

INTRA-LABORATORY CORRESPONDENCE

OAK RIDGE NATIONAL LABORATORY

June 24, 1980

717401

TO: T. T. Odell
FROM: *C. R. Richmond*
C. R. Richmond
SUBJECT: Request from HEW Office for Protection from Research Risks

Attached is a memo from Dr. MacKay, Deputy Director, Office for Protection from Research Risks, officially requesting that Dr. Lushbaugh investigate and report to HEW on the TPA incident. Note that copies were provided to Domanski in NCI and to Slaga, Fry, and Postma here at ORNL.

It is apparent from MacKay's letter that he does not understand the relation between ORNL and ORAU as regards the Review Board. I spoke to Lushbaugh and he agrees that we should coordinate a response to MacKay.

Please coordinate the Division activities on this matter with Lushbaugh until Dr. Griesemer arrives. I will need to review and approve any Laboratory input to MacKay's request prior to transmittal to HEW.

CRR:sh

Attachment

cc: R. J. M. Fry
C. C. Lushbaugh
T. T. Odell/R. A. Griesemer
Herman Postma
T. J. Slaga

REPOSITORY MMES / ORNL

COLLECTION Director's Files

BOX No. _____

FOLDER _____

1120635
JUN 30 1980
(3 5-61)

A-00229

Human Subjects Project

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

June 17, 1980

C. C. Lushbaugh
Medical and Health sciences Division
Oak Ridge Associated Universities
Post Office Box 117
Oak Ridge, Tennessee 37830

Dear Dr. Lushbaugh:

This letter is an official request from the Office for Protection from Research Risks (OPRR) for an investigation and report concerning the involvement of individuals as subjects of research that had not been reviewed and approved by the institutional review board (IRB) at Oak Ridge National Laboratories. The incidents are described in the enclosed report to Dr. Thaddeus J. Domanski of the National Cancer Institute.

The General Assurance of Oak Ridge Associated Universities (G01716) with the Department requires review and approval of all research activities that involve human subjects conducted at or supported by Oak Ridge National Laboratories. The activities of Dr. Thomas J. Slaga and his colleagues, described in the enclosed letter, in applying 12-0-tetradecanoylphorbol-13-acetate (TPA) to themselves, were required to be reviewed and approved in advance by the IRB.

This office requests information on the following points:

1. confirmation from the institution of the reported incidents, including whether or not IRB review of the activities took place, and if so, minutes of the review;
2. in the event that there had been no prior IRB approval, a report of any follow-up or corrective action taken by the institution, including measures to prevent the recurrence of similar incidents;
3. a statement of the institutional policy regarding IRB review of such activities and what is being done administratively to insure understanding of, and compliance with, the policy on the part of researchers;

1120636

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Page 2 - C. C. Lushbaugh

4. how the current institutional policies regarding use and handling of known carcinogenic and other hazardous materials adequately cover research involving human subjects.

The enclosed letter to NCI states that the incidents were connected with research supported by the Department of Energy. It is important to note that, in addition to the Department of Health and Human Services requirement for IRB review of all research involving human subjects, the Department of Energy imposes the same requirements for research which it supports. The Department of Energy may take steps independently of this office to determine whether Oak Ridge National Laboratories is materially fulfilling its responsibilities for protection of human subjects.

Thank you for your cooperation in this matter. I look forward to your prompt response.

Sincerely yours,

Charles R. Mackay, Ph.D.
Deputy Director
Office for Protection
from Research Risks
Office of the Director

Enclosure

cc: Dr. Domanski, NCI
Dr. Slaga, ORNL
Dr. Fry, ORNL
Dr. Richmond, ORNL
Dr. Herman Postma ✓

Ms. Graham

1120637