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Lawrence Berkeley Laboratory	
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Records Series Title	<u>LBL Life Sciences Division</u>
	<u>R & 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>
Folder No.	<u>Encls Box</u>
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Found By	<u>John Stoner</u>
Dates	<u>Copied 7-21-94</u>

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OFFICE OF THE PRESIDENT
VICE-PRESIDENT—ADMINISTRATION

photo to Jim Born

January 29, 1973

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DE-Will

MR. WILLIAM D. DOUGLASS:

Re: Policy and Procedures Governing the Protection of Human Subjects

In your memo DC 72-1021 of November 14, 1972, you asked about the relationship between the Berkeley campus policy of November 8, issued by Chancellor Bowker, and the corresponding policy of the Office of the President also issued on November 8 by Vice President McCorkle.

The campus policy was an implementation of the University-wide policy dated March 29, 1972. The Berkeley campus policy had been approved by the General Counsel's office and by the National Institutes of Health Division of Research Grants.

As a related issue, we have explored the ramifications of Manager Robert Thorne's letter of August 18, 1972 in which he had indicated AEC believed that the University's policy went beyond the DHEW policy in its assumption of responsibility for the care of human subjects. This exploration resulted in a letter from Vice President Perkins to Dr. Donald T. Chalkley of NIH dated January 16, 1973, and a letter to Mr. Thorne of the same date, copies of which are enclosed. As you will see, the responses to these letters should result in a meeting of the minds among DHEW, AEC, and the University as to the status of the University's human subjects policy vis-a-vis that of DHEW and AEC.

Richard D. Wolfe
Richard D. Wolfe

Encls.

cc: Vice President Perkins, w/o encls.
Special Assistant Powell, w/o encls.
Clinton Longwill, w/encls.
Bill Harford, w/encls.
Dr. Schreiber, w/encls.

1/30/73 - Cy. sent to J. L. Born

HUMAN SUBJECTS I
HISTORICAL 1972-1975

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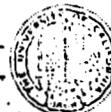
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	<u>R & D Administrative Files</u>
Accession No.	<u>434-90-0236</u>
File Code No.	<u>13-11-26</u>
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UNIVERSITY OF CALIFORNIA

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CHARLES J. HITCH
President of the University

JOHN A. PERKINS
Vice President—Administration

OFFICE OF THE PRESIDENT
BERKELEY, CALIFORNIA 94720

January 16, 1973

Mr. Robert D. Thorne
U. S. Atomic Energy Commission
San Francisco Operations Office
2111 Bancroft Way
Berkeley, California 94704

Dear Mr. Thorne:

I am sorry for the delay in replying to your letter of August 18, 1972 regarding the University's policy on the protection of human subjects.

You indicate that, based on your examinations and discussions with DHEW personnel of Vice President C. O. McCorkle's memorandum of March 29, 1972, our policy appears to go far beyond DHEW's interpretation of their policy in respect to assuming liability for medical care of subjects. Vice President McCorkle's memorandum (which was modified by the attached memorandum of November 8, 1972, although not in this respect) was issued in response to DHEW's publication of their policy as Chapter 1-40 of the HEW Grants Administration Manual. In compliance with DHEW policy each of our campuses has submitted to the NIH Division of Research Grants an "Institutional Assurance" based on the sample provided in Chapter 1-40 and containing an assurance substantially as follows:

"This institution will provide for the facilities and professional attention required for subjects who may suffer physical, psychological or other injury as a result of participation in an activity".

For ready comparison I'd like to quote the pertinent passage from the University policy:

"Adequate preparations shall be made and adequate facilities shall be provided to protect a subject against even remote possibilities of injury, disability, or death. This includes medical treatment and hospitalization which may be required during or as a result of an experiment. In this regard, attention is invited to Vice President McCorkle's letter of February 2, 1972" (I have also attached a copy of this).

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Prior to the issuance of the University's policy, University personnel attended NIH workshops on the implementation of the HEW policy and subsequently all of the individual campus assurances and the University policy contained in Vice President McCorkle's memorandum were carefully reviewed by the NIH Division of Research Grants. We do not recall that there was any discussion whether the requirement that each institution seeking a general assurance assume responsibility for the care of subjects was limited in any respect. Consequently, we are unaware of the interpretation of DHEW policy by DHEW to which you refer. I am therefore requesting from DHEW advice on whether our policy is broader than that required by DHEW. Nevertheless, I would appreciate it if you would advise me of the particulars imparted to AEC by DHEW.

We naturally feel that the University policy is consistent with DHEW's and that in our policy we are holding ourselves out to do no more than what we have agreed to do in our institutional assurances. We do not believe we are "assuming responsibility for the care of subjects over and above the responsibility recognized in the DHEW policy".

Attached hereto is a copy of my letter to the Division of Research Grants. I will advise you of their response, which I hope will resolve this matter.

Sincerely,



John A. Perkins

Att.(3)

cc: Chief, Institutional Relations Section
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20014

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