

John Cerino
From: E. Rubenstein

STANFORD UNIVERSITY
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DATE: January 7, 1986

TO: E. Rubenstein, M.D.,
R. Hofstadter, Ph.D. & D.C. Harrison, M.D.
Department of Medicine

FROM: Chairman, Medical Committee for the
Protection of Human Subjects in Research

PROTOCOL TITLE:
K-edge Angiography with Synchrotron X-rays.
(Grant: K-edge Subtraction Angiography with Synchrotron X-rays)

The Committee approved human subjects involvement in your research project on January 7, 1986.

The expiration date of this approval is January 6, 1987. If this project is to continue beyond that date, please submit an updated proposal in advance for the Committee's re-approval. If this proposal is used in conjunction with any other human experimentation or if it is modified in any way, it must be re-approved for these special circumstances. In addition, the Committee requests prompt notification of any complications which may occur during any experimental procedure.

All continuing projects and activities must be reviewed and re-approved at least annually by the Committee. Committee approval of any project is for a maximum period of one year. It is the responsibility of the investigator to resubmit the project to the Committee for annual review.

for Kathy McClelland
Don R. Goffinet, M.D., Chairman

cc: Sponsored Projects
Marshall O'Neill

0021397

REPOSITORY Stanford Site Office (SSO)
COLLECTION SSRL 284-2 Human Research
BOX No. N/A
FOLDER SSRL 284-2 Human Research

Funding Agency: (NIH HL29024; NIH HV38039; DOE DE-AT03-84ER60200) (R)
Period of Time: 01/07/86 through 01/06/87
Investigational New Drugs: N, N/A
Investigational New Device: N, N/A
Cooperating Institution: N

REQUEST FOR INSTITUTIONAL APPROVAL OF PROJECT INVOLVING HUMAN SUBJECTS AT RISK
THE MEDICAL COMMITTEE FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

To: Kathy Callahan, 851 Welch Rd., #115

Date: November 20, 1985

PI for Grant/Project:	<u>Robert Hofstadter, Ph.D.</u>	MD/PhD	Title: <u>Professor</u>
Other Investigators:	<u>Edward Rubenstein, M.D.</u>	MD/PhD	<u>Professor (Clinical)</u>
	<u>Donald C. Harrison, M.D.</u>	MD/PhD	<u>Professor</u>

Title of Research Project: K-edge Angiography with Synchrotron X-rays

(AND GRANT, IF DIFFERENT) K-edge Subtraction Angiography with Synchrotron X-rays

Contract/Grant #	<u>1 HV-38039</u>	Sponsor	<u>NIH Grant</u>	Period	<u>7/1/83-6/30/86</u>
	<u>DE-AT03-84ER60200</u>		<u>DOE Grant</u>		<u>2/1/84-1/31/87</u>

Investigator's Address Rm. TC-129 Dept. Medicine Ext. 7-7188

Sponsored Unsponsored Investigational Drug Investigational Device

Department Chairman *Tex Hanner*
SIGNATURE

REVIEW PROCESS - Check One: REGULAR REVIEW PLEASE SEND 4 COPIES (DO NOT STAPLE)

EXPEDITED REVIEW PLEASE SEND 2 COPIES (See regulations on reverse side of this form)

(VA Not Eligible) Paragraph number under which expedited review is requested.

APPROVAL OF THE HUMAN SUBJECTS COMMITTEE SHOULD BE OBTAINED PRIOR TO SUBMISSION OF THE RESEARCH PROJECT TO HHS/NIH. THE COMMITTEE MEETS THE FIRST TUESDAY OF EVERY MONTH AND APPLICATIONS SHOULD REACH THE COMMITTEE 30 DAYS PRIOR TO THE MEETING DATE.

PLEASE PROVIDE INFORMATION IN THE FOLLOWING AREAS AND ATTACH TO THIS FORM:

- Protocols Involving Use of Radioactive Materials.
A separate form for projects involving radioactive materials should be obtained from the Health Physics Department, Room 67, Encina Hall, X-3201.
- Number of Subjects Involved to Date.
- Description of Results to Date.
- Problems or Complications.
- Description of Remainder of Project.
- Describe Any Changes Since Original Approval.
- Attach the Consent Form(s) You are Using for this Study.
(Even if it is the same as previously approved.)

OR:

If this project is the same as a previously approved study under a different name, please supply the title, investigator, date approved and consent form approved by Committee:

0021398

RENEWAL

Request for Institutional Approval of the Protocol Entitled:
"K-Edge Subtraction Angiography with Synchrotron X-rays"

Additional Information:

1. Protocols Involving Use of Radioactive Materials.

Radioactive materials are not used in this project.

2. Number of Subjects Involved to Date.

Human subjects have not been studied to date. Experiments have been conducted on anesthetized dogs. The first experiments on human subjects are currently scheduled for April 1986.

3. Description of Results to Date.

The left anterior descending, the right coronary and the circumflex arteries have been visualized following transvenous injections of contrast agent in anesthetized dogs.

