believed to outweigh the hazards of any untoward effects. I hereby consent to treatment on the above understanding and with full knowledge of possible side effects.

also 2
above
the first
3
John
Stoner

I further consent that medical records and other information relative to my illness may be available to the physicians conducting said treatments.

I also agree that the period of receiving such treatments, the need for and length of hospitalization, shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for followup studies.

Witness: Marie Beck RN Date: Oct 31, 1958

Witness: Anette Cook RN Signed: [redacted]

DOCUMENT SOURCE
 Lawrence Berkeley Laboratory
 Archives and Records Office

Records Series Title Research Program and Project
Grant files

Accession No. _____
 File Code No. 13-11-26
 Carton No. 1/1 (1958-1959)
 Folder No. Pituitary Irradiation Program (loss of papers)
 Notes Consent form
 Date John Stoner
1958

3004178

TREATMENT PERMIT

PRIVACY ACT MATERIAL REMOVED

I (we) [REDACTED], bearing the relationship of parent(s) and legal guardian(s) to [REDACTED] am (are) fully aware of the serious nature of his illness and the fact that no presently known form of treatment can be expected at most to achieve any more than a temporary remission of his disease. I (we) therefore on the advice of my (our) physicians have applied to the Donner Laboratory of the University of California for consideration of treatment with radioactive yttrium. It is fully understood that the treatment proposed is new and that the results are uncertain. The treatment consists of injection and intravenous recirculation of the urine containing a chelated yttrium compound throughout his body which is anticipated and hoped will affect tumor cells and their proliferative processes. It is further understood that other cells and organ systems may be adversely affected and the risks and hazards of the procedure itself and any future effects thereof are hereby acknowledged and accepted.

I further consent that medical records and other information relative to his illness may be available to the physicians conducting said treatments.

I hereby consent to and authorize the taking of photographs to be used in following the course of his illness and further consent to the use of such photographs for medical presentation.

I also agree that the period of receiving such treatments, the need for and length of hospitalization shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for followup studies.

Witness: Galvan M. Hain

Signed: [REDACTED]

Witness: William E. Peterson

Signed: [REDACTED]

Date: 28 NOV 61

I (we), [REDACTED], bearing the relationship of parent(s) and legal guardian(s) to [REDACTED] am (are) fully aware of the serious nature of his illness and the fact that no presently known form of treatment can be expected at most to achieve any more than a temporary remission of his disease. I (we) therefore on the advice of my (our) physicians have applied to the Donner Laboratory of the University of California for consideration of treatment with radioactive yttrium. It is fully understood that the treatment proposed is new and that the results are uncertain. The treatment consists of injection and intravenous recirculation of the urine containing a chelated yttrium compound throughout his body which is anticipated and hoped will affect tumor cells and their proliferative processes. It is further understood that other cells and organ systems may be adversely affected and the risks and hazards of the procedure itself and any future effects thereof are hereby acknowledged and accepted.

I further consent that medical records and other information relative to his illness may be available to the physicians conducting said treatments.

I hereby consent to and authorize the taking of photographs to be used in following the course of his illness and further consent to the use of such photographs for medical presentation.

I also agree that the period of receiving such treatments, the need for and length of hospitalization shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for followup studies.

Witness: Graham M. Hair DOCUMENT SIGNATURE
Lawrence Berkeley Laboratory
Archives and Records Office
Signed: [REDACTED]
 Witness: William E. Fitch

Date: 28 NOV 61

Records Series Title	Lawrence Berkeley Laboratory Edward Medical Records Case 514
Accession No.	034-89-0022
File Code No.	8-3-9
Carton No.	1194
Folio	61-96 Marion, David
Name	Anna George
Date	1961

COPY

3004180

DATE 10-16-75

PRIVACY ACT MATERIAL REMOVED

I, [REDACTED] DO HEREBY PERMIT MY
PHYSICIAN John A. Linfoot M.D. TO USE
L-Dopa IN THE THERAPY FOR MY CONDITION.
IT IS MY UNDERSTANDING THAT THIS IS AN INVESTIGATIVE DRUG,
AND I HEREBY ABSOLVE DONNER PAVILION FROM ALL LIABILITY.
THE TYPE OF DRUG USED AND ITS SIDE EFFECTS HAVE BEEN
EXPLAINED TO ME.

Signed [REDACTED]

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title Lawrence Berkeley Laboratory
Patient Medical Record Case Files

Accession No. 424 89 0036

File Code No. R-3-9

Carton No. 45/55

Folder No. Resquinin Ignace

Notes _____

Found By Anna Perge

Dates 1975

COPY

PRIVACY ACT MATERIAL REMOVED

TREATMENT PERMIT

I, [REDACTED] RA of [REDACTED] Sonora, Mexico

am fully aware of the serious nature of my illness and that at the present time there is progression of the disease process. I, therefore, on the advice of my own physicians, have come here for treatment. It is fully understood that the effectiveness of the treatment on the course of my disease cannot be predicted with accuracy. However, its possible benefit is believed to outweigh the hazards of any untoward effects.

