UCLA Policy 991: Protection of Human Subjects in Research

Issuing Officer: Vice Chancellor for Research & Creative Activities
Responsible Dept: Office of the Human Research Protection Program
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I. PURPOSE AND SCOPE

In order to safeguard the rights and welfare of Human Subjects in Research, the University of California, Los Angeles (UCLA) ascribes unequivocally to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. UCLA has established policies, including Policy 991, to assure full compliance with all federal regulations, state laws, and University of California policies governing the participation of Human Subjects in Research.

This policy summarizes the responsibilities of UCLA administration, its Research Investigators and its Research Affiliates for the appropriate conduct of Human Subjects Research, and for compliance with all related federal regulations and local policies. The University recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving Human Subjects fulfills the ethical principles set forth in the Belmont Report, applicable federal regulations, local laws, and policies. For further information on the protection of Human Subjects, contact the UCLA Office of the Human Research Protection Program (OHRPP), or see its Web site at http://ohrpp.research.ucla.edu/.

II. DEFINITIONS

Human Research Protection Program (HRPP) is the global UCLA program which oversees the safety and welfare of participants in Human Subjects Research projects in accordance with all applicable federal regulations, state law and institutional policy. At the institutional level, the HRPP includes five areas: UCLA as an academic institution; the Office of the Human Research Protection Program (OHRPP) which includes the Institutional Review Boards; the investigators; the study sponsors; and the Research participants themselves. Within the OHRPP, the program consists of the following three units:

IRB Review Unit is the unit that coordinates and supports the activities of the five federally mandated Institutional Review Boards (IRBs) responsible for reviewing all Research protocols that involve Human Subjects.

Education & Trainings is the unit responsible for the education and training of the UCLA human Research community.

Quality Improvement Units (QIU) is the unit that monitors and measures the effectiveness and quality of the HRPP.

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 *Department of Health and Human Services (DHHS)* regulation 45 CFR 46.102, Human Subject means "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

As defined in *Food and Drug Administration (FDA)* regulation 21 CFR 50.3(g) and 21 CFR 56.102(e), 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 812.3(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."

In addition, California law expands the definition of human to require Institutional Review Boards (IRB) approval for any research using individually identifiable information from death data files held by the State Registrar, local registrars, and county recorders.

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.

UCLA's IRBs are designated by campus location and discipline: North General Institutional Review Board (NGIRB); South General Institutional Review Board (SGIRB); Medical Institutional Review Board 1 (MIRB1); Medical Institutional Review Board 2 (MIRB2); and, Medical Institutional Review Board 3 (MIRB3).

An external IRB may review on behalf of UCLA researchers in those circumstances where OHRPP formalizes a written agreement between UCLA and the external IRB.

Office of the Human Research Protection Program (OHRPP) is the functional division within the UCLA Office of Research Administration that supports the Human Research Protection Program (HRPP).

Research means the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, in accordance with the Department of Health and Human Services (DHHS) definition of research (45 CFR 46.102(d)).

III. POLICY STATEMENT

UCLA adheres to all federal regulations, state laws and University of California policies governing the participation and protection of Human Subjects in Research. Principal from among these policies and regulations are the following:

A. From Federal Policy on the Protection of Human Subjects

- Any institution that receives funds from and is accountable to departments and agencies of the federal government for funds awarded for the support of Research using Human Subjects is required to safeguard the rights and welfare of those subjects.
- No federal grant or contract for Research involving definite plans for Human Subjects may be made to any institution unless the application for such support has been reviewed and approved by the appropriate IRB. (See Section III.B.).
- The FDA restricts data used in support of market permits to that from IRB-approved studies.
- The use of any test article not approved by the FDA in humans is subject to review and approval by an IRB. The sole exception to this requirement is in the case of certain emergencies that require treatment by the use of an unapproved drug or device to save the life of a patient.

- Reviews by an IRB must determine that Human Subjects will be adequately protected according to established criteria involving an evaluation of risks and benefits, equity of selection, and the informed consent process and documentation.
- New studies and modifications to approved studies must be approved before they are implemented.

B. From University Policies on the Protection of Human Subjects

1. Guiding Principles

   The principles espoused in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research have been adopted by the University of California, UCLA and the OHRPP for all Research involving Human Subjects.

2. Scope of Authority

   UCLA holds a Federalwide Assurance of Compliance with DHHS regulations (FWA # 00004642) for the protection of Human Subjects (45 Code of Federal Regulations (CFR) 46). This assurance, which is regularly renegotiated and approved, applies to all federally-funded Research with Human Subjects (as defined in 45 CFR 46.102[3] and [f]) being conducted by investigators acting as agents of UCLA regardless of the site of the activity. The Assurance applies to all human Research involving any UCLA facilities, personnel, patients, or students or Research that is supported either by federal funds granted to, or applied for through, The Regents of the University of California, or for Research conducted at non-UCLA sites.