4. Problems or Complications.

None

5. Description of Remainder of Project.

As previously described.

6. Describe Any Changes Since Original Approval.

Results of experiments on anesthetized dogs indicate that some injections of contrast agent may be made into a central vein, such as the superior or inferior vena cava, rather than into a vein in the upper extremity. For the central venous injections, the injection rate will vary from 5-20 ml per second. For the higher injection rates, a power injector will be employed.

7. Consent forms are attached.

0021399

INFORMED CONSENT FOR SYNCHROTRON ANGIOGRAPHY BY MEANS OF VENOUS INJECTION
OF CONTRAST AGENT

You are invited to participate in a study of angiography. We hope to develop a means of visualizing arteries without the direct injection into the arteries of x-ray contrast agents. You were selected as a possible participant in this study because your physician(s) has recommended that you undergo angiography by the invasive technique, involving arterial catheterization and the direct injection of contrast agents into the arteries.

If you decide to participate, we will perform an angiographic procedure (coronary, cerebral, other,) by means of a venous injection of contrast agent, employing x-rays produced at the Stanford Synchrotron Radiation Laboratory. You will be given injections into a vein of a radiographic contrast agent, as employed in routine clinical practice. The injection may be given directly into a vein in the arm or may be given into a vein in the chest. In the latter instance a flexible, hollow tube, called a catheter, will be inserted into a vein in an extremity (usually the arm), and the catheter is then advanced into the chest so that its tip is in a central vein adjacent to the intake chamber (right atrium) of the heart. The contrast agent will then be administered using a power injector, at a rate up to 20 ml/kg of body weight per injection. Following the injection, scanning digital radiographs will be taken of the arterial structures being studied. The procedure will probably require 1/2 to 1 1/2 hours. The risks of this procedure include the following: severe allergic (anaphylactoid) reaction to the iodine contrast agent; mechanical tear of a vein; impaired kidney function; reaction to local leakage of dye; the radiation exposure inherent in an x-ray examination.

It would be impractical and even misleading to describe in detail all of the possible risks and complications which might result from the procedure. Any questions should be discussed with a member of the angiography team who will be performing the study. This person will review the procedure as is planned for your individual case.

0021400

Potential benefits that may be accrued to you relate to information about the status of the arteries to be studied. Such information might be accumulated without the necessity of performing invasive arterial injections. We can not or do not guarantee or promise that you will receive any benefits from this study. After analyzing the results of this examination, your physician may recommend that you undergo the alternative procedure, that of routine angiography employing arterial catheterization and direct injection of radiocontrast agents into the arteries.

Any data that may be published in scientific journals will not reveal the identify of the subjects. In the interest of public safety, patient information will be provided to federal and regulatory agencies as required.

There will be no fee charged for the non-invasive angicram.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at any time without prejudice to you or effect on your medical care. If you have any questions, we expect you to ask us. If you have any additional questions later, we will be pleased to try to answer them.

In the event of physical injury that arises solely out of the negligence of the Stanford Univeristy Medical Center or its staff in this study, reimbursement for expenses incurred for necessary medical treatment and hospitalization is available. For further information,

please call 497-5244 or write the Medical Center Committee for the Protection of Human Subjects at 851 Welch Road, Room 115, Palo Alto, California, 94304. In addition, if you are not satisfied with the manner in which this study is being conducted, you may report any complaints to the same telephone number and address.

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to: be informed of the nature and purpose of the experiment; be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized; be given a description of any attendant discomforts and risks reasonably to be expected; be given an explanation of any benefits to the subject reasonably to be expected, if applicable; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks and benefits; be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise; be given an opportunity to ask any questions concerning the experiment or the procedures involved; be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice; be given a copy of the signed and dated consent form; and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PRINCIPAL INVESTIGATOR(S) AND HIS OR HER STAFF, AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM IS AVAILABLE TO YOU UPON REQUEST.

Signature

Date

Signature of Investigator or Witness

11/81

STANFORD UNIVERSITY HOSPITAL
STANFORD MEDICAL CENTER

CONSENT TO OPERATION, ADMINISTRATION
OF ANESTHETICS, AND FOR DIAGNOSTIC
OR THERAPEUTIC PROCEDURES

Date _____ NAME OF PATIENT _____

Hour _____ NAME OF ATTENDING PHYSICIAN _____

NAME OF SURGEON OR PHYSICIAN PERFORMING PROCEDURE _____

1. Your physician(s) has determined that the operation or procedure listed below may be beneficial in the diagnosis or treatment of your condition. All surgical operations and diagnostic and therapeutic procedures involve risks of complication, or even death, from both known and unknown causes. No warranty or guarantee has been made as to result or cure.

2. OPERATION/PROCEDURE TO BE PERFORMED: _____

3. Physicians performing professional services, such as anesthesia, radiology, pathology and the like, are not employees of the Hospital. These physicians are either in private practice in the community or faculty members of the Stanford University School of Medicine.

