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| NOTES                 | Metabolic Unit - Liability / release 7 of 8   |      |
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UNIVERSITY OF CALIFORNIA  
BERKELEY 4, CALIFORNIA  
FORM 187  
OFFICE OF THE  
VICE-PRESIDENT-BUSINESS AFFAIRS

May 27, 1950

MR. JAMES MILLER  
ASSISTANT BUSINESS MANAGER,  
UNIVERSITY OF CALIFORNIA  
ADMINISTRATION BUILDING

Dear Mr. Miller:

Attached herewith are copies of proposed forms for our use with the Cowell Unit as follows: Exhibit A. - Release; Exhibit B. - Statement to the Patient About to be Hospitalized; Exhibit C. - Overnight Pass.

These forms have been worked out by Dr. John H. Lawrence and his medical staff. As you may recall, we were originally requested through your office to submit proposed forms for a decision to be rendered by the University attorneys regarding this matter.

It would be appreciated if this matter could receive your early attention in that it has taken some considerable time to work up, and it would be very desirable if a decision could be reached prior to Dr. Lawrence's departure for Europe approximately the first of July.

Sincerely,

BEST COPY AVAILABLE

/s/ R. A. San Souci  
Administrative Officer

RAS:mg

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BERKELEY: OFFICE OF THE BUSINESS MANAGER

June 5, 1950

*copy to  
Dr. Rogers*

*call shell + jmc  
med. Sci.*

*aug 7*  
~~Sept~~  
*Oct 9*

*Nov 27*

MEMORANDUM TO MR. CORLEY:

The Division of Medical Physics has submitted three proposed forms of release to be used in connection with patients being treated at Donner Laboratory.

As you know the medical cases admitted to medical attention at Donner, and in some instances actual hospitalization at Cowell for purposes of clinical investigation, involve very serious medical cases wherein a majority of the patients are given up as hopeless medical cases by their regular physician. For example, they recently had a case wherein the patient was admitted as a hopeless case and was treated by Donner Laboratory out of research funds of various donors. The patient's condition became so grave that even Donner Laboratory agreed that further expense and care at Cowell was unwarranted. Steps were taken to have the patient returned to his home or his own physician but the patient's family refused to allow the patient to be moved. It was at this point that necessary releases were required in order to protect the University. No releases had been obtained, however, and we therefore kept the patient at Cowell until his death.

May I request, therefore, that the attached proposed releases be reviewed by the Attorney for the purpose of giving to Donner Laboratory the necessary legal protection involving admittance and care of these unusual medical cases.

*J. Miller*  
James M. Miller  
Assistant Business Manager

JEM/if

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| NOTES                 | Metabolic Unit - liability release 4/28   |
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**COPY**

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BERKELEY 4, CALIFORNIA  
FORM 187  
OFFICE OF THE  
VICE-PRESIDENT-BUSINESS AFFAIRS

**DONNER METABOLIC UNIT**  
For Clinical Investigation.  
Cowell Memorial Hospital  
University of California  
Berkeley, California

(Exhibit C)

OVERNIGHT PASS

Date: \_\_\_\_\_

Patient's name \_\_\_\_\_ Service \_\_\_\_\_

has permission to be absent from \_\_\_\_\_

Signed \_\_\_\_\_  
(Chief of Service)

per \_\_\_\_\_  
(Attending Physician)

Release: - I hereby release the University from all responsibility during my absence.

\_\_\_\_\_  
(Signature of Patient)

1. This form is to be prepared in duplicate.
2. The duplicate copy will be filed with the patient's Donner Clinic record.
3. The original copy will be filed with the patient's Hospital Chart.

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**DONNER METABOLIC UNIT**  
For Clinical Investigation.  
Cowell Memorial Hospital  
University of California  
Berkeley, California

(EXHIBIT B)

Dear \_\_\_\_\_:

You will be hospitalized in the Donner Metabolic Unit at the Cowell Memorial Hospital for purposes of clinical investigation and treatment under the care of the Chief of Service of the Donner Metabolic Unit and his staff of attending physicians. You will be hospitalized for a period of \_\_\_\_\_ days at our expense for the purpose of carrying out the studies and treatment which we have previously discussed with you. Should you become ill in the hospital, we will undertake to hospitalize you for an additional period of \_\_\_\_\_ days at our expense. At the end of this period of time we will require that the cost of hospitalization be undertaken by you or that you leave the hospital provided your condition permits and the Chief of Service approves your transfer.

I have read the above statement.

DATE \_\_\_\_\_

Signature \_\_\_\_\_

Signed \_\_\_\_\_  
(Chief of Service)

per \_\_\_\_\_  
(Attending Physician)

Note: A copy of this letter will be retained by the patient and an additional copy filed with your hospital records.

