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LBL ATTACHMENT MEMO

Jan 29, 1973

TO P. J. Belcher FROM W. D. Douglas

Subject

For initial signature approval comments discussion information

Please file return draft reply route to

Message

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7600-54738 (Rev. 7/71)

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signed

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UNIVERSITY OF CALIFORNIA

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SANTA BARBARA

CHARLES J. HITCH
President of the University

JOHN A. PERKINS
Vice President—Administration

OFFICE OF THE PRESIDENT
BERKELEY, CALIFORNIA 94720

January 16, 1973

BIO-334-384

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 submitted to the NIH Division of Research Grants an "Institutional Policy" 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 the slightest possibility 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 directed to the assurance in McCorkle's letter of January 2, 1972 (copy of which is attached to the back 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

February 2, 1972

CHANCELLORS
VICE PRESIDENT -- AGRICULTURAL SCIENCES
VICE PRESIDENT -- PUBLIC SERVICE PROGRAMS

Gentlemen:

Research on Human Subjects - Responsibility for Medical Care

A recent contract proposal to the Berkeley campus from the U.S. Army Medical and Research Development Command contained the following new condition:

"Adequate preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. This includes hospitalization and medical treatment as may be required."

Correspondence between the Office of the General Counsel and representatives of the U.S. Army resulted in clarification by the Army Contracting Officer as follows:

"The words 'hospitalization and medical treatment,' as used in paragraph 0.11 of the contract means that you are required to provide the experimental subject with any hospitalization and/or medical treatment, which may be required during or as a result of the experiment."

The Office of the General Counsel has pointed out that this provision, would obligate the University to provide medical care, including permanent medical care, required as the result of the experiment, even "in the absence of any negligence or any wrongdoing on the part of the University," and would thus extend the obligation of the University beyond that legally required in the absence of this provision.

However, I do not believe that the University should or could ignore its moral and ethical responsibility to provide medical care required as the result of experimentation which it conducts on humans, irrespective of our legal obligations to provide such care in the absence of negligence or other wrongdoing. I have therefore authorized the execution of the proposed contract with the Army, including the provisions quoted above.

It is our understanding that this provision will become a standard clause in future proposals for research on humans from the Department of the Army, Navy, and Air Force. I am bringing it to your attention with the thought that you may want to alert your Contract and Grant Officers, your Deans, Chairmen of appropriate departments, and especially your Campus Committee

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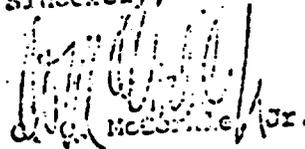
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On Human Experimentation, to be sure that all are aware of this situation. While the primary consideration in the review of proposals for experimentation involving humans must remain the health and wellbeing of the subjects, those responsible for the review and conduct of such experiments should be aware of the financial implications, including those of an extended nature, which might be required as a result of the experiment.

Sincerely,



C. G. McCord, Jr.

cc: President Hitch
Vice Presidents
Laboratory Directors
Special Assistant Goldschmidt
Special Assistant Powell
General Counsel Cunningham

November 8, 1972

CHANCELLORS

VICE PRESIDENT -- AGRICULTURAL SCIENCES

VICE PRESIDENT -- EXTENDED ACADEMIC AND PUBLIC SERVICE PROGRAMS

Gentlemen:

Policy on The Protection of Human Subjects

Subsequent to the issuance of a U.S. Public Health Service policy titled "Protection of the Individual as a Research Subject" (May 1, 1969), President Hitch issued, on June 25, 1970, a University policy concerning research involving human subjects. That University policy provided that the USPHS policy " . . . shall be applicable to all investigations involving human subjects for which the University is responsible, not just those funded by the USPHS . . ."

On April 15, 1971, the USPHS policy was superseded by a Department of Health, Education, and Welfare policy. Consequently, I issued on March 29, 1972 a revised policy statement, to supersede the University's June 25, 1970 policy. During subsequent discussions with representatives of the campuses, the Office of the President, and the Office of the General Counsel it became clear that certain modifications of the March 29 policy were needed. These have been incorporated in the attached policy which is to be effective immediately. The principal changes in the revised statement are (1) the extension of the applicability of the policy as required by DHEW to a broader scope of activities than just research, i.e., to classroom activities, demonstrations, and other activities in which human subjects may be at risk; and (2) the permissibility of obtaining consent after the fact in unusual circumstances.

