



702621

December 29, 1986

Dr. Susan Rose
Human Health & Assessments Division, ER-73
Office of Health & Environmental Research
Office of Energy Research
U.S. Department of Energy
Washington, D.C. 20545

Dear Dr. Rose:

The following research proposals were approved by the LLNL Human Subjects Committee on November 25, 1986.

<u>Title</u>	<u>Principal Investigator</u>	<u>Agency Sponsor</u>	<u>Approval</u>
Transfer of Particulates to Hands	Arthur H. Bierman	US Army	new
Human Subjects Experiments (Divers) with Air Tagged With Radioisotopes ¹³ N and ⁴¹ Ar	Paul Meyer	US Navy	annual
Chromosome Aberration Frequencies in Patients Undergoing Radiation Therapy with X-rays or Fast Neutrons	Tore Straume	DOE	annual

Certification of the review of involvement of human subjects in this research by the LLNL Human Subjects Committee is attached. A draft consent form for each project is also attached, but you should be aware that the Committee frequently requires the investigator to make minor improvements in the consent form before the project is finally implemented.

Sincerely yours,

Fred Hatch

Frederick T. Hatch, M.D., Ph.D.
Assistant Associate Director
Biomedical and Environmental
Research Program

Attachments

REPOSITORY DOE-OAK
COLLECTION Env & Safety Sup Div
BOX No. Central File
FOLDER 1300-3.6. Human Subj Testing
1986-1987

00211161

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 designated)

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—35 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

Transfer of Particulates to Hands

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Arthur H. Biermann

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 OLXB 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.)

11/25/86 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)  12/19/86	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)



Lawrence Livermore National Laboratory

UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Human Subjects Committee
Approval Number: 87R-107
Approval Date: November 25, 1986

Transfer of Particulates to Hands

Subjects Name: _____

Date: _____

1. I hereby agree to participate in the Particle Transfer tests being conducted by the Hazards Control Department of Lawrence Livermore National Laboratory.
2. I understand that the procedures for conducting these tests are as follows:

Volunteer participants will press their hand on a metal plate which has been coated with fine particles. Immediately after, they will wash any collected particles off their hand. A single test will last approximately 1.5 minutes.
3. I understand that the possible risks and discomfort from participation in this experiment would be associated with individual allergic responses to the chemical composition of the fine particles.
4. At the conclusion of this procedure it is expected that I will be able to function normally immediately.
5. I understand that the purpose of performing these procedures is to determine the parameters governing the amount of fine particles which may be transferred from metallic surfaces to hands by physical contact.
6. I further understand that this study may result in no direct benefit to me but it may benefit some individuals in the future.
7. I understand that Arthur H. Biermann, the Principal Investigator, and/or such assistants as may be selected will answer any inquiries I may have at any time concerning the procedures and/or investigation.

Subjects Initials
Page 1 of 2

0021118

LLNL Human Subjects Committee
Approval Number: 87R-101
Approval Date: November 25, 1986

8. Any publication arising from this study will be made without specific reference to my name.
9. I recognize that my participation in this experiment is entirely voluntary and I may refuse to participate or may withdraw at any time without jeopardy. Owing to the scientific nature of the study, the investigator may in his absolute discretion terminate the procedures and/or investigations at any time.
10. Arthur H. Biermann, an employee of the University of California, Lawrence Livermore National Laboratory, is responsible for the conduct of the research in which I am to participate. This research is sponsored by the Hazards Control Department of Lawrence Livermore National Laboratory which is operated by the University of California under contract with the United States Department of Energy, and the United States Department of the Army.
11. I understand that I am entitled to a copy of this consent form and the Lawrence Livermore National Laboratory Experimental Subject's Bill of Rights.
12. I understand that I am participating in this experiment as an employee of the University of California, Lawrence Livermore National Laboratory as a part of the work performed under Contract W7405-ENG-48 between the University of California and Department of Energy.
13. I understand that if I have any complaints or concerns about the procedures, I may address them to Vivian L. Shepherd, Secretary of the Human Subjects Committee, in person, by telephone, or in writing. Ms. Shepherd can be reached at (415) 423-2887, L-319, Lawrence Livermore National Laboratory, P.O. Box 808, Livermore, CA. 94550.