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BERKELEY 4, CALIFORNIA  
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VICE-PRESIDENT-BUSINESS AFFAIRS

DONNER METABOLIC UNIT  
For Clinical Investigation.  
Cowell Memorial Hospital  
University of California  
Berkeley, California

(EXHIBIT A)

RELEASE

Berkeley 4, California

19

This is to state that I am a patient of the Donner  
Metabolic Unit for Clinical Investigation, (Cowell Memorial Hos-  
pital) University of California, Berkeley; that I have been ad-  
vised by the doctors who are attending me at said hospital that  
I should not at this time leave the hospital but should remain  
for further care and attention; that I hereby release the said  
hospital, all of its employees and members of its staff, and  
The Regents of The University of California from any and all  
responsibility to me of any kind or sort whatsoever, and I agree  
that I have not, nor will I claim, any right of compensation  
from them, or any of them, from any cause or causes whatsoever.

Witness:

I am a relative, to wit, \_\_\_\_\_ of the  
patient who has signed the above statement and release, and I do  
hereby approve and join in said statement and release.

Witness:

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360-B

June 10, 1950

Memorandum to Mr. J. M. Miller:

I am returning Mr. San Souci's letter to you of May 27, 1950 and enclosures, which you sent to me concerning the request for approval of release forms for the handling of patients at the Donner Laboratory and Cowell Hospital. This proposal brings to light the general subject of patients being treated at Donner Laboratory and Cowell Hospital under our research programs. It does seem to me that this important subject should be discussed with members of the University staff in San Francisco responsible for the operation of hospitals and handling of patients within our medical facilities. It is my suggestion that the activities on the Berkeley Campus be supervised and coordinated by our staff in San Francisco.

*(in reply to Miller memo to Corley dated 6-5-50)*

The University Attorney has indicated that release forms of this type have very little legal significance in avoiding claims for liability either against individuals or the University. Most important is the proper care in the handling of patients and it is the best protection against claims.

This matter was presented to the Coordinating Council on Medical Sciences on June 7 and will be a subject for discussion before this group at an early date. In the meantime, it is my suggestion that you request the assistance of Mr. Stull and others at the Medical Center in San Francisco, to advise in connection with the handling of patients in these two buildings.

I am sending a copy of this to the President for his information.

James H. Corley  
Vice-President - Business Affairs

Enclosures

ccs: President Sproul  
Mr. Calkins  
Dr. Donald  
Dean Rogers  
Mr. Stull

JHC:DC

1157781

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COMMITTEE ON RADIOISOTOPES AND RADIOLOGICAL SAFETY

Policies

(As amended by the Administrative Committee on December 4, 1956)

(1) This Committee is responsible to the Administrative Committee of the San Francisco Campus and shall report its discussions, decisions, and actions to them.

(2) The function of this Committee is to examine all aspects of applications for use of ionizing radiations on the San Francisco Campus and to approve or to withhold approval of the project.

(3) Members of the faculties of the schools and colleges on the San Francisco Campus will be eligible to use ionizing radiation in studies other than those involving administration of ionizing radiation to humans providing the application is accepted on the basis of the other criteria which this Committee must approve.

(4) When ionizing radiations are to be administered to humans in any amount for therapeutic or diagnostic purpose, the user must first have the permission of the Committee.

(5) Projects involving the administration of ionizing radiation to humans with therapeutic intent or in levels which will achieve therapeutic results must be under the direction of one trained in therapeutic radiology who is a member of the Staff in the Department of Radiology.

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| NOTES   | 10/15/57                                 |
| FOUND BY  | A. MUGLIER                               |

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COMMITTEE ON RADIOISOTOPES AND RADIOLOGICAL SAFETY

The following is to be The Thinking of the Committee, as of September 10, 1957  
and to be Used as a Guide for Considering Requests for the Use of Radioisotopes in  
Normal Human Volunteers.

The Committee, after mature consideration of an individual radioisotope application, is willing to grant permission to use radioisotopes in normal volunteers, if the experiment passes their judgement, and with the permission of the normal human volunteer.

Each individual investigator is to be personally responsible for establishing whether or not a prospective normal volunteer has ever had previous administration of radioisotopes. If he has, that person is not to receive further dose without permission of the Committee.

A volunteer should be used only if he or she has passed the age of 40 years, or is afflicted with some disease that would shorten his or her life expectancy.



Earl R. Miller, M. D.  
Chairman, Committee on the  
Use of Radioisotopes and  
Radiation Safety.

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| NOTES                | Consent Forms  |         |
| FOUND BY             | M. HONES   | 11/7/94 |

111-5

SAN FRANCISCO UNIVERSITY OF CALIFORNIA MEDICAL CENTER  
UNIVERSITY OF CALIFORNIA HOSPITALS

April 14, 1959

John Adams, M. D.  
Chief of Staff  
Department of Neurosurgery  
University of California Hospitals

Dear Doctor Adams:

Re: Consent Forms for Patients Receiving  
Radioactive Isotopes

Currently, before administration of radioactive iodine to a patient for purpose of diagnosis or therapy, we are requesting the patient to sign a consent form. Initially, these forms were adopted at the request of the Atomic Energy Commission. However, in recent years, the Atomic Energy Commission no longer makes such a request.

