Research Administration Office

University of California

Memo Operating Guidance

C& G No. 86-21

August 21, 1986

Subject: Contract and Grant Manual, Chapter 18, "Protection of Research Subjects" -Source Documents

This memo distributes the documents referenced in Chapter 18 "Protection of Research Subjects" of the University Contract and Grant Manual issued by Contract and Grant Circular 5 on August 8, 1986.

The documents attached are as follows:

Presidential Memorandum, September 2, 1981, University Policy on the Protection of Human Subjects in Research

Presidential Memorandum, January 19, 1979, University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research

Presidential Memorandum, October 15, 1984, University Policy on the Use of Animals in Research and Training

45 CFR Part 46, Protection of Human Subjects

21 CFR Part 50, Protection of Human Subjects

21 CFR Part 56, Institutional Review Boards

Declaration of Helsinki

Nuremberg Code

The following Contract and Grant Memos are hereby canceled and may be disposed of:

- 24-76, I -1 - 24-75, I -3 - 3-74, I -4 - 24-72, I-2

Department of the Army Regulations Governing the Use of Human Subjects in Research, Development, Tests and Evaluation Submission of Certification Concerning Protection of Human Subjects

Department of Health, Education and Welfare Grants, Administration Manual, Chapters 1-43, Animal Welfare

Research Involving Human Subjects

Refer: Barbara Yoder ATSS 8-582-2866 (415) 642-2866

Subject Index: 18

Organization Index: U-115, F-350

David F. Mears

University Contracts and Grants Coordinator

Enclosures (Distributed to Contracts and Grants Officers only)

UNIVERSITY OF CALIFORNIA

Office of the President

September 2, 1981

CHANCELLORS

LABORATORY DIRECTORS

VICE PRESIDENT--AGRICULTURE AND UNIVERSITY SERVICES ACADEMIC VICE PRESIDENT

Dear Colleagues:

I am issuing the attached policy on the protection of human subjects in research, to be effective immediately. The attached supersedes the policy issued on November 8, 1972 and the November 24, 1972 modification to that policy.

University policy has been revised in response to the recently promulgated regulations of the Department of Health and Human Services (HHS) issued January 26, 1981, which were effective on July 27, 1981. As you know, these regulations are the result of a process that began with the enactment of the National Research Act on July 12, 1974, and culminated in the current regulations which provide for reduction in the scope of HHS regulatory coverage. The higher education community has been actively involved in commenting on Federal initiatives throughout this period.

Since 1970 when the first University policy on the protection of human subjects was issued by then President Hitch, University policy has required that all activities involving human beings be reviewed to determine whether these persons were being placed at risk. The policy did not distinguish between research and other activities (e.g., demonstration projects), however,-and given our experience over the past decade and the development of numerous studies and reports, it appears that there are adequate protections for individuals who participate in activities other than research. Consequently, I am limiting the requirements for review by the campus' Institutional Review Board to research which, under the HHS regulations, would be subject to formal review.

Under the former Department of Health, Education, and Welfare regulations, the Institutional Review Board had the authority to determine whether an activity constituted research involving human subjects. The new regulations authorize institutions to determine whether activities are subject to

review. As the officer responsible for developing implementing procedures, you will also be responsible for developing an appropriate process to determine whether these activities constitute research, and if so, whether they are exempt from formal review.

Consistent with past practices, you are authorized to take appropriate action in complying with this policy and all other applicable human subject regulations.

I will delegate responsibility for this area to the Academic Vice President. Implementation of the policy for Systemwide Administration will also be the responsibility of the Academic Vice President except for those areas under the Jurisdiction of the Vice President--Agriculture and University Services.

Sincerely,

David S. Saxon President

Attachment

cc:

Vice President Fretter

General Counsel Reidhaar

Assistant President Everett

Office of the President September 2, 198l

UNIVERSITY POLICY ON THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

1. PREAMBLE

The University of California is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research./1 The University recognizes and accepts responsibility, which it shares with its investigators and other researchers, for .determining that research involving human subjects fulfills these ethical principles.

2. POLICY ON APPLICABILITY OF REGULATIONS

It is University policy that the regulations of the Department of Health and Human Services (HHS), set forth in 45 CFR Part 46, are applicable to all research involving human subjects, as defined by these regulations, for which the University is responsible, regardless of the source of funding or whether the research is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS the more restrictive regulations shall prevail.

3. RESPONSIBILITY FOR COMPLIANCE

The Chancellors, the Academic Vice President, the Vice President-Agriculture and the University Services and the Directors of the Department of Energy Laboratories are responsible for compliance with this policy. They are authorized to take appropriate action to implement the human subjects

regulations of all funding or regulatory entities covering activities under their jurisdiction. In developing implementing procedures for research the Chancellors, Vice Presidents and Directors shall establish a process for determining whether an activity. constitutes research under the regulations and whether the research activity is exempt. from formal review. As a minimum, such a process should provide some form of consultation by investigators.

4. REVIEW BY THE OFFICE OF THE GENERAL COUNSEL

When significant legal issues are identified by investigators or Institutional Review Boards in connection with a specific research proposal they shall be forwarded to the Office of the General Counsel for review. The assurances developed to implement government regulations shall also be forwarded to the Office of the General Counsel to assure that legal requirements are met.

5. MEDICAL CARE AND TREATMENT

The scope and extent of medical care that the University will provide to human subjects in research is described in the University policy, Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research, issued January 19, 1979.

1/A copy of these principles is attached to this policy.

January 19, 1979

CHANCELLORS

MEMBERS, EXPANDED PRESIDENT'S ADMINISTRATIVE COUNCIL LABORATORY DIRECTORS

I am issuing the attached University policy which sets forth the scope and extent of medical care the University will provide to human subjects who suffer an injury as a result of participation in an authorized University activity. This revision replaces the policy issued on February 2, 1972, Research on Human Subjects - Responsibility for Medical Care.

The immediate impetus for this revision is a new Federal regulation, effective January 2, 1979, which amends the definition of informed consent to require advising prospective subjects as to whether medical treatment or compensation for physical injuries resulting from participation in biomedical and behavioral research is available and, if so, what it consists of, and where further information about it may be obtained. My understanding is that University Institutional Review Boards (IRBs) have been advised by the General Counsel of The Regents as to what is now required in informed consent forms and we assume that appropriate statements have been prepared by IRBs. The attached policy provides information you will need for responding to inquiries.

The decision on an appropriate fund source with respect to a claim will be made, as is usual, on a case. by case basis.

You may want to be in touch with Belle Cole, Director-Legislation and Public Policy and David Dorinson, Associate Counsel, about these changes.

Sincerely,

Attachment

David S. Saxon, President

cc:

Chair, Academic Council

Principal Officers of The Regents

Campus and Laboratory Chairs, University IRBs

BC:DSS:MH

Office of the President January l9, 1979

University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research

The University under existing policy has agreed to provide medical care to human subjects for any injury or illness suffered as a result of participation in an authorized University activity. Over the years, various questions have arisen concerning the policy which require further elaboration of it. As a result, I am issuing the following University policy which will supersede existing policy, issued on February 2, 1972:

The University of California will provide to any injured subject any. and all medical ,treatment reasonably necessary for any injury or illness which a human subject suffers as a direct result of participation in an authorized University activity covered by University policy on the protection of human subjects in research or reimburse the subject for the costs of such treatment, except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly.

2. The obligation of the University undertaken in paragraph 1. shall be subject to the following conditions:

a. It must be demonstrated that the injury resulted directly from participation in the specified activity.

b. Written notification of any such injury is to be given to the University by the human subject within a reasonable time after discovery.

c. Any claim for reimbursement is to be supported by appropriate documentation.

It is the preference of the University that the medical treatment available under this policy be provided at a University of California medical facility.

Chancellors and other chief administrators, as appropriate, shall designate an individual or office as a contact for inquiries about implementation of this policy.

October 15, 1984

CHANCELLORS

LABORATORY DIRECTORS

VICE-PRESIDENT--AGRICULTURE AND NATURAL RESOURCES SENIOR VICE PRESIDENT--ACADEMIC AFFAIRS

Dear Colleagues:

I am issuing the attached policy on "the use of animals in research and teaching to be effective immediately. Appointments to your animal research committee should be in compliance with University policy by January 1, 1985.

You are authorized to take appropriate action in complying with this policy and all other applicable animal use regulations. I have delegated responsibility to the Senior Vice President--Academic Affairs for functions appropriate to the Office of the President.

The University policy sets forth common procedures that assure the continued maintenance of high standards of animal care and use within the University. The policy-calls for University compliance with specific federal standards and requirements, some of which are in the process of being revised. The University is participating actively in the review of these standards and policies.

Thank you for. your active assistance in developing this policy.

Sincerely,:

Attachment

cc:

Vice Presidents

General Counsel Reidhaar Executive Assistant Copeland

Academic Senate Chair Smith Director Cole

Director Rogin

UNIVERSITY OF CALIFORNIA

OFFICE OF THE PRESIDENT

October 15, 1984

UNIVERSITY POLICY ON THE USE OF ANIMALS IN RESEARCH AND TEACHING.

PREAMBLE.

The University of California recognizes the importance of the use of animals in its research and teaching programs. Animals are vital both for understanding basic biological processes and in developing treatment for human and animal diseases.

The University, committed to maintaining high standards for the care and use of animals in research and teaching, therefore adopts as its own principles the National Institutes of Health (NIH) "Principles for Use of Animals." (See Attachment) The University, including its investigators and researchers, accepts responsibility for determining that research and teaching involving the use of animals fulfill-these principles.

POLICY ON APPLICABILITY OF THE FEDERAL GUIDELINES AND REGULATIONS.

It is University policy that University practices for the procurement, housing, care, and use of animals should conform to the NIH Guide for the Care and Use of Laboratory Animals in Research (DHEW 78-23), reprinted in 1980 (DHEW 80-23 or succeeding editions), all requirements of the United States Department of Agriculture (USDA) and all regulations issued by the USDA implementing the Animal Welfare Act (P.L. 89-544) as amended. The Chancellor, Vice President, or Director shall take appropriate action to meet such standards. The policy applies to all research and teaching irrespective of whether the research is funded from extramural or internal sources.

RESPONSIBILITY FOR COMPLIANCE.

The Chancellors, the Directors of the Department of Energy Laboratories, and the Vice President--Agriculture and Natural Resources are responsible for compliance with this policy in their institutions. They are authorized to take appropriate action for those activities under their jurisdiction to implement regulations required by all funding and regulatory agencies on the care and use of animals in research and teaching. Each Chancellor and .Director and the Vice President shall-establish implementing procedures including an animal research committee to assure adequate review of animal facilities, procedures, research, and teaching protocols.

The committee shall consist of no fewer than five members with varying backgrounds. At least one member shall be a licensed doctor of veterinary medicine and at least one member shall be a person whose-primary vocation is in a nonscientific area. One member shall be unaffiliated with the institution,

ACCREDITATION

All facilities in Which animals are housed shall be fully accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) or the Chancellor, Vice President, or Director shall be taking appropriate action to achieve such accreditation.

RESPONSIBILITY IN OFFICE OF THE PRESIDENT

The Senior Vice President--Academic Affairs is responsible, on behalf of the President, for assuring University compliance with the policy and for developing-any modifications or exceptions to policy as appropriate.

ATTACHMENT

"October 15, 1984

National Institutes of Health Policy on Humane Care and Use of Animals

PRINCIPLES FOR USE OF ANIMALS

The Personnel

1. Experiments involving live, vertebrate animals and the procurement of tissues from living animals for research must be performed by, or under the immediate supervision of, a qualified biological, behavioral, or medical scientist.

2, The housing, care, and feeding of all experimental animals must be supervised by a properly qualified veterinarian. or other scientist competent in such matters.

The Research

3. The research should be such as to yield fruitful results for the good of society and not random or unnecessary in nature.

4. The experiment should be based on knowledge of the disease or problem

under study and so designed that the anticipated results will justify its performance.

5. Statistical analysis, mathematical models, or in vitro biological systems should be used when appropriate to complement animal experiments and to reduce numbers of animals used.

6. The experiment should be conducted so as to avoid all unnecessary suffering and injury to the animals.

7. The scientist in charge of the experiment must be prepared to terminate it whenever he/she believes that its continuation may result in unnecessary injury or suffering to the animals.

8. If the experiment or procedure is likely to cause greater discomfort than that attending anesthetization, the animals must first be rendered incapable of perceiving pain and be maintained in that condition until the experiment or procedure is ended. The .only exception to this guideline should be in those cases where the anesthetization would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure. -Such procedures must be carefully supervised by the principal investigator or other qualified senior scientist.

9. Post-experimental care of animals must be such as to minimize discomfort and the consequences of any disability resulting from the experiment, in accordance with acceptable practices in veterinary medicine.

10. If it is necessary to kill an experimental animal, this must be accomplished in a humane manner, i.e., in such a way as to insure immediate death in accordance with procedures approved by an institutional committee. No animal shall be discarded until death is certain.

The Facilities

11. Standards for the construction and use of housing, service, and surgical facilities should meet those described in the publication, Guide for the Care and Use of Laboratory Animals, (DHEW 78-23, or as "otherwise required by the U.S. Department of Agriculture regulations established under the terms of the Laboratory Animal Welfare Act (P.L. 89-544) as amended 1970 and 1976 (P.L. 91-579 and P.L. 94-279).

12. Transportation of animals must be in accord with applicable standards and regulations, especially those intended to reduce discomfort, stress to the animals, or spread of disease..All animals being received for use as experimental subjects and having arrived at the terminal of a common carrier must be promptly picked up and delivered, uncrated, and placed in acceptable permanent facilities.

NUREMBERG CODE

"1. The voluntary consent of the human subject is absolutely essential...

"The duty and responsibility-for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which many not be delegated to another with impunity.

"2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

"3. The experiment should be so designated and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

"4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

"5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

"6. The degree of risk to be taken should never exceed that determined by the. humanitarian importance of the problem to be solved by the experiment.

"7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

"8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

"9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

"10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any state, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability or death in the experimental subject."

*Projects involving human subjects who are unable to give consent will require legally effective informed consent from guardians/conservators.