The treatment consists of repeated irradiation of the pituitary with the cyclotron beam, which is expected to cause some degree of ablation of the pituitary, either total or partial, and would, therefore, effect some metabolic changes which will require replacement therapy. These possible endocrine changes may further result in loss of fertility. I have also been informed that since the pituitary is located in the center of the brain and is surrounded by the brain, brain stem and certain of the cranial nerves that there might be some injury to these closely adjacent structures as a result of irradiation. It is understood that such possible injury might affect the function of these organs and the risk of these hazards is hereby accepted. I hereby consent to treatment on the above understanding and with full knowledge of possible side effects.

I further authorize the release of any medical information regarding my illness from any physician who has or will be treating me.

I also consent to the taking of such photographs and x-rays as may be considered desirable or useful for the staff of Donner Laboratory and Pavilion for the purpose of evaluating my illness and the use of such photographs and x-rays for teaching, research or reproduction in scientific publications.

I also agree that the period of receiving such treatments, the need for and length of hospitalization, shall be determined by the physicians in charge and that I will, thereafter, fully cooperate for follow-up studies. In the event of my death from any cause whatsoever I hereby authorize and permit a post mortem examination and it is my express intent that such permission shall have the same effect and validity as a testamentary disposition. I further grant permission for the post mortem removal and use of such tissues as may be deemed necessary or desirable by my physicians for medical and research purposes.

Signature: [REDACTED] Date: 29/I/76
Witness: [Signature] Date: 29/I/76
Witness: Mary [Signature]

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title	Lawrence Berkeley Laboratory Patient Medicine Records
Accession No.	434-87-0038
Filo Code No.	2-3-9
Carton No.	45/55
Folder No.	Pesqueira, Ignacio
Notes	
Found By	Anna Berge
Date	1976

COPY

3004182
XBG-396-6171

PRIVACY ACT MATERIAL REMOVED

CONSENT TO THE USE OF RESIDUAL BLOOD

For Purposes Not Directly Related To Medical Care

Patient's Name [REDACTED] Date 3-13-78

In the investigation, diagnosis and treatment of my disease at Donner Pavilion, blood is routinely withdrawn for recognized clinical and laboratory tests or for control of my illness. The amounts withdrawn are calculated for requirements directly pertaining to my care. Varying amounts remain (residual blood), which are ordinarily discarded, but which can be used to advantage for medical and scientific research purposes not directly related to my care. I hereby consent to the use of such residual blood for the above purposes.

I understand that JOHN A. JENFOOT, M.D., F.A.C.P. and/or such assistants as may be selected by him/her will answer any inquiries I may have concerning the foregoing uses.

I understand that there will be confidentiality maintained as to the identification of the residual blood.

I understand that there will be no risk, hazard or discomfort to me as a consequence of this consent.

I understand that the use of residual blood may have no direct benefit to me but will benefit the understanding of the bio-medical basis of disease processes and teaching and education in the bio-medical sciences.

I understand that I may withdraw my consent at any time without prejudice to my medical care.

Patient's Signature [REDACTED]

If patient is a minor (age)

Signature of parent or legal guardian [REDACTED]

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title Lawrence Berkeley Laboratory
Patient Medical Records Case Files
Accession No. 434-89-0038
File Code No. 8-3-9
Carton No. 45/55
Folder No. Perreira, Ignacio
Notes _____
Found By Anne Berg
Date 1978
(Please indicate)

COPY

3004183

PRIVACY ACT MATERIAL REMOVED

CONSENT TO THE USE OF PATIENT DATA DERIVED FROM STANDARD TESTS

For Purposes Not Directly Related to Medical Care

Patient's Name [REDACTED] Date 3/13/78

1. In the investigation, diagnosis and treatment of my disease at the Donner Pavilion, standard diagnostic tests are performed for the evaluation of my illness. The data generated from these tests will be sent to my private physicians and will also be kept on file at the Donner Laboratory and Donner Pavilion to be used to advantage for medical and scientific research not directly related to my care. I hereby consent to the use of such data for the above purposes, including publication in scientific journals.

2. I understand that JOHN A. LIEFOOT, M.D., F.A.C.P. and/or such assistants as may be selected by him/her will answer any inquiries I may have concerning the foregoing uses.

I understand that the information will be used anonymously.

I understand that there will be no risk, hazard or discomfort to me as a consequence of this consent.

I understand that the use of the data may have no direct benefit to me but will benefit the understanding of the bio-medical basis of disease processes and teaching and education in the bio-medical sciences.

I understand that I may withdraw my consent at any time without prejudice to my medical care.