With the passage of time, the various diagnostic and therapeutic procedures with radioisotopes have tended to become accepted clinical procedures, and it no longer seems necessary to single these procedures out to request patient permission. The exception would be the rare therapeutic use of radioisotopes in minors. In general, it would seem dangerous to continue to use these forms inasmuch as their use implies to the patient some unusual hazard.

We, therefore, request permission to discontinue use of consent forms for procedures with radioactive isotopes excepting where therapy is being so administered to patients less than 21 years of age.

Sincerely,



Robert S. Stone, M. D.  
Chairman  
Department of Radiology

GES:ajs

Encl.

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| NOTES                | Consent forms  |             |
| FOUND BY             | M. HONES   | 11/7/94     |

INFORMATION FOR PATIENTS RECEIVING RADIOIODINE

In order to study how your thyroid gland (goiter) is acting, we need to give you a small amount of radiiodine.

Radiiodine gives off radiations called beta rays and gamma rays. These rays are like x-rays and too many of them are harmful, but thousands of people are examined by means of x-rays every day with no harmful effects. To the best of our knowledge, the amount of radiation you will receive will do you no harm.

We want you to understand that you are receiving small quantities of radiation after you drink the solution of radiiodine and ask you to sign that you have read and understand this brief statement.

DO NOT SIGN THIS IF YOU ARE PREGNANT.

Signature \_\_\_\_\_

Date \_\_\_\_\_

Witness:

\_\_\_\_\_

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| FOLDER NAME           | WILLIAM STEWART, <del>WILLIAM</del> HUFFMAN Pg 1/9  |      |
| NOTES                 | REVISED PROC. ON CLINICAL RESEARCH INVOLVING HUMAN SUBJECTS 7/1/66                                |      |
| FOUND BY/DATE FOUND   | KAREN HOLMES 10/24/94   |      |



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
9000 ROCKVILLE PIKE  
BETHESDA, MD. 20014

July 1, 1966

TO : Heads of Institutions Receiving Public Health Service Grants  
FROM : Surgeon General, Public Health Service  
SUBJECT: Revised procedure on clinical research and investigation involving human subjects

On February 8, 1966, I issued a policy statement relating to investigations involving human beings, including clinical research, pointing out the need for group review to protect the rights and welfare of the human subjects involved. The original policy involved only the support of research and research training. The application of this policy has been extended to all grants and awards of the Public Health Service in the support of research, training, or demonstration projects, including the projects supported through general research support and those of fellows and trainees. The policy is not applicable to grants in support of construction, alterations, renovations, or research resources -- it is obviously applicable to the Public Health Service projects using these facilities and resources.

Experience gained in administering this policy has led to revision and simplification of procedure. The major procedural revision is one for making agreements between each grantee institution and the Public Health Service which will obviate the necessity for providing detailed assurance with each application. Attached to this memorandum is a statement of revised policy and procedure (Policy and Procedure Order 129) which has been issued at my instruction.

The Public Health Service will continue its study of the issues of investigations involving human subjects. As experience shows the need for revised or augmented policy or procedures, these will be developed. I shall be pleased to receive suggestions and information from officials and investigators of grantee institutions to assist the Service in the conduct of its study.

I trust that these revisions, reflective of the advice I have received from many of you, will facilitate your discharge of this important obligation.

*William H. Stewart*  
William H. Stewart, M.D.

Attachment

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| Revised proc. on CLINICAL RESEARCH<br>involving human subjects 7/1/66                             |      |
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| H. HOLMES 10/24/94  |      |

U. S. Public Health Service  
Division of Research Grants  
Bethesda, Maryland 20014

PPO #129, Revised  
POLICY  
July 1, 1966

SUBJECT : Investigations Involving Human Subjects, including  
Clinical Research: Requirements for Review to Insure  
the Rights and Welfare of Individuals

APPLICABILITY : All Public Health Service Grants and Awards

EFFECTIVE DATE: Immediately

SUPERSEDES : PPO #129, February 8, 1966  
PPO #129 Supplement, April 7, 1966

#### I. BACKGROUND:

Culminating several years of study by various Public Health Service  
and advisory groups, the National Advisory Health Council passed  
the following resolution on December 3, 1965:

"Be it resolved that the National Advisory Health Council  
believes that Public Health Service support of clinical  
research and investigation involving human beings should  
be provided only if the judgment of the investigator  
subject to prior review by his institutional associates  
assure an independent determination of the protection of  
the rights and welfare of the individual or individuals  
involved, of the appropriateness of the methods used to  
secure informed consent, and of the risks and potential  
medical benefits of the investigation."

#### II. POLICY:

The Surgeon General accepted the resolution of the National Advisory Health  
Council and promulgated the following policy statement on February 8, 1966:

"No new, renewal, or continuation research, or research  
training grant in support of clinical research and  
investigation involving human beings shall be awarded  
by the Public Health Service unless the grantee has  
indicated in the application the manner in which the  
grantee institution will provide prior review of the  
judgment of the principal investigator or program  
director by a committee of his institutional associates.  
This review should assure an independent determination:  
(1) of the rights and welfare of the individual or  
individuals involved, (2) of the appropriateness of the  
methods used to secure informed consent, and (3) of the  
risks and potential medical benefits of the investigation.  
A description of the committee of the associates who will  
provide the review shall be included in the application."