As was the case with the USPHS policy, the new DHEW policy shall be applicable to all activities involving human subjects (as defined in the DHEW policy) for which the University is responsible except for those supported by other granting agencies which have their own regulations. In the case of conflict between regulations of another funding agency and DHEW, the more restrictive regulations shall prevail.

The University policy has three attachments*: (1) a copy of DHEW Grants Administration Manual Chapter 1-40 (dated April 15, 1971) which

*These attachments are not being circulated with this revised policy, since they are identical to the attachments sent with the March 29 policy with one correction: the title of attachment (3) should be changed from "Supplement to The Policy on Research Involving Human Subjects" to "Supplement to The Policy on The Protection of Human Subjects."

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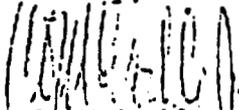
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includes a basic statement of the policy, its applicability, and implementing procedures; (2) a copy of The Institutional Guide to DHEW Policy on Protection of Human Subjects, DHEW Publication No. (OS) 72-102, December 1, 1971, and (3) a "supplement to the Policy on The Protection of Human Subjects," consisting of a compilation of memoranda from the campuses, the Office of the President, and the Office of the General Counsel on several issues related to the implementation of the policy.

The DHEW policy is clearly derived from the old PHS policy, with two differences which deserve special mention: (1) The DHEW policy provides for two types of assurances, a "general assurance" and a "special assurance" (Grants Administration Manual Chapter 1-40, pages 5-6) -- the University falls into the general assurance category, and (2) minor changes have been made in the "Informed Consent" provisions (*ibid.*, pages 2, 16 and 17) and the applicable ones have been incorporated in the University's form "Consent to Act as Human Subject" (attached to the University's policy).

As was mentioned in connection with the issuance of the earlier University policy, no policy such as this can provide for all possible circumstances. Thus we recognize that, in practice, this policy will have to be interpreted with some flexibility, although this must be done with strict adherence to its spirit. For example, while this policy applies to all subjects "at risk," defined as exposure ". . . to the possibility of harm -- physical, psychological, sociological, or other -- as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs," there will be many instances, particularly in the social and behavioral sciences, for which it will be difficult to determine whether the applicability of this policy is indicated. As the policy states, "The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question. Responsibility for this determination resides at all levels of institutional and Departmental review. Definitive determination will be made by the operating agency" (page 2).

Sincerely,


C. O. McCorkle, Jr.

Attachments

cc: President Hitch
Other Vice Presidents
Laboratory Directors
Special Assistant Powell
General Counsel Cunningham
Assistant Vice President Everett

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November 8, 1972

POLICY ON THE PROTECTION OF HUMAN SUBJECTS

1. The responsibility for compliance with regulations concerning activities in which human subjects may be at risk shall rest with the Chancellors, the Vice President -- Agricultural Sciences, and the Vice President -- Extended Academic and Public Service Programs.
2. The policy of the Department of Health, Education, and Welfare, as contained in the attached copy of Grants Administration Manual Chapter 1-40 (April 15, 1971), shall be applicable to all activities involving human subjects (as defined in that Chapter) for which the University is responsible, not just those funded by the DHEW, except for those supported by other granting agencies which have their own regulations. In the case of conflict between regulations of the funding agency and DHEW, the more restrictive regulations shall prevail.
3. In order to provide maximum protection from legal liability the individuals responsible for activities in which human subjects may be at risk, the campus review committees, and The Regents, one of the two attached standard forms titled "Consent to Act as Human Subject" and subtitled "(Regular Form)" and "(Short Form)", respectively, is to be used on all campuses and in all cases except those where the Committee has determined that consent is ". . . implicit in voluntary participation in an adequately advertised activity . . . in the light of the risks to the subject . . ." (see pages 7-8 of the attached copy of The Institutional Guide to DHEW Policy on Protection of Human Subjects). Either of these forms may be modified, if deemed necessary, with the approval of the campus review committee. In keeping with the opinion of the General Counsel, in those cases in which the basic elements of informed consent are to be presented orally to the subject, i.e., cases for which a Short Form is to be used, the complete statement of what is to be said to the subject is to be approved by the Committee, not just "written summaries," as required by the "Institutional Guide" (page 16). In those cases in which the Committee agrees to waive the requirement of informed consent altogether, the Committee must have been advised of the information which is to be provided to the subjects.
4. Only in rare and unusual circumstances, where the obtaining of informed consent would prejudice the outcome of a proposed activity, may the committee approve an activity which does not provide for consent. Advance committee approval for such a procedure is required and is to be given only after consideration of the proposed justification for the waiver of the consent requirement. In all such circumstances, the committee shall require debriefing of the subject and shall approve the debriefing procedure.
5. Adequate preparations shall be made and adequate facilities shall be provided to protect a subject against even remote possibilities of injury,