Patient's signature [REDACTED]

If the patient is a minor (age)

Signature of parent or legal guardian (please indicate)

DOCUMENT SOURCE	
Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<u>Lawrence Berkeley Laboratory</u>
Accession No.	<u>434-89-0</u>
File Code No.	<u>8-3-9</u>
Carton No.	<u>45/55</u>
Folder No.	<u>Pasquerra, Ignacio</u>
Notes	
Found By	<u>Anna Berg</u>
Date	<u>1978</u>

COPY

INFORMED CONSENT

PRIVACY ACT MATERIAL REMOVED

NAME

[REDACTED]

DATE

3-16-78

Use of the drug synthetic thyrotropin releasing hormone has been explained to me. I understand that the drug will be injected in the vein and that serial blood samples will be taken for 2 hours after the injection.

I understand that possible side effects include a transient urge to urinate, flushing, and very rarely, nausea.

I understand that this is a test to measure pituitary hormone reserve, and that it is not a treatment in any way.

I understand that any questions that I might have about the treatment procedure will be answered in full and that I or my physician may terminate my participation in the study at any time.

SIGNATURE

[REDACTED SIGNATURE]

WITNESS

M. Hunter, MD

If patient is a minor, signature of guardian _____

Relationship to patient _____

DOCUMENT SOURCE
Lawrence Berkeley Laboratory
Archives and Records Office

Records Series Title Lawrence Berkeley Laboratory
Patient Medical Record Case Files
Accession No. 434-89-0038
File Code No. 2-3-9
Carton No. 45/55
Folder No. Bonquerra, Ignacio
Notes _____
Found By Lina Becap
Dates 1972

COPY

3004185

Use of the drug synthetic gonadotropin releasing hormone has been explained to me. I understand that the drug will be injected in the vein after appropriate baseline samples of blood are drawn, that 5 more blood samples will be withdrawn after the drug is injected, that the main part of the test will take 2 1/2 hours, and that an additional sample will be drawn 4 hours later.

I understand that there are no known side effects associated with the use of this drug, but that there may be transient discomfort associated with venipuncture.

I understand that this test is a diagnostic test to measure hormones from my pituitary gland that are associated with reproductive function, and that it is not a treatment in any way.

I understand that this test will provide information regarding current pituitary function as well as the effects of pituitary surgery or irradiation which may be important with respect to fertility and testicular or ovarian hormone secretion.

I understand that any questions that I might have about this test will be answered in full and that I or my physician may terminate my participation in the test at any time.

PRIVACY ACT MATERIAL REMOVED

SIGNATURE

WITNESS

patient is a minor, signature of guardian _____

relationship to patient _____

DOCUMENT SOURCE Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<u>Lawrence Berkeley Laboratory Patient Medical Records Case Files</u>
Accession No.	<u>434-89-0038</u>
File Code No.	<u>8-3-9</u>
Carton No.	<u>38189 45/55</u>
Folder No.	<u>1528 Penicillin Therapy</u>
Notes	
Found By	<u>Anna Garcia</u>
Dates	<u>1970</u>

COPY

February 1978

PRIVACY ACT MATERIAL REMOVED

M. J. Albrink

CONSENT FORM: BLOOD GROUP STUDY

If you are participating in the LBL lipid-cholesterol screening program, the Donner Laboratory Lipoprotein Group is also interested in the relationship between lipoprotein patterns and blood group. Blood group typing will be done, using the blood drawn for the lipoprotein screening. No extra blood will be needed. Even though you may know your blood group, for the purpose of this study we would like to do the test at LBL.

Blood Group O persons may have less coronary artery disease than do Group A persons, possibly because Group O persons tend to have lower cholesterol than Group A persons. Lipoproteins have not previously been correlated with blood groups.

The Donner Laboratory Lipid Research Group will use the information gained to determine whether there are differences in one or more lipoproteins amongst the blood groups. Since sex, age, weight, height, race, and other genetic factors may also influence lipoproteins, it would be highly desirable to have the information requested below. The information will be confidential, and any resulting publications will report only statistical results. The identity of individual participants will be confidential, and will not be disclosed.

The study will aid the understanding of genetic aspects of hyperlipidemias, and will therefore advance knowledge regarding the treatment and prevention of coronary artery disease and atherosclerosis.

Your participation in the Blood Group study and provision of the information requested below is entirely voluntary. If you have any questions concerning this study, or wish to know what your blood group is, please call Dr. M. J. Albrink at 642-7639.

Age [redacted], F M Height: [redacted] Feet [redacted] Inches. Weight [redacted] Pounds, Eye color BLUE
Race: White Oriental , Black , Other

Please notify my physician (listed on lipoprotein consent form) of my blood group:

Yes No

Signature [redacted]

3004187

DOCUMENT SOURCE Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<u>Research + Development File Operations</u>
Accession No.	<u>434 - 93 - 0231</u>
File Code No.	<u>DATE Aug 3 1978 2-4-6</u>
Carton No.	<u>1215</u>
Folder No.	<u> </u>
Notes	<u> </u>
Found By	<u> </u>

COPY