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| NOTES   | Revised proc. on clinical research<br>involving human subjects 7/1/66 |
| FOUND BY/DATE FOUND   | K. HOLMES 10/24/94  |

III. REVISED POLICY:

By decision of the Surgeon General, the application of this policy has been extended to all grants and awards of the Public Health Service in the support of research, training, or demonstration projects, including the projects supported through general research support and those of fellows and trainees. The policy is not applicable to grants in support of construction, alterations, renovations, or research resources -- it is obviously applicable to the PHS projects using these facilities and resources.

This policy will be included in all pertinent grant program policy and instruction statements, and will be among the conditions of award agreed upon by grantee institutions and the Public Health Service. The policy applies to all investigations involving human subjects, including clinical research.

A. Assignment of Responsibility

Safeguarding the rights and welfare of human subjects in research support by PHS grants is the responsibility of the institution to which the grant is awarded. The institution must assure the Public Health Service that in the case of investigations and activities supported directly by the PHS, it will provide group review and decision, maintain surveillance, and provide advice for investigators on safeguarding the rights and welfare of human subjects. The institution also has the responsibility to provide whatever professional attention or facilities may be required for the safety and well-being of human subjects. The institution shall be responsible for developing the administrative mechanism for review, surveillance and advice; however, the PHS requires that, prior to inception of each course of investigation, objective decisions be made at the three points cited in the Surgeon General's policy statement (above) by an appropriate committee of associates of the investigator having no vested interest in the specific project involved. The grantee institution may utilize staff, consultants, or both to carry out the review. Any group responsible for review should possess not only specific scientific competence to comprehend the scientific content of the investigations reviewed, but also other competencies pertinent to the judgments that need to be made.

The grantee is required to make and keep written records of the group reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent relating to investigations carried out with the assistance of PHS financial support.

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| NOTES                | Revised proc. on clinical research involving human subjects 7/1/66                                |      |
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B. Timing of Review

While this policy requires that review be conducted prior to the use of human beings as subjects, there are advantages both the PHS and the grantee in having the review conducted prior to application for PHS support. The PHS encourages the institution to do so, if the review can be accomplished without causing unreasonable delay in the application process and if the application is of the type that normally contains a reviewable scientific protocol.

IV. PROCEDURAL REVISIONS -- ASSURANCES OF APPLICANTS AND GRANTEEES

Upon issuance of this policy statement, the PHS will require necessary assurances from the grantee institutions which sponsor investigations involving human subjects, including clinical research. These assurances will cover both the general principles of safeguarding human rights and welfare in the conduct of research and the specific points of the Surgeon General's policy. The assurance should provide explicit information on the policy and procedure it employs for review and decision on the propriety of plans of research involving human subjects. The descriptions will include the competencies represented in the committees of associates utilized for review, the sources of consultants (if used), the administrative mechanisms by which surveillance is provided for projects involving human subjects -- particularly to deal with changes in protocol or emergent problems of investigations, the means of guidance and advice provided for investigators, and the manner in which the institution will assure itself that the advice of the committee of associates will be followed. Copies of documents of institutional policies on these issues should be attached to the memorandum of assurance. An example of an acceptable assurance is attached.

Assurances can be provided which apply only to individual major components of universities or other large institutions in those instances where assurances covering the total institution are impracticable or inadvisable.

Each assurance and its attachments shall be transmitted to the Public Health Service, in care of the Chief, Division of Research Grants. When the Public Health Service has reviewed and accepted the assurance, the Chief, Division of Research Grants, shall so notify both the responsible official of the grantee institution involved and all Public Health Service extramural research program offices.

Each grantee institution shall report currently any changes in its policies, its procedures, or the competencies represented on its committee of associates.

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| NOTES<br>REVISED PROC. ON CLINICAL RESEARCH<br>INVOLVING HUMAN SUBJECTS 7/1/66                                       |      |
| FOUND BY/DATE FOUND<br>H. HOLMES 10/24/94  |      |

4

For each application that includes or is likely to include investigations involving human subjects, including clinical research, the applicant institution should make reference to the certification as follows:

"The investigations encompassed by this application have been or will be approved by the committee of associates of the investigator(s) in accordance with this institution's assurance on clinical research dated \_\_\_\_\_."

Until an institution-wide assurance has been accepted by the PHS, the institution can fulfill requirements of this policy for individual studies by submitting an assurance with each application for PHS financial support stating that prior to inception of investigations, the requirements of section III. A. of this Policy and Procedure Order will be followed. The statement must also describe the composition of the group which will conduct the review.

This interim procedure will be acceptable until November 1, 1966. After that date no new, supplemental, renewal, or continuation application for a Public Health Service grant or award to support investigations involving human subjects will be accepted for review unless the PHS has approved an institution-wide assurance.

