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Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	<u>LBL Life Sciences Division</u>
	<u>R &amp; D Administrative Files</u>
Accession No.	<u>434-90-0236</u>
File Code No.	<u>13-11-26</u>
Carton No.	<u>26/30</u>
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Notes	
Found By	<u>John Stoner</u>
Dates	<u>Copied 7-21-94</u>

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## UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

OFFICE OF THE  
DEAN OF THE GRADUATE DIVISION

BERKELEY, CALIFORNIA 94720

October 10, 1966

## Institutional Assurance on Investigations Involving Human Subjects,

## Including Clinical Research

The University of California, Berkeley, agrees with the principles of the Public Health Service policy (identified as Policy and Procedure Order 129 dated July 1, 1966) with regard to investigations involving human subjects, including clinical research. This institution agrees that review independent of the investigator is necessary to safeguard the rights and welfare of human subjects of research investigations and assures the Public Health Service that it will establish and maintain advisory groups competent to review plans of investigations involving human subjects, prior to initiation of investigations, to insure adequate safeguard. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to obtain informed consent, and (3) the risks and potential medical benefits of the investigations.

The University of California, Berkeley, also agrees to exercise surveillance of PHS-supported projects using human subjects for changes in protocol which may alter the investigational situation with regard to the criteria cited above. The University of California, Berkeley, further assures the Public Health Service that it will provide advice and consultation to investigators on matters of employing human subjects in investigation, and also that it will provide whatever professional attention or facilities may be required to safeguard the rights and welfare of human subjects involved in investigation. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by the University.

Attached as part of this statement are copies of policy and procedure of this institution with regard to use of human subjects in investigation, as well as a description of the groups utilized to review projects for enforcement of these policies and the manner in which the institution will assure itself that the advice of the committee of associates is followed.

BEST COPY AVAILABLE

*Sanford S. Elberg*  
Sanford S. Elberg  
Dean of the Graduate Division

Attachement

Approved by the Public Health Service on October 28, 1966.

HUMAN SUBJECTS I  
HISTORICAL 1972-197

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- H. SPACE AND ALTERATION REQUIREMENTS: (Approved by \_\_\_\_\_ date \_\_\_\_\_)
- (1) Space required: \_\_\_\_\_ sq. ft. Give room(s) and building(s): \_\_\_\_\_  
Do you have a firm commitment that this space will be available throughout entire period of proposed project? \_\_\_\_\_  
If not, explain alternatives. \_\_\_\_\_
- (2) Will alterations to existing or proposed space be required? \_\_\_\_\_ If so, how will they be financed? \_\_\_\_\_
- I. OFFICE EQUIPMENT REQUIREMENTS: Will office equipment be needed? \_\_\_\_\_ How will it be acquired? \_\_\_\_\_
- J. HEALTH AND SAFETY IMPLICATIONS:
- (1) Will animals be used? \_\_\_\_\_ Do animal facilities meet State of California Burns Act requirements? \_\_\_\_\_  
Have these facilities been inspected by the Office of Environmental Health? \_\_\_\_\_
- (2) Will toxic solvents or noxious gases be used? \_\_\_\_\_ Is ventilation adequate? \_\_\_\_\_
- (3) Will radioactive materials be used? \_\_\_\_\_ Have facilities been approved by the Office of Environmental Health? \_\_\_\_\_  
Give date and number of active application to use radioisotopes. Date: \_\_\_\_\_ No.: \_\_\_\_\_
- K. COMPUTING SERVICE REQUIREMENTS: All computing services for project must be financed through project funds. If such services are required, complete the following:
- Computer Center: Hrs: 1st yr. \_\_\_\_\_ 2nd yr. \_\_\_\_\_ 3rd yr. \_\_\_\_\_ 4th yr. \_\_\_\_\_ 5th yr. \_\_\_\_\_  
Surv. Res. Center: Est. Cost: 1st yr. \$ \_\_\_\_\_ 2nd yr. \$ \_\_\_\_\_ 3rd yr. \$ \_\_\_\_\_ 4th yr. \$ \_\_\_\_\_ 5th yr. \$ \_\_\_\_\_
- L. BRIEF LAYMAN'S DESCRIPTION OF PROJECT:

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If proposal is to any unit of the U. S. Public Health Service, will human subjects be used? \_\_\_\_\_  
If yes attach protocol in accordance with the Policy and Rules of the University of California (Berkeley) Governing the Participation of Human Beings as Subjects in Research for USPHS Grants and Awards.

- M. SUBMITTED BY: (Signature) \_\_\_\_\_  
Principal Investigator Department or Institute Date
- N. APPROVALS:
- |                     |      |                               |      |
|---------------------|------|-------------------------------|------|
| Department Chairman | Date | Dean of the Graduate Division | Date |
| Institute Director  | Date | Campus Research Office        | Date |
| 1089680             | Date | Chancellor                    | Date |