



Protection of Human Subjects in Research

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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. This Policy applies to all University of California locations, including the campuses and Lawrence Berkeley National Laboratory, University of California faculty and staff who are conducting Research involving Human Subjects within the course and scope of their University duties, and University of California students who are conducting Research involving Human Subjects within the course and scope of their University studies.

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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.—.~~

This Policy describes the responsibilities of the University, its campuses and researchers, in protecting the rights and welfare of Human Subjects who participate in Research in which the University is engaged.

II. DEFINITIONS

~~Not applicable.~~

Common Rule means the Federal Policy for the Protection of Human Subjects as adopted by (and codified in the regulations of) multiple federal agencies. For the purposes of this Policy and related policy guidance or procedure documents, the Common Rule refers to Subpart A of Department of Health and Human Services (HHS) regulations at Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46, Subpart A).

Human Subject generally means an individual who becomes a participant in Research. However, more specific definitions must be applied depending upon the type of Research and its funding source:

As defined in HHS regulation 45 CFR 46.102(e), Human Subject means “a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

As defined in Food and Drug Administration (FDA) regulation 21 CFR 312.3(g) and 21 CFR 312.3(h), Human Subject means “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.” See also 21 CFR 312.3(b) for additional definitions related to Human Subjects Research. Regulation 21 CFR 312.3(p) defines subject as “a human who participates in an investigation, either as an individual on whom or on whose specimen an

investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.”

Institutional Review Board (IRB) is the generic name for any board, committee, or other group formally designated by an institution to review the conduct of Research involving Human Subjects.

Research means the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, consistent with the HHS definition of research (45 CFR 46.102(l)).

III. POLICY TEXT

Introduction

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

~~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 that underlie relevant federal regulations. The principles include:~~

- **Respect for persons** involves the ~~Protection~~ recognition of the personal autonomy and dignity of individuals, and the need for special protection of individuals with diminished autonomy. Under this principle, individuals must be given sufficient and comprehensible information to decide whether to participate in a study, and their consent must be voluntarily given, free from coercion and undue influence.
- **Beneficence** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle requires assessing the nature and scope of the risks and benefit, and systematically assessing the risks and benefits.
- **Justice** requires that the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition--as children, prisoners, patients, impoverished persons--places them in a vulnerable or dependent position.

Policy Statement

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)].~~

~~In order to safeguard the rights and welfare of Human Subjects of Biomedical and Behavioral Research, The, the University recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these of California (UC) follows the ethical principles. of the Belmont Report and adheres to all applicable federal or state law or regulations, and University policies and guidelines governing the participation and protection of Human Subjects in Research. Coupled with this responsibility, each University of California location, which includes all 10 campuses and the Lawrence Berkeley National Laboratory, holds a current Federalwide Assurance filed with the Department of Health and Human Services Office of Human Research Protection (OHRP) for the protection of Human Subjects. This assurance applies to all Research with Human Subjects in which the University is engaged and that is funded or supported by a federal agency that has adopted the Common Rule, regardless of the site of the activity.~~

~~The University's commitment to protecting Human Subjects applies to all Human Subjects Research in which it is engaged, regardless of funding source or the institution that provided the IRB review. When engaged in Research that is not subject to the Common Rule (because, e.g., the Research is not federally funded), each UC location may replace specific Common Rule requirements with commensurate protections for Human Subjects so long as the University follows the ethical principles referenced above and that those commensurate protections are consistent with other applicable federal or state laws.~~

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.~~

~~Each UC location is responsible for compliance with this Policy. Implementing guidance specific to each campus may supplement this Policy to assure full compliance with all federal and state laws and regulations, and with all UC policies governing the participation of Human Subjects in Research. Further responsibilities are provided below.~~

Campus Responsibilities:

The Chancellors, the ~~Academic Vice President~~, the Vice President-Agriculture and the ~~University Services~~ Natural Resources, 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, or their designees,~~ are responsible for designating an Institutional Official who oversees Human Subject protections at the campus and serves as the signatory official on the Federalwide Assurance filed with OHRP. The Institutional Official appoints members of the IRBs and ensures that the IRBs remain free from undue influence on their decision-making. The Institutional Official shall ensure that adequate resources are provided to support the IRB's review.

Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve Human Subjects Research if it has not been approved by an IRB.

Institutional Review Board Responsibilities:

Each UC location maintains IRBs that are charged with the review and continuing oversight of Research involving Human Subjects, in accordance with University policies and federal regulations. The IRBs have the authority to:

- Approve, disapprove, or require modifications to research protocols;
- Suspend or terminate approval of Human Subject Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects;
- Observe, or have a third party observe, the consent process and/or the conduct of Research; and
- Establish written procedures for ensuring prompt reporting of any unanticipated problems involving risks to Human Subjects or others and serious or continuing noncompliance.

Campuses may grant the IRBs additional authorities.

Other Campus Offices and Committees:

The protection of Human Subjects participating in Research expands beyond the IRB and involves multiple groups, such as, the Office of Research, Conflict of Interest and Conflict of Commitment committees, Biosafety Committee, Radiation Safety Committee, hospital and campus risk management, research compliance, privacy, legal counsel, and staff who provide support services to researchers. These offices and committees may work in concert with the IRB when carrying out their core functions supporting Research.

Investigator Responsibilities:

All University of California faculty and staff who are conducting Research involving Human Subjects within the course and scope of their University duties, as well as University of California students who are conducting Research involving Human Subjects within the course and scope of their University studies, regardless of whether the Research is funded and regardless of the source of funding, must submit Human Subject Research protocols

to the IRB for approval or follow campus policies and/or procedures for obtaining an exempt determination prior to commencing Research. Investigators shall maintain IRB approval for the lifespan of the project and shall submit continuing review documents to the IRB as necessary to maintain the approval.

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.~~

Implementing procedures or additional guidance related to this Policy may be found on the UCOP Research Policy Analysis and Coordination website.

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~~

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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

Resources:

- Experimental Subject's Bill Of Rights (California Health & Safety Code 24172)
- 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
- Standard Language In Research Informed Consent Forms For Research In Which Biospecimens And/Or Information Derived From Biospecimens Are Obtained From Research Participants
- Guidance on Retention and Disposition Requirements for Administrative Records Relating to Research
- Finance Bulletin, IS-3 Electronic Information Security

II.VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

February 25, 2020: This Policy was updated to include:

- A new definition section for the Policy.
- An explanation of the ethical principles that the University follows for Human Subjects Research.
- A statement that the University's commitment to Human Subjects applies to all Human Subjects Research in which the University is engaged, regardless of funding source or the institution that provided the IRB review.
- An explanation that campuses may replace specific Common Rule requirements with commensurate protections for Human Subjects when the University is engaged

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in research that is not subject to the Common Rule (e.g., research that is not federally-funded or otherwise subject to federal oversight).

- A description of the responsibilities of the campuses, IRBs, other oversight offices and committees, and researchers for compliance with this Policy.

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

September 1, 1981: A new UCOP policy written in response to the January 26, 1981 containing extensive revisions to 45 CFR 46.

IX. APPENDIX

Not applicable