Nothing in the institution-wide assurance or in the interim policy procedure used in some cases until November 1, 1966, should inhibit PHS staff, advisory groups, or consultants (1) from identifying concern for the welfare of human subjects, and communicating this concern to the grantee institution, or (2) from recommending disapproval of the application if the gravity of the hazards and risks so indicate.

In the case of awards to U.S. citizens receiving fellowships for training abroad, special conditions or circumstances relating to the place at which the training is being provided may upon occasion justify modification of these requirements. Requests from the sponsor for approval of such modifications must be reviewed by the Office of International Research, NIH, and approved by the PHS bureau chief concerned.

Attachment

ORIGINATING OFFICE: Office of the Surgeon General, PHS

APPROVED BY: Grants Policy Officer, OSG

Ernest M. Allen

Date: July 1, 1966

Index: Clinical Research  
Human Subjects, Investigations Involving  
Individuals, Rights and Welfare of

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Example of an Acceptable Assurance

Institutional Assurance on  
Investigations Involving Human Subjects,  
Including Clinical Research

The \_\_\_\_\_ (name of institution) agrees with the principles of the Public Health Service policy (identified as Policy and Procedure Order 129 dated July 1, 1966) with regard to investigations involving human subjects, including clinical research. This institution agrees that review independent of the investigator is necessary to safeguard the rights and welfare of human subjects of research investigations and assures the Public Health Service that it will establish and maintain advisory groups competent to review plans of investigation involving human subjects, prior to initiation of investigations, to insure adequate safeguard. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved (2) the appropriateness of the methods used to obtain informed consent and (3) the risks and potential medical benefits of the investigations.

The institution also agrees to exercise surveillance of PHS-supported projects using human subjects for changes in protocol which may alter the investigational situation with regard to the criteria cited above. The institution further assures the Public Health Service that it will provide advice and consultation to investigators on matters of employing human subjects in investigation, and also that it will provide whatever professional attention or facilities may be required to safeguard the rights and welfare of human subjects involved in investigation. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by the institution.

Attached as part of this statement are copies of policy and procedure of this institution with regard to use of human subjects in investigation, as well as a description of the groups utilized to review projects for enforcement of these policies and the manner in which the institution will assure itself that the advice of the committee of associates is followed.

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Attachments

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The attached statement of Public Health Service policy and procedure, identified as PPO #129, Revised, July 1, 1966, requires that each institution receiving support from the Public Health Service for projects that include the investigation of human subjects send to us, and have approved, an institution-wide statement of assurance concerning investigations that involve human subjects.

We shall accordingly need for your institution an institutional statement of agreement which covers in substance the points of the sample statement attached to the Public Health Service policy issuance of July 1, 1966 (#129), and which bears the signature of the official authorized to sign for the institution.

We shall also need as attachments to this statement a description of the following:

1. The requirements at your institution for the following --
  - a. Group review and decision on the adequacy of provisions for protecting the rights and welfare of the subjects, on the appropriateness of the methods used to secure the informed consent of the subjects, and on the risks and medical benefits of the investigation (please see section A on page 2 and section IV on page 3)
  - b. Bringing to the attention of the committee of associates changes in investigative protocol, which may affect the subjects, before such changes are made, and emergent problems of investigation, which may affect the subjects, when such problems occur
  - c. Conveying the advice of the committee of associates to the investigator concerned
  - d. Assuring the institution that the investigator follows the advice of the committee of associates ( please see section IV on page 3)
2. The competencies represented in the committee of associates (please see section III A on page 2 and section IV on page 3)
3. The sources of consultants, if employed (please see section IV on page 3)
4. Provision of facilities and professional attention necessary for the health and safety of the subjects (please see section III A on page 2)

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Pl. (Cont)

5. The applicability of your statement, i.e., whether institution as a whole or to a specified component of the institution (please see section IV on page 3)

Your early reply will help us hasten the review.

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CONTROL 5

CHECK LIST FOR REVIEW OF ASSURANCES  
REGARDING RESEARCH INVOLVING HUMAN SUBJECTS

PLEASE INITIAL AT RIGHT OF EACH INSTRUCTION YOU WISH TO GIVE

|      |  |  |
|------|--|--|
| A    | Accept   |  |
| A1   | Accept, provided no medical or surgical procedures.  |  |
|      | Do not review because:   |  |
| B1   | Human subjects not involved  |  |
| B2   | Evidently no risks to rights or welfare of subjects  |  |
| B3   | Institution not receiving or requesting PHS support  |  |
| B4   | Get statement of agreement   |  |
| B41  | Statement of agreement inadequate (see comments below)   |  |
|      | Get additional information about:  |  |
|      | Requirements at the institution for group review and decision on --  |  |
| B40  | All three below  |  |
| B401 | The adequacy of provisions for protecting the rights and welfare of the subjects   |  |
| B402 | The appropriateness of the methods used to secure the informed consent of the subjects   |  |
| B403 | The risks and potential medical benefits of the investigation  |  |
|      | Requirements at the institution for --   |  |
| B50  | All three below (surveillance)   |  |
| B51  | Bringing to the attention of the committee of associates changes in investigative protocol, which may affect the subjects, before such changes are made, and emergent problems of investigation, which may affect the subjects, when such problems arise |  |
| B52  | Conveying the advice of the committee of associates to the investigator  |  |
| B53  | Assuring the institution that the investigator follows the advice of the committee of associates   |  |
| B6   | Competencies represented in the committee of associates  |  |
| B7   | Sources of consultants, if employed  |  |
| B8   | Provision of facilities and professional attention necessary for the health and safety of the subjects   |  |
| B9   | The applicability of the statement (to whole institution? to which components? etc. -- see comments below)   |  |

