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June 26, 1975

SENIOR RESEARCH COORDINATOR LORRAINE MC GRAW
Campus Research Office
Berkeley

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VICE PRESIDENT
BUSINESS & FINANCE
JUL 21 1975
JLN

Re: Legal Responsibility of University
for Acts of Principal Investigators
Where Research Involving Human Subjects
Not Approved by Institutional Review
Committee

During the meeting on Thursday, June 19, 1975, with representatives of DHEW to discuss the review by the Berkeley Campus of LBL activities involving human subjects, I indicated that if a Principal Investigator conducts an activity involving human subjects but does not obtain the approval of the Campus Institutional Review Committee, The Regents would not be obligated to defend or indemnify the Principal Investigator if legal action were instituted by the subject.

The University is legally responsible for the acts and omissions of its employees while acting in the course and scope of their University duties. In the event of suit against an employee based on his or her actions in connection with an activity involving human subjects alleged to have resulted in injury to a participant therein, the University would be obligated to assume the employee's defense if the research project was approved by the Institutional Review Committee. If a Principal Investigator has knowledge of, or should have knowledge of, the applicable University policy which requires every activity involving human subjects to be reviewed by an Institutional Review Committee and fails to obtain such approval prior to involvement of human subjects, the Principal Investigator would be acting outside of the scope of his or her duties.

In addition, as the University is obligated to provide for the medical care of any subject who suffers an injury as a result of his or her participation in an activity involving human subjects, the University would have the right to seek reimbursement from the Principal Investigator for any amounts expended if the Principal Investigator knew

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| Dates | |



SENIOR RESEARCH COORDINATOR LORRAINE MC GRAN
June 26, 1975

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or should have known that University policy requires all activities involving human subjects to receive the prior approval of the Institutional Review Committee.

Please let me know if you have any questions or wish to discuss this matter further.

David A. Dorinson
Assistant Counsel

cc: Charcellor Fowler
Chairman Phillips
Special Assistant to the President Powell, M.D.

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