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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 (Attachment B of the Supplement).

6. The campuses shall submit to the Office of the General Counsel the policies and procedures required to be formulated and submitted to DHEW to assure that legal and policy requirements are met, prior to promulgation or submission of the campus' general assurance to DHEW. Furthermore, in the event that, in connection with a specific research proposal, the investigator or the campus review committee identifies a significant legal issue, approval of that proposal shall be sought from the General Counsel.

In order to assist the researchers as well as the campus review committees in their effort to identify the common types of legal issues which might be presented and to develop criteria for their resolution, the General Counsel has provided the following list of criteria which may be used in determining whether to submit a particular project for legal review:

- a. The involvement of minors.
 - b. The involvement of adults whose competence to give an informed consent may, in the opinion of the principal investigator, or the campus review committee, be subject to question.
 - c. Doubt in the minds of the principal investigators or members of the campus review committee as to whether the explanation set forth on the consent form is sufficient fully to inform the subject of the activity in regard to the procedures to be performed and the risks attendant thereto.
 - d. The necessity for the principal investigator or those working under his direction to perform acts requiring licensure under the provisions of law relating to the healing arts.
 - e. Questions concerning interpretation of DHEW policy.
7. If a proposed activity is to include students of the University as subjects, the Student Health Service Director of the campus responsible for the activity to be conducted, if not already a member of the campus review committee, shall be consulted in the review of that particular activity.

UNIVERSITY OF CALIFORNIA

CONSENT TO ACT AS HUMAN SUBJECT

(REGULAR FORM)

Subject's name _____

Date: _____

1. I hereby authorize _____
[name of person(s) who will perform the

_____ and/or such assistants as may
procedure(s) and/or investigation(s)]

be selected by him to perform the following procedure(s) and/or
investigation(s): (Describe in detail in language which will provide a
fair explanation of the procedure(s) to be followed, including an identifica-
tion of those which are experimental.)

on _____
(Subject)

2. The procedure(s) and/or investigation(s) listed in Paragraph 1
has (have) been explained to me by _____
(Name)

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and my participation is terminated by me or by the investigator I understand that I will be entitled to payment of a sum based upon the scientific value to the study of the information obtained from my participation; provided, however, that in no event shall I receive less than _____ per cent of the agreed compensation if I continue to participate beyond the _____
(Describe the applicable time period)
_____ of the study.

SUBJECT'S SIGNATURE _____

WITNESS _____

(If subject is a minor, or otherwise unable to sign, complete the following):

Subject is a minor (age _____), or is unable to sign because

Father

Guardian

Mother

Other person and relationship

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CONSENT TO ACT AS HUMAN SUBJECT

(SHORT FORM)

Subject's Name: _____

Date: _____

Name of Project: _____

I hereby consent to be a participant in the activity named above.

An explanation of the procedure(s) and/or investigation(s) to be followed, including an identification of those which are experimental, was provided to me by _____ . I was provided with a
Name

description of the attendant discomforts and risks to be expected. I was assured that any inquiries concerning the procedure(s) and/or investigation(s) would be answered. I was assured that I am free to withdraw my consent and to discontinue participation in the project or activity at any time.

Subject's Signature: _____

Auditor-Witness: _____
(To oral presentation and signature)

(If subject is a minor or otherwise unable to sign, complete the following):

Subject is a minor (age _____), or is unable to sign because

Father

Guardian

Mother

Other person and relationship

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