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BERKELEY: COMMITTEE FOR PROTECTION  
OF HUMAN SUBJECTS

March 10, 1978

GUIDELINES FOR THE PREPARATION OF A PROTOCOL

Introduction

This guide outlines the Committee for Protection of Human Subjects's (CPHS) requirements for the preparation of a human subject protocol. It replaces the identically titled set of guidelines last issued on July 20, 1977. Should you have any questions regarding these guidelines, please contact the Committee staff at M-11 Wheeler Hall, 2-7461.

The Guidelines

Protocols must be prepared for all research, development, or related activities in which human subjects are involved or in which there is a question of involvement.

A protocol, suitably titled or identified, is a statement by the investigator which includes the following information, as applicable:

1. A brief summary of the nature and purpose of the research, development, or related activity.
2. A full description of the subjects, including the number proposed, their characteristics, and how they will be selected or recruited. Indicate explicitly whether any are minors (under age 18 according to California law) or otherwise members of "vulnerable" populations (the mentally or physically infirm, prisoners, or other individuals whose ability to give voluntary informed consent may be in question). Also, the protocol must indicate if any subjects are University of California students.
3. A detailed description of how the subjects are to be involved in the activity. If human remains or residual material are to be used, details on their origin, nature, and disposition should be given.
4. A description of the benefits, if any, to the human subjects and/or the benefits to knowledge.
5. A description of the risks, if any, to the subjects. Such risks may be physical, psychological, or social (see Appendix A).
6. A description of the means to be taken to minimize such risks, including the means by which the subject's personal privacy is to be protected and the confidentiality of information obtained from him or her maintained. Occasionally some human subjects do not want confidentiality of information maintained; if that circumstance pertains, it should be specified clearly in the protocol.

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7. If, and only if, human subjects are to be put at risk, a description of the procedures to be used in obtaining and documenting the informed consent of subjects. If written consent forms are to be used, a copy of the consent form and/or verbatim copy of any accompanying oral instructions should be attached to the protocol (see Appendix B). If subjects are put to no risk, a written consent form is unnecessary.
8. If subjects are to be put at risk and a waiver from the requirement of written informed consent is sought, the justification for the waiver should be specified (see Appendix C).
9. If questionnaires or interview schedules are to be used in the project, one copy of each should be attached. If they are not available at the time of submission, an informative description of their content and manner of administration should be included in the protocol, along with an assurance that when completed they will be filed with the CPHS.
10. The original and sixteen copies of the protocol should be submitted for review by the CPHS. The protocol must be signed by the investigator and either the appropriate chairman, chairwoman, dean or director. If the investigator is a student, the signature of the faculty advisor is also required. A telephone number where the investigator may be reached should be included. If the investigation is part of a larger project or training program, the title and CPHS identifying number of this activity should be provided.

Again, should you have any questions about preparing a protocol, the Committee staff may be reached at 2-7461.

NOTE: The Committee's deadline for receiving and processing protocols is two weeks prior to each of its meetings. The following are scheduled meetings for the remainder of 1978:

April 21, 1978  
May 19, 1978  
June 23, 1978  
July 14, 1978  
August 4, 1978

September 15, 1978  
October 13, 1978  
November 17, 1978  
December 15, 1978

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#### Appendix A

Subject at Risk. A subject is at risk if, as a participant in a research, development, or related activity, he or she may be exposed to the possibility of harm--physical, psychological, or social--which goes beyond the ordinary risks of public or private living. This includes, for example, the possibility of harm which 1) is greater than the recognized risks inherent in a chosen activity, occupation, or field of service; or 2) is due to a departure from the application of those established and accepted methods necessary to meet a subject's needs.

There is human subject involvement, but no human subjects are put at risk, in research, development, or related activities which propose the use of 1) observations of public behavior, 2) materials in the public domain, or 3) statistical data used in a purely statistical study which is conducted so that no one except the researcher is able to trace the identity of the subjects.

There is no human subject involvement in the use of statistical data which are anonymous and not traceable to individuals by the researcher.

#### Appendix B

Informed Consent. Informed consent means the knowing consent of an individual (or his or her legally authorized representative) to participate in a research, development, or related activity. The individual, or the authorized representative, must be so situated as to be able to exercise free power of choice without undue inducement or any element of fraud, deceit, force, duress, or other form of constraint or coercion. No informed consent, oral or written, shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any legal rights, including any release of the University or its agents from liability for negligence.

