



204-2-SSRL

U.S. DEPARTMENT OF ENERGY

Stanford Site Office (SLAC/SSRL)
Energy Research Division/SAN
Stanford University
P.O. Box 4349 - BIN 8A
Stanford, California 94305

702649

COMM: (415) 854-3300
X2261
FTS: (8) 415-470-9040

May 8, 1987

Jim Davis, Director
Environmental Safety &
Quality Assurance Division
U.S. Department of Energy
San Francisco Operations Office
1333 Broadway
Oakland, CA 94612

Subject: SSRL Planned Human Angiography Experiment

Reference: SSRL Memorandum Dated April 21, 1987

Dear Jim,

Enclosed you will find the final version of the subject SSRL memorandum entitled "Planned Human Angiography Experiment". A draft had been provided to ESQA (Jim Foster) on April 21, 1987 a copy of which is enclosed. We believe that the final version of the memorandum will be satisfactory to ESQA based upon Jim Foster's original comments. If you have any questions regarding this matter, please feel free to call me at FTS 470-9040.

Sincerely,

W.C. Gough

Fa
William C. Gough, Director
Stanford Site Office (SLAC/SSRL)
ER Division, SAN

cc: Jim Foster

M18/ANGIOG.LTR

REPOSITORY Stanford Site Office (SSO)

COLLECTION SSRL 284-2 Human Research

BOX No. N/A

FOLDER SSRL 284-2 Human Research

0021349

RECEIVED
APR 22 1987
Bill
GHS
MJC
284-2/
155

SSRL MEMORANDUM

Date: April 21, 1987

TO: WILLIAM GOUGH
FROM: A. BIENENSTOCK
Director
SUBJECT: PLANNED HUMAN ANGIOGRAPHY EXPERIMENT

Dear Bill,

This memo is to inform you of the planned second series of "Iodine Dichromography" experiments with human subjects to be carried out at SSRL.

The experiments will be carried out by the same reseach team which performed the original experiments last year. The exposure control hardware and the medical and experimental protocols are unchanged.

The medical protocols and informed consent material have been reviewed and re-approved by the Stanford University Human Subjects Committee. A copy of the approval is included herewith.

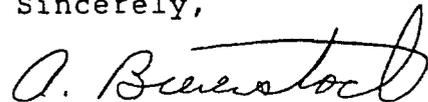
The present plan is to use four subjects, one of whom participated in the first experiment, commencing Friday, April 24, and at the rate of one per day through Monday, April 27.

Since the original experiment, the safety interlock system has been further analysed by our engineering staff and design changes proposed which are intended to improve the reliability of the system. These designs have been subjected to critical review by interlock designers from both SLAC and LBL.

Today, those reviewers met with SSRL engineering and safety personnel and a SLAC safety representative. They reported the results of their analyses. The conclusion of the review meeting is that the personnel protection interlock design provides adequate radiation protection to the experimenters and angiography subjects. At the same meeting the operational and check-out procedures were confirmed to be identical to last run.

Since the previous review of the experimental conditions and protocols resulted in a low hazard classification, and since no changes of conditions or procedures have been made, we believe that that rating is still in effect.

Sincerely,



cc w/att:
J. CERINO

0021350

*Rec'd
3-21-88
JA*

DATE: January 6, 1987

TO: E. Rubenstein, M.D.,
R. Hofstadter, Ph.D., J. Giacomini, M.D.
& H.J. Gordon, M.D.
Department of Medicine

FROM: Chairman, Administrative Panel
on Human Subjects in Medical Research

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

The Panel approved human subjects' involvement in your research project on January 6, 1987.

The expiration date of this approval is January 5, 1988. If this project is to continue beyond that date, please submit an updated proposal in advance for the Panel'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 Panel 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 Panel. Panel 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 Panel for annual review.

for *Patty Glennon*
Don R. Goffinet, M.D., Chairman

cc: Sponsored Projects

00213511

Funding Agency: (NIH HL29824, NIH HV38039 & DOE DE AT03 84ER60200)
Period of Time: 01/06/87 through 01/05/88
Investigational New Drugs: N,
Investigational New Device: N

CO;OHC2J
#16

21-APR-1987 16:45:58

MAIL

From: SSRLO1::CERINO "John Cerino at SSRL."
To: A. GOUGH, WINICK
Subj: LAST SRAFT, I HOPE

SSRL MEMORANDUM

Date: April 21, 1987

TO: WILLIAM GOUGH

FROM: JOHN CERINO

Press RETURN for more...

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21-APR-1987 16:45:58

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Sincerely,

cc w/att:

A. Bienenstock

A. Thompson

G. Warren

H. Winick

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