Subject's Signature _____

Witness _____



Lawrence Livermore National Laboratory

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The management and staff of the University of California, Lawrence Livermore National Laboratory, wish you to know:

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment, if complications should arise.
7. Be given the opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. 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.

If at any time you have any questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may also seek assistance from the Human Subjects Committee which was established for the protection of volunteers in research projects. The Secretary of that Committee, Vivian L. Shepherd, may be reached by calling, (415) 423-2887, from 8:00 a.m. until 5:00 p.m., Monday through Friday, or writing to the Human Subjects Committee, L-319, Lawrence Livermore National Laboratory, P.O. Box 808, Livermore, CA 94550.

00211201

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

GRANT CONTRACT FELLOW OTHER US Navy
 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

Human Subjects Experiments (Divers) with Air Tagged with Radioisotopes ¹³N and ⁴¹Ar

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Paul Meyer

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.)

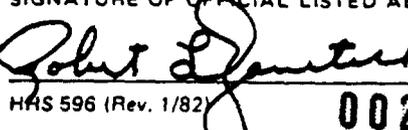
11 25/86 Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)
 (month/day/year)

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)  12/19/86	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)



Lawrence Livermore National Laboratory

UNIVERSITY OF CALIFORNIA
LAWRENCE LIVERMORE NATIONAL LABORATORY

Consent to Act as a Human Subject

LLNL Human Subjects Committee

Title: Air Tagged with Radioisotopes ^{13}N and ^{41}Ar

Approval Number: BCR-109

Approval Date: June 13, 1980, December 15, 1981, October 11, 1984
November 19, 1985, November 25, 1986

Subject's Name: _____

Date: _____

1. I hereby consent to act as a test subject in the joint Naval Medical Research and Development Command - Lawrence Livermore National Laboratory study titled Human Subject Experiments With Air Tagged with Radioisotopes ^{13}N and ^{41}Ar .
2. I understand that the procedures for conducting this test will involve:

Breathing ^{13}N and ^{41}Ar labeled air for up to 120 minutes.
3. I understand that any possible risks and discomfort that may result from the procedures are considered unlikely but include:
 - a. The discomfort from breathing through a mouthpiece for up to two hours.
 - b. Any exposure to ionizing radiation carries a risk of causing cancer--in this case potentially of the lung or upper air passages where the most significant part of the radiation dose is delivered. The best estimate of the risk of lung cancer from this procedure lies between one chance in 100,000 and one chance in 10,000. The radiation exposure to the lung and air passages in this procedure will be less than 0.4 rem. This amount is slightly below the Federal exposure limit for annual exposure of the general population; is one tenth of the permissible annual exposure of radiation workers; and is approximately three to four times the radiation received by the public in most geographical areas of the United States from natural sources and average usage for medical and dental purposes."

Subjects Initials _____

Page 1 of 3

00211221

LLNL Human Subjects Committee
Air Tagged with Radioisotopes ^{13}N and ^{41}Ar
Approval Number: 8CR-109
Approval Date: June 13, 1980, December 15, 1981, October 11, 1984
November 19, 1985, November 25, 1986

4. Since this activity does not involve medical treatment, there is no alternative procedure which might be advantageous to me.
5. At the conclusion of this procedure it is expected that I will be able to function normally immediately.
6. I further understand that this study may result in no direct benefit to me but it may contribute to the understanding of nitrogen uptake and elimination in the body and may therefore, aid in the understanding of decompression sickness. The findings will be of significant benefit to the diving profession in the future, and will be made available as soon as the studies are completed.
7. I understand that _____ and/or such assistants as may be selected will answer any inquiries I may have at any time concerning the procedures and/or investigation.
8. Any publication arising from this study will be made without specific reference to my name.
9. I recognize that my participation in this experiment is entirely voluntary and I may refuse to participate or may withdraw at any time without jeopardy. Owing to the scientific nature of the study, the investigator may in his absolute discretion terminate the procedures and/or investigations at any time.
10. I understand that I am entitled to a copy of this consent form and the Experimental Subject's Bill of Rights.
11. Paul Meyer, an employee of the University of California, Lawrence Livermore National Laboratory, is responsible for the conduct of the research in which I am to participate. This research is sponsored by the Naval Medical Research and Development Command and Lawrence Livermore National Laboratory.