The basic elements of informed consent are:

- (1) a fair and understandable explanation of the nature of the activity, its purpose, and the procedures to be followed, including identification of any procedures which are experimental;
- (2) an understandable description of any attendant discomforts and risks reasonably to be foreseen;
- (3) an understandable description of any benefits reasonably to be expected;
- (4) an understandable disclosure of any appropriate alternative procedures that might be advantageous for the subject;
- (5) an offer to answer any inquiries concerning the procedures, providing, when appropriate, the telephone number or address of the investigator; and

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- (6) a clear instruction that participation in the activity or project is voluntary, and that the subject is free to withdraw consent and discontinue participation at any time prior to its termination and wholly without prejudice.

The Committee has found that in order to satisfy the above six elements of informed consent, the consent form should include information for those following items which may be relevant:

- (1) specifics on the amounts and timing of any proposed taking of blood or any other human materials, and their subsequent disposal;
- (2) details regarding authorization for access to a subject's personal records (school, medical, employment, or others);
- (3) a description of efforts proposed to protect the privacy of a subject and the confidentiality of personal data;
- (4) details regarding the use of tape recorders or other recording methods, and an explanation of the proposed uses and disposition of recorded materials;
- (5) the amounts and terms of any proposed payments to subjects; or
- (6) assurance that should the investigator discover any untoward medical condition in the subject, this will be brought, if possible, to the attention of the subject's own physician, or the subject will be informed of the condition and advised to seek the proper assistance.

Written Informed Consent. There are two alternative procedures for obtaining the written consent of subjects. The differences between the two have to do with the amount of information about the project that is contained in the form that the subject (or legally authorized representative) is asked to sign. The regular form contains all the relevant detail about the nature, purpose, and procedures of the project; its risks and discomforts; the assurances and obligations of the investigator; and the like. The short form indicates that these matters have been explained to the subject orally by the investigator, and on the basis of this prior explanation, that he or she agrees to participate. When the short form is used, the protocol must contain a verbatim copy of the matter to be read or explained to the subject, and the consent form must include the signature of an auditor-witness to the oral presentation along with that of the subject.

Written consent must be legally effective, i.e., it must contain all of the elements of informed consent.

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Appendix C

Waiver of Written Informed Consent. When human subjects are to be put at risk, a waiver of the requirement for written informed consent is granted only under carefully justified circumstances. Any such waiver must be regularly reconsidered as a function of continuing reviews, and on DHEW sponsored projects, as a function of annual review. Waivers are permitted only when the following three criteria are met:

- (1) the risk to the subjects is minimal, and
- (2) the use of either of the primary procedures for obtaining written informed consent would surely invalidate objectives of considerable immediate importance, and
- (3) any reasonable alternative means for attaining these objectives would be less advantageous to the subjects.

The CPHS typically honors requests for waiver when the subjects of the investigation are illiterate; when the risks (usually psychological risks) inherent in asking subjects for their signatures outweigh the risks of not obtaining the signatures; or when requests for signatures demonstrably violate or distort the subjects' perceptions of the nature and purpose of the investigation.

Of course, no consent is required and hence no waiver need be sought when human subjects are involved and put to no risk.

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University of California, Berkeley  
Lawrence Berkeley Laboratory

CONSENT TO ACT AS A PATIENT RESEARCH SUBJECT

RADIOLOGICAL NEUROSURGERY FOR TREATMENT OF  
BLOOD VESSEL DISEASE IN THE BRAIN

- I. I agree to be included as a patient-subject in a medical research study in radiological neurosurgery. As a patient-subject, I understand that the following medical procedures will be done:
- A. Special radiological (x-ray) and neurological (nervous system) examinations will be carried out to diagnose precisely the size, shape, and location of the blood vessel abnormalities in my brain. These diagnostic studies are exactly the same as those done on patients with my disease in major (e.g. university) hospitals in the United States. These studies are required to insure the greatest possible success from the experimental radiation procedures planned.
  - B. Careful planning of the radiation treatments require the construction of a specially-fitted plastic face-mask molded to my head and face. It may be necessary to cut my hair very short in order to achieve perfect fit of the mask. The mask-preparation and fitting will cause a little discomfort, but no pain medications are necessary.
  - C. I will be treated with radiation beams which will be delivered inside my brain. There will be no pain during the entire radiation procedure from the radiation exposure. It may be necessary to inject a special solution into my blood vessels which make my blood vessels opaque to x-rays. This is required to position the radiation beam in my brain with very careful precision. This blood vessel examination, or angiogram, is the same as the examination done on me previously for diagnosis.
  - D. Special diagnostic research studies, particularly (a) radioisotope scanning studies of the blood vessels in my brain, may be carried out in the specially-designed research scanner at the Donner Laboratory, University of California, Berkeley, under the direction of Professor Thomas Budinger, M.D., Ph.D. Isotopes will be injected into my bloodstream for the examination; there will be discomfort during the injection, but no pain. These special studies are designed to measure the blood flow in the abnormal blood vessels in my brain, before and after the treatment. The radiation treatment is designed to close down and block the abnormal blood vessels. Thus, the success of the radiation treatment can be measured scientifically. (b) Special diagnostic radiographs much like x-rays, may also be done to obtain a picture of my brain with heavy ions. This study, under the direction of Professor Jacob I. Fabrikant, M.D., Ph.D., is regularly carried out on patients at the Donner Laboratory. It has only slight discomfort due to the need for me to remain perfectly still for about 10 minutes.
  - E. All these procedures are necessary to diagnose, locate, and treat the blood vessel disease in my brain.
- II. The diagnostic and treatment procedures will be done both at the Lawrence Berkeley Laboratory, and at University of California Medical Center, San Francisco. The overall period for the evaluation of my disease, preparation of my mask, x-ray and neurological examinations and treatments, will take approximately 2-4 weeks. I understand that I will be in the treatment room about 1 1/2 - 2 hours, maximum, each day for about 5-8 days for the entire treatment. It is not expected that all

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CONSENT TO ACT AS A PATIENT RESEARCH SUBJECT (continued) Page 2 of 3

- these procedures will be repeated, but consideration to repeating some or all of the procedures sometime in the future may be necessary if additional treatments are required.
- III. The purpose of this study is to cause radiation damage to the abnormal blood vessels in my brain so that they will eventually fill with tissue and blood clots, thereby decreasing the chance and possibly preventing any further bleeding into my brain.
- IV. I have been told that the procedures described above involve the following possible risks and/or discomforts or inconveniences:
- (1) Injections (needles or very fine tubes) into my blood vessels (arm, groin, or neck) will be uncomfortable with a small amount of pain, exactly the same way as in the x-ray examination blood vessel studies I have already experienced.
  - (2) Slight discomfort or inconvenience when my face mask is being prepared and fitted. A very close haircut, if necessary, may be a minor inconvenience.
  - (3) Slight discomfort---due to having to be still---during the radiation treatments. I understand that more than 800 patients have been treated with radiation treatments with this radiation machine, and there is no pain or discomfort at the time of the radiation treatments.
  - (4) I may experience some headache after the radiation treatments, within hours or days, but ordinary pain medications will treat this problem satisfactorily.
  - (5) Radiation can damage blood vessels in the brain, and there is a small chance of bleeding occurring into my brain as a result of this damage. This is an uncommon complication that could occur.
  - (6) Radiation can injure vital centers in the brain, and every possible scientific means will be used to protect these vital centers from radiation injury.
- V. The benefits to be achieved in doing this experimental medical radiosurgical procedure are:
- A. Directly to me:
    - (1) to decrease the chance of further bleeding into my brain;
    - (2) to decrease or arrest the progressive damage to my brain as a result of the bleeding;
    - (3) to decrease the chance of further paralysis from further bleeding into my brain;
    - (4) to decrease the chance of dying from massive bleeding into my brain.
  - B. To others:  
As this experimental medical procedure is developed and perfected on patients with vascular disease of the brain as I have, other patients in the future will benefit from the improved techniques and procedures.
- VI. I have been told that certain alternative surgical procedures exist, but in my special case, they would be too dangerous to my life to be used.
- VII. All this information was discussed with my by Professor Jacob I. Fabrikant, M.D., Ph.D. and my other physicians and surgeons. He will answer any further questions I have concerning all these experimental and medical procedures. I can always reach him at the University of California, Berkeley (415) 642-2314 or 486-6033 or at his home (415) 845-8005).

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| DOCUMENT SOURCE   |   |
|---|---|
| Lawrence Berkeley Laboratory<br>Archives and Records Office |   |
| Records Series Title  | SCIENTISTS' RECORDS -<br>CORNELIUS TOBIAS |
| Accession No.   | 434-92-0154                               |
| File Code No.   | 17-14-43                                  |
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| Found By  | Karen Holmes                              |
| Dates   |   |

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CONSENT TO ACT AS A PATIENT RESEARCH SUBJECT (continued) Page 3 of 3

- VIII. I recognize that my decision to undergo these experimental medical procedures is a voluntary one. I recognize that the procedure is not without danger, but in my special case, it is the only procedure available which may contribute to arresting my disease and/or ultimately saving my life. I am free to refuse to undergo the experimental procedure or withdraw from it without any jeopardy to my normal course of treatment otherwise. The medical investigator in charge of the medical research program may release me from the experimental study---that is, drop me from the study--as long as it is not detrimental or dangerous to my medical care.
- IX. Confidentiality will be maintained. My identity will not be disclosed in the use of information obtained in connection with this study.
- X. I will receive no compensation from being in this experimental medical study.
- XI. I acknowledge receiving and reading the Medical Research Subject's Bill of Rights. I have also received a copy of this consent form.
- XII. If I am physically injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University, depending upon a number of factors. For information, I may call the LBL Human Use Committee (415) 486-5507; 642-2461.

\_\_\_\_\_  
Signature of Patient/Subject

\_\_\_\_\_  
Date