4. Stanford University Hospital and Clinics is an educational institution, and as part of the medical education program residents, interns, medical students, postgraduate fellows, and other health care students may, under the supervision of the attending physician, participate in the care of teaching patients.

5. As a patient you have a right to receive as much information as you may need in order to give informed consent or to refuse the recommended course of treatment. Except in emergencies, your physician(s) should describe in language you can understand the proposed treatment or procedure, the medically significant risks involved, and the alternate courses of treatment or nontreatment, including the respective risks of each. If you have questions, you should consult your physician(s) prior to giving your written consent to such operation or procedure.

Having read the above and having received the above information from my physician(s), I hereby authorize the above-named physician(s) and any associates or assistants of my physician(s) to perform the above-named operation or procedure and to perform such additional services as may be deemed medically reasonable and necessary, including, but not limited to, the administration and maintenance of anesthesia and services involving pathology and radiology. I further authorize the pathology service to exercise discretion in the disposal of any severed tissue or member, except: _____

SIGNATURE OF PATIENT, LEGAL GUARDIAN, CONSERVATOR OR
LEGAL REPRESENTATIVE

SIGNATURE OF WITNESS

(If patient is a minor or unable to sign, complete the following.)

Patient is a minor _____, or is unable to sign because _____

SIGNATURE OF FATHER

SIGNATURE OF MOTHER

LEGAL GUARDIAN, CONSERVATOR, OR LEGAL REPRESENTATIVE

0021404

HOSPITAL DE LA UNIVERSIDAD DE STANFORD
CENTRO MEDICO DE STANFORD

PERMISO PARA OPERACION, PARA LA APLICACION
DE ANESTESICOS Y PARA PROCEDIMIENTOS
DIAGNOSTICOS O TERAPEUTICOS

Fecha _____

NOMBRE DEL PACIENTE

Hora _____

NOMBRE DEL MEDICO DE CABECERA

NOMBRE DEL CIRUJANO O MEDICO A CARGO DEL PROCEDIMIENTO

1. Su Médico (o Médicos) ha determinado que la operación o procedimiento que se consigna más adelante puede ser de beneficio para el diagnóstico o tratamiento de su estado de salud. Todas las operaciones quirúrgicas y procedimientos diagnósticos y terapéuticos implican riesgos de complicación, lesión o aún muerte, de causas conocidas o desconocidas. Ninguna garantía de seguridad se ha determinado en cuanto al resultado o cura.

2. OPERACION/PROCEDIMIENTO A EJECUTAR: _____

3. Los médicos que prestan servicios profesionales tales como anestesia, radiología, patología y servicios semejantes no son empleados del hospital. Estos médicos se dedican a la práctica privada en la comunidad o son miembros de la Facultad de Medicina de la Universidad de Stanford.

4. El Hospital y la Clínica de la Universidad de Stanford constituyen una institución educacional, y como parte del programa de educación médica, los residentes, los internos, los estudiantes de medicina, los becarios graduados y otros estudiantes del cuidado de la salud pueden, bajo la supervisión del Médico en asistencia, participar en el cuidado de los pacientes que están bajo el plan de estudios.

5. Como paciente, usted tiene derecho a recibir tanta información como usted pueda necesitar a fin de dar el correspondiente permiso, o a rechazar o negar el curso del tratamiento recomendado. Excepto en casos de emergencia su Médico (o Médicos) deben describir, en lenguaje que usted pueda entender, el tratamiento o procedimiento propuesto, los significantes riesgos médicos comprendidos y los métodos alternativos de tratamiento o no tratamiento, incluyendo los respectivos riesgos de cada uno. Si usted desea saber algo o tiene preguntas que hacer, usted debe consultar a su Médico (o Médicos) antes de otorgar su permiso por escrito para tal operación o procedimiento a seguir.

Habiendo leído lo explicado anteriormente y habiendo recibido la información anterior de mi Médico (o Médicos), por la presente autorizo al Médico (o Médicos) mencionado anteriormente y a cualquiera de sus colaboradores o ayudantes de mi Médico (o Médicos) para llevar a cabo la operación que se detalla anteriormente o procedimiento a seguir y a proveer tales servicios adicionales como fueren razonables y necesarios desde el punto de vista médico, incluyendo, pero no limitados, la aplicación y mantenimiento de anestesia y servicios de patología y de radiología. También autorizo al servicio patológico para usar su criterio en la disposición de cualquier tejido o miembro removido, excepto: _____

FIRMA DEL PACIENTE, TUTOR, ENCARGADO, O REPRESENTANTE LEGAL

FIRMA DEL TESTIGO

0021405

(Si el Paciente es menor de edad o no puede firmar, complete lo siguiente.)

El Paciente es menor de edad _____, o no puede firmar porque _____

FIRMA DEL PADRE

FIRMA DE LA MADRE

FIRMA DEL TUTOR, DEPENDIEN O REPRESENTANTE LEGAL