



June 13, 1988

702620

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

VIA

Mr. James Foster
Environmental Health and Safety
U. S. Department of Energy
San Francisco Operations Office
1333 Broadway
Oakland, CA 94612

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

SUBJECT: Interagency Technical Contract #4990/RBTC, "Biological Dosimeter Using a New Cyto-immunological Method: Glycophorin-based Flow Cytometric Analysis of Human Red Blood Cells," Principal Investigator Ronald Jensen

Dear Dr. Rose:

Attached is information on the subject project as follows:

- (1) Project protocol
- (2) IRB protocol submitted to LLNL Institutional Review Board
- (3) Notification of Approval from the LLNL Institutional Review Board to Dr. Jensen
- (4) Protection of Human Subjects Assurance/Certification/Declaration, form HHS-596

Please note that a copy of the minutes of the 6/2/88 IRB meeting will be forwarded to your office after approval by the IRB at its next scheduled meeting on July 18. Also note that due to the nature of this project, neither a human subjects consent nor a human subjects bill of rights form will be prepared by the LLNL IRB for this project.

Sincerely,


Barton L. Gledhill, V.M.D., Chairman
Institutional Review Board

BLG:gw
Attachments as stated

cc: R. Jensen

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**INSTITUTIONAL
REVIEW BOARD**

PROTOCOL FOR HUMAN SAMPLES

Interagency Technical Contract #4990/RBTC

International Atomic Energy Agency
Vienna, Austria

and

Lawrence Livermore National Laboratory, USDOE
Livermore, CA.

Purpose

This contract is to undertake a research project entitled "Biological dosimeter using a new cyto-immunological method: glycophorin-based flow cytometric analysis of human red blood cells". Three specific aims are included in this project.

1. Perform collaborative arrangements between LLNL and Soviet Society to obtain blood samples for performing the flow analysis on the cohorts desired.
2. Arrange for Soviet scientist(s) as visiting scientist(s) at LLNL.
3. Begin pilot study on samples from a cohort of individuals exposed to modest levels of ionizing radiation as a result of the accident at the nuclear reactor in Chernobyl, USSR.

Samples

Small blood samples (1-5 ml) will be obtained by medical staff of the USSR Ministry of Health using conventional venipuncture on individuals who were in the area of the nuclear power plant accident on April 26, 1986 in Chernobyl, USSR. These samples will be obtained under conditions that are difficult for us to control or to monitor, but we request that donors will be:

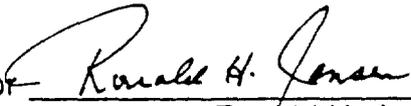
- informed of the nature and purpose of the experiments;
- given a description of any attendant discomforts and risks;
- given the opportunity to ask questions concerning the procedures;
- given the opportunity to decide to consent or not to consent without intervention or influence on the subject's decision;
- instructed that consent to participate may be withdrawn at any time;
- given a copy of the signed and dated written consent form;

Samples from each donor will be drawn at a rate of at most one per month. Each sample will be coded by the Soviet Medical Staff before sending them to LLNL. Scientists at LLNL will perform cytometric experiments on these samples and record the pertinent data. Periodically these data will be

transmitted to the Soviet collaborators and independent data obtained by these collaborators will be correlated with the results from LLNL.

Subjects

Volunteers will be sought among the higher exposed of the 135,000 people that were in the vicinity of the accident and were subsequently evacuated. Individuals who were older than 18 yrs, were not (and are not) pregnant, and who are in good health will be the requirements for qualifying as donors.

Principal Investigator  Date: 5/19/88
Ronald H. Jensen

Approved by Expedited Review of
Human Subjects Committee
Institutional Review Board
Lawrence Livermore National Laboratory
Livermore, CA.

IRB, Chairman  Date: 19 May 88
Barton L. Gledhill

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PROTECTION OF HUMAN SUBJECTS
LAWRENCE LIVERMORE NATIONAL LABORATORY MAY 27 1988

(TO BE COMPLETED BY P.I. AND SUBMITTED TO INSTITUTIONAL REVIEW BOARD PRIOR TO MEETING) INSTITUTIONAL REVIEW BOARD

Project Title Biological dosimeter using a new cyto-immunological method: glycophorin-based flow cytometric analysis of human red blood cells

Funding Source DOD/DNA and IAEA

AGREEMENT OF COMPLIANCE STATEMENT

I agree to conduct my experiments according to this protocol and conform with the policies of Lawrence Livermore National Laboratory and Biomedical Sciences Division. Before any changes in this protocol can be implemented, a written notice of the proposed changes must be submitted to the Institutional Review Board as an amendment to the protocol.

