



February 12, 1988

Mr. James Ricks
Energy Research Division
U. S. Department of Energy
1333 Broadway
Oakland, CA 94612

Subject: Human Subjects Certification for Project titled "Chromosome Aberrations and Somatic Mutations in Radiotherapy Patients", Principal Investigator Tore Straume
LLNL AWP No. L763A

Dear Mr. Ricks:

Attached is a form HHS-596, Protection of Human Subjects Assurance/Certification/Declaration, for the referenced project. At its meeting of 11/30/87 the LLNL Institutional Review Board fully approved LLNL collaboration with the University of Washington. All paperwork is in hand for LLNL IRB Committee approval of the supplementary collaborations with U.C. Davis (VA Hospital, Martinez) and Stanford University; formal approval for these collaborations is expected from our Committee at its next meeting to be held in March 1988. Note that LLNL approval of these latter two collaborations is essentially pro forma since the U.C. Davis and Stanford Institutional Review Boards have primary responsibility for review of the use of human subjects in this project, and the respective Boards have approved the protocol.

I strongly recommend that the funding for this project be released.

Sincerely,

Barton L. Gledhill, Chairman (gr)
Institutional Review Board

BLG:gw

Attachment

cc: T. Straume
D. Braff

bcc: J. Foster (DOE/SAN)

REPOSITORY DOE-OAK
COLLECTION Env + Safety Sup-Div
BOX No. Central File
FOLDER 1300.3.B Human Subj. Testing
1986-1987

0021069

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PROTECTION OF HUMAN SUBJECTS
ASSURANCE/CERTIFICATION/DECLARATION

- GRANT CONTRACT FELLOW OTHER
- New Competing continuation Noncompeting continuation Supplemental

- ORIGINAL FOLLOWUP EXEMPTION (previously undesignated)

APPLICATION IDENTIFICATION NO. (if known)

POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY

Chromosome Aberrations and Somatic Mutations in Radiotherapy Patients

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Tore Straume

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (see reverse side)

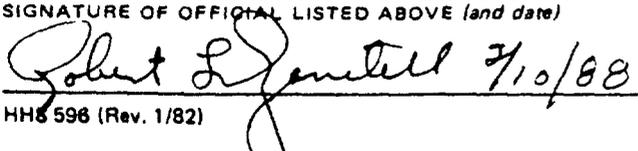
4. HHS ASSURANCE STATUS

- This institution has an approved assurance of compliance on file with HHS which covers this activity.
 M-1415 Assurance identification number 01XB IRB identification number
- No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

- This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)
 11/30/87 Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)
 (month/day/year)
- Full Board Review Expedited Review
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification (Form HHS 596) will be submitted.
- Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ (insert paragraph number of exemption in 46.101(b), 1 through 5), but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO. Lawrence Livermore National Laboratory P.O. Box 808 Livermore, CA 94550 (415) 422-9136	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL (print or type) Robert L. Zanetell, Finance Manager	NAME AND TITLE OF OFFICIAL (print or type)
SIGNATURE OF OFFICIAL LISTED ABOVE (and date)  7/10/88	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

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