Subjects Initials _____
Page 2 of 3

1013S/4

00211231

LLNL Human Subjects Committee
Air Tagged with Radioisotopes 13N and 41Ar
Approval Number: 802-109
Approval Date: June 13, 1980, December 15, 1981, October 11, 1984
November 19, 1985, November 25, 1986

12. I understand that if I have any complaints or concerns about the procedures, I may address them to Vivian L. Shepherd, Secretary of the Human Subjects Committee, in person, by telephone, or in writing. Ms. Shepherd can be reached at (415) 423-2887, L-319, Lawrence Livermore National Laboratory, P.O. Box 808, Livermore, CA, 94550.

Subject's Signature _____

Witness _____

To be completed if Subject is a minor or otherwise unable to sign:

Subject is a minor (age __) or otherwise unable to sign because:

Father

Legal Guardian

Mother

Witness

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROTECTION OF HUMAN SUBJECTS
ASSURANCE/CERTIFICATION/DECLARATION

ORIGINAL FOLLOWUP EXEMPTION
(previously undesignated)

GRANT CONTRACT FELLOW OTHER DOE
 New Competing continuation Noncompeting continuation Supplemental

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 Aberration Frequencies in Patients Undergoing Radiation Therapy with X-rays or Fast Neutrons

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

O1XB

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.)

11/25/86

(month/day/year)

Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)

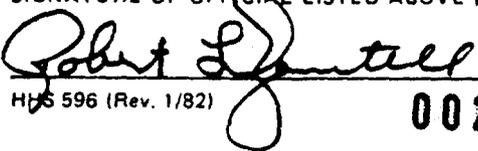
Full Board Review

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)  12/19/86	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

UNIVERSITY OF WASHINGTON
SEATTLE WASHINGTON 98195

*School of Medicine and University Hospital
Department of Radiation Oncology*

*DIAGNOSIS
CLINICAL RADIATION ONCOLOGY
MEDICAL RADIATION PHYSICS
EXPERIMENTAL BIOLOGY*

August 7, 1985

Tore Straume, Ph.D.
Neutron Hazard Research Program
Biomedical and Environmental Sciences Division
Lawrence Livermore National Laboratory
PO Box 5507
Livermore, CA 945510

Dear Tore:

Our joint project to quantitate the chromosomal aberration frequencies in patients treated with neutron irradiation has been approved for our Human Subjects. Enclosed is a copy of the approval for your institution. We can begin the project at your convenience.

Yours truly,


George E. Laramore, Ph.D., M.D.
Professor of Radiation Oncology
Clinical Director, University of Washington
Fast Neutron Radiotherapy Project

GEL:jt

encl.

0021126

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

GRANT CONTRACT FELLOW OTHER
 New Continuing continuation Noncontinuing continuation Subsequent

ORIGINAL FOLLOWUP EXEMPTION
(previously under grant)

APPLICATION IDENTIFICATION NUMBER
12260

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
Radiation Therapy Oncology Group
Project Title: Protocol to Measure the Chromosomal Aberration Frequencies in Patients
2. PRINCIPAL INVESTIGATOR PROGRAM DIRECTOR OR FELLOW Undergoing Radiation Therapy with X-rays or Fast Neutrons
Dr. George E. Laramore

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

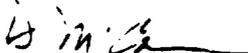
4. HHS ASSURANCE STATUS

This institution has an approved assurance of compliance on file with HHS which covers this activity.
M1183 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).
8-5-85 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. University of Washington Seattle, Washington 98195 (206) 543-0098	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL (print or type) Ms. Diana McCann, Director Human Subjects Office	NAME AND TITLE OF OFFICIAL (print or type)
SIGNATURE OF OFFICIAL LISTED ABOVE (and date)  8-5-85	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

0021127

UNIVERSITY OF WASHINGTON
DEPARTMENT OF RADIATION ONCOLOGY

CONSENT FORM

PROTOCOL TO MEASURE THE CHROMOSOMAL ABERRATION FREQUENCIES IN PATIENTS
UNDERGOING RADIATION THERAPY WITH X-RAYS OR FAST NEUTRONS

G.E. Laramore, Ph.D., M.D., Principal Investigator	548-4100
T.W. Griffin, M.D., Professor	548-4100
K.H. Luk, M.D., Associate Professor	548-4100
A.H. Russell, M.D., Assistant Professor	548-4100
R.S. Scott, Ph.D, M.D., Acting Assistant Professor	548-4100
B.R. Griffin, M.D., Acting Assistant Professor	548-4100
J.G. Pelton, M.D., Acting Assistant Professor	548-4100

DEPARTMENT OF RADIATION ONCOLOGY

Emergency Day phone 8:00 a.m. to 5:00 p.m. 548-4100
(state name, nature of call, attending physician)

Emergency phone nights/weekends 548-3300
(ask for radiation oncologist on call)

INVESTIGATORS' STATEMENT

PURPOSE AND BENEFITS

The purpose of this study is to quantify the nature of radiation-induced changes for both neutrons and x-rays in a population that is already undergoing planned radiotherapy for various malignancies; and to determine the effects of reproducing white blood cells (chromosomal changes) due to neutron radiation. These changes will be followed for a period of time and compared with similar changes induced by x-ray. There will be no additional health hazard to subjects in this study. Chromosomal changes are an indicator of both short and long term radiation exposure. The information obtained in this study will be important in analyzing the risk factors of carcinogenesis (cancer causing substance) and mutagenesis (radioactive substance) in the Hiroshima and Nagasaki atomic bomb survivors, in critical accident victims, and for personnel working in the radiation field.

PROCEDURES

10 PATIENTS RECEIVING PELVIC RADIATION WITH NEUTRONS
10 PATIENTS RECEIVING PELVIC RADIATION WITH PHOTONS
10 PATIENTS RECEIVING NO RADIATION

All subjects must not have received any prior or planned chemotherapy. The 10 patients having received no radiation, must not have had or planned radiation in the immediate future.

If you decided to participate in this study you will have 10cc (approximately 2 teaspoonsful) of blood drawn from your vein in your arm. The blood sample will be placed into a tube that contains 0.1cc of EDTA (prevent clotting). Standard sterile techniques for blood drawing will be used. If you are receiving or have received radiotherapy, this blood sample will be coordinated with any other planned blood test to minimize the discomfort or inconvenience.

The first sample will be obtained prior to radiotherapy to measure the changes that might occur. If you are receiving radiotherapy you will have your blood drawn every month for the first 6 months, and again at 9 months, 1 year, 18 months, 2 years, 2 1/2 years, and 3 years.

If you are not receiving radiotherapy, you will have your blood drawn at the beginning of the study and again at 12 months, 2 years, and three years.

The blood samples will then be packed in standard shipping container and sent via an "overnight" delivery service to the Lawrence Livermore Laboratory where the actual blood tests will be performed.

RISKS, STRESS, OR DISCOMFORTS

The insertion of the needle to draw blood may cause temporary discomfort or pain and a bruise may form where the needle enters the vein.

OTHER INFORMATION

Your identity will remain confidential with the following exception: Livermore Laboratory will receive your name and has the right to review study data which may contain identifying information. Study data will be retained by the investigator indefinitely. Controls over access to the information have been approved by the National Cancer Institute.

You will be informed of any significant new findings based on this research which may affect your willingness to continue participation. Your physician will answer any future questions you may have about the research.

0021189

0021189