Principal Investigator signature: *Ronald Jensen*
Date: 5/27/88

A. NEW PROJECTS

1. What is the involvement of human subjects in this project and what human samples will be used?
2. What is the present or actual benefit to society in doing this project?
3. Outline Protocol. *See P. 2*
4. List source(s) of human samples

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5. How will confidentiality be insured?

6. Attach copy of filled-in consent form that subjects will be asked to sign (*Use the attached copy of the Duke University checklist as a guide in completing the consent form.*)

7. List name(s) of collaborative institutions. Approvals from those institutions must be on file with the LLNL Human Subjects Committee

B. RENEWAL PROJECTS

1. Outline Protocol.

See attached page

2. Date of first Human Subjects Committee approval: March 18, 1987
Approval No. _____

3. Date of latest approval: Expedited May 20, 1988

4. Will consent form need to be changed? If so, attach revised consent form.

5. Are there any changes in protocol for human subjects from most recent review?

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6. Since most recent review, have any additional potential hazards been identified?

7. List any new collaborative institutions. Approvals from those institutions must be on file with the LLNL Human Subjects Committee

8. List any new sources of human samples

C. PROJECTS THAT INVOLVE SAMPLES COLLECTED ELSEWHERE

1. Has this project been reviewed and approved by the other institution's human subjects institutional review board?

Unknown

2. Date of approval: *unknown*

3. Does the consent form include a statement stating that some of the work will be done at LLNL?

unknown

4. Does the LLNL Human Subjects Committee have on file a copy of the form signed by subjects? *No*

NOTE: Copies of these documents must be provided to the LLNL Human Subjects Committee

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Biological dosimeter using a new cyto-immunological method: glycophorin-based flow cytometric analysis of human red blood cells

PROTOCOL

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- informed of the nature and purpose of the experiments;
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Institutional Review Board
 (Human Subjects Committee)
 Lawrence Livermore National Laboratory
 P.O. Box 5507
 Livermore, California

NOTIFICATION OF APPROVAL

Principal Investigator: Ronald Jensen
Mail Code: L-452

Department: Biomedical Sciences
Phone Number: Ext. 25709

Project Title: Biological Dosimeter Using a New Cyto-immunological Method:
 Glycophorin-based Flow Cytometric Analysis of Human Red Blood Cells

The LLNL Institutional Review Board (Department of Health and Human Services assurance #M-1415) has approved the above request to involve humans as research subjects.

IRB PROJECT NUMBER: 88-105

APPROVAL DATE: 6/2/88
 5/19/88

Full Board Review
 Expedited Review

EXPIRATION DATE: 6/1/89

If the project is to continue, it must be renewed by the expiration date.

CONDITIONS OF APPROVAL:

N/A

MODIFICATIONS: *All protocol changes involving subjects must have prior IRB approval.*

QUESTIONS: Please contact the Institutional Review Board office at Ext. 2-3883, L-452.

APPROVAL FOR THE BOARD


 Barton L. Gledhill, V.M.D.

Chairman, Institutional Review Board

13 June 1988

 Date

IRB-1 (6/13/88) 00211131

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (from front side)

According to 45 CFR 46.121, if an application is made to HHS requiring certification and involving use of an investigational new drug or device, additional information is required. In addition, according to 21 CFR 312.1(a)(2), 30 days must elapse between date of receipt by FDA of Form FD-1571 and use of the drug, unless the 30 day delay period is waived by FDA.

3a. INVESTIGATIONAL NEW DRUG EXEMPTION (if more than one is involved, list others below under NOTES):

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER

NUMBER ISSUED

3b. INVESTIGATIONAL DEVICE EXEMPTION:

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (ii) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a nonsignificant risk device; and (2) the IRB has approved the study. (Check applicable box.)

The IRB agrees with the sponsor that this device is a nonsignificant risk device.

OR

The IDE application was submitted to FDA on (date) _____ . Number issued _____ .

NOTES: