UCM DA 195

UNIVERSITY OF CALIFORNIA

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University of California, Merced
5200 N. Lake Road
Merced, CA 95343

June 23, 2020

VICE CHANCELLOR RESEARCH

RE: Delegation of Authority (DA) – Protection of Human Subjects in Research

Effective immediately, as Chancellor and pursuant to the authority delegated to me, I delegate to you as Institutional Official the responsibility for the protection of human subjects involved in biomedical and behavioral research, regardless of funding source. Your responsibilities include authorization to take appropriate action to implement the human subjects regulations of all funding or regulatory entities covering activities under your jurisdiction.

- Source of Authority: **UCOP Policy on the Protection of Human Subjects in Research**
- This authority may not be redelegated by you.

This Delegation supersedes the relevant delegation in UC Merced DA 048, UCOP DA 0710

Sincerely,

[redacted]

Nathan Brostrom
Chancellor

cc: Director Ethics and Compliance, Viola Kinsman

Protection of Human Subjects in Research

Responsible Officer:	VP - Research & Graduate Studies
Responsible Office:	RG - Research & Graduate Studies
Issuance Date:	9/1/1981
Effective Date:	9/1/1981
Scope:	The protection of human subjects involved in biomedical and behavioral research, regardless of funding source, at all UC campuses and the Lawrence Berkeley National Laboratory

Contact:	Jeff Hall
Email:	jeff.hall@ucop.edu
Phone #:	(510) 987-0688

I. POLICY SUMMARY

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. UC recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles. 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. .

II. DEFINITIONS

Not applicable.

III. POLICY TEXT

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. 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.

It is University policy that the regulations of the Department of Health and Human Services (HHS), set forth in *45 CFR Part 46*,(and known informally as the "Common Rule"), 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. The University is also obligated by law to adhere to the regulations of the Food and Drug Administration (*21 CFR Parts 50 and 56*) governing projects involving investigational new drugs [within the meaning of 21 U.S.C. sections 355(i) or 357(d)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].

IV. COMPLIANCE / RESPONSIBILITIES

The Chancellors, the Academic Vice President, the Vice President-Agriculture and the University Services and the Director of the Lawrence Berkeley National Laboratory 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 Director 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.

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.

V. PROCEDURES

It is University policy that each campus and Laboratory comply with current HHS policy requirements to provide written assurances acceptable to the Office for Protection from Research Risks, National Institutes of Health, HHS. . The specific instructions for preparation of such assurances are set forth in *45 CFR Part 46.103*.

Implementing procedures and other guidance related to this policy may be found in the University Contracts and Grants Manual, Chapter 18-200.

Cooperative Research

When the University contracts or subcontracts research to a cooperating institution, the University as a grantee or prime contractor is committed to and remains responsible for safeguarding the rights and welfare of human subjects. The University may use joint review, seek reliance upon the review of the qualified IRB at the cooperating institution, or undertake other appropriate arrangements aimed at protecting the rights of human subjects in research.

VI. RELATED INFORMATION

Belmont Report

Nuremberg Code

The Declaration Of Helsinki

Experimental Subject's Bill Of Rights (California Health & Safety Code 21472)

UC Contracts & Grants Manual, Chapter 18, Protection of Human Subjects in Research

University Policy for Medical Treatment of Human Subjects for Injuries Resulting From Participation In Research

Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects -Guidance Memo No. 95-05
Guidance on Surrogate Consent for Research

Use of Specimens (Moore Clause) Disclosure in the Research Consent Form

Guidance on Retention and Disposition Requirements for Administrative Records Relating to Research

VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

This policy was reformatted into the standard University of California policy template effective June 1, 2012.