   Commensurate protections are in place for all other human Research conducted at or under the jurisdiction of UCLA. UCLA also assures compliance with FDA regulations (21 CFR parts 50, 56, 312 and 812), applicable state laws, and University of California and UCLA policies for the protection of Human Subjects in Research.

   - The IRB has sole authority to grant IRB approval for human Research applications.
   - If the IRB does not grant IRB approval or suspends or terminates IRB approval, these decisions may not be overturned at any higher level.
   - Implementation of IRB-approved studies may be prevented or terminated by decision at any other level in the institution, although the IRB approval will not be voided by such action.
   - There are various avenues for IRB members and IRB staff to communicate concerns, suggestions, and instances of undue influence. Reports may be made to the IRB Chairs, OHRPP Directors, the Vice Chancellor for Research/Institutional Official, and the Executive Vice Chancellor & Provost.
   - IRB approval may not be the only approval required to conduct human subjects research and does not supersede other approvals that may be required. Investigators must consult with the appropriate research, business, and legal offices to ensure all requirements are met.

3. Jurisdiction

   All faculty and staff who are conducting studies involving Human Subjects within the course and scope of their duties, as well as UCLA students who are conducting studies involving Human Subjects within the course of their studies, regardless of the source of the funding, or even in certain cases in which no funds are involved, are required without exception to have prior approval from the IRB before Research is initiated.

   Regardless of percent of effort, prior approval of the IRB is required, without exception, when Human Subjects Research studies conducted by UCLA faculty, staff or students access any UCLA or UCLA-affiliated facilities, patients, personnel, or students and/or

when the human Research is supported either by extramural funds granted to, or applied for through, The Regents of the University of California, or for Research conducted with UCLA funding at non-UCLA sites.

Prior approval of the UCLA IRB is not required when part-time or unpaid faculty are not acting as staff members, employees, or agents of the University, when no University facilities, patients, personnel or students are used and when the activity is not represented to subjects as being conducted under the aegis of the University. However, in such cases investigators holding University appointments nevertheless are required to obtain approval for the use of Human Subjects from a duly constituted IRB.

4. Activities Accessing UCLA Facilities, Patients, Staff, or Students Being Conducted by a Non- UCLA Principal Investigator (PI)

   All non-UCLA investigators involved in Human Subjects Research projects that access any UCLA facilities, patients, or personnel (faculty, staff or students) must submit an application for Administrative Review to the UCLA OHRPP for a determination of whether proposed Research involving Human Subjects falls within the UCLA OHRPP jurisdiction and requires IRB review and approval or Certification of Exemption from IRB review.

5. Emergency Care and Compensation for Injury

   The University policy on treatment and compensation for injured Research subjects must appear on all consent forms for studies in which there is a more than minimal risk of biomedical harm.

6. Research Participant's Bill of Rights

   Any individual who is asked to consent to participate as a subject in a medical experiment or who is asked to consent on behalf of another must be given a copy of the UCLA Research Participant's Bill of Rights in a language in which the person is fluent or in Braille if the participant is visually impaired. Numerous translations of this document are posted on the OHRPP Web site and available for use by the investigator.

IV. RESPONSIBILITIES

Vice Chancellor for Research has overall responsibility for implementation of and compliance with federal regulations, state laws, and University policy concerning Human Subjects Research at UCLA. He or she appoints the IRB chairs and members after consultation with appropriate constituencies and has delegated the daily operation of the OHRPP to the OHRPP Director.

Institutional Review Board (IRB) is obligated and authorized to ensure that:

- Human Subjects are adequately informed of the nature of the study;
- Human Subjects' participation is voluntary;
- the benefits of a study outweigh its risks;
- the risks and benefits of the study are evenly distributed among the possible subject populations. The IRB is obligated and authorized to:
    - require necessary modifications of study applications to secure approval;
    - observe, or have a third party observe, the consent process and/or the conduct of Research;
    - suspend or terminate any human Research activity that violates regulations, policies, procedures, or an approved protocol, and report such violations, suspensions or terminations to the Vice Chancellor for Research, other appropriate parties within the institution and appropriate federal agencies.

OHRPP IRB Review Unit is responsible for:

- conducting timely review of all applications for the use of Human Subjects;

- notifying investigators and appropriate UCLA officials in writing of decisions to approve or withhold approval of applications or modifications of ongoing activities;
- developing policies and procedures in consultation with the Executive Vice Chancellor and Provost as appropriate;
- referring legal issues to UCLA Legal Affairs, which may seek the advice of the UC General Counsel;
- directing and reviewing investigations of concerns about issues of Human Subject protection and directing corrective actions as needed.

OHRPP Quality Improvement Unit (QIU):

- is authorized to conduct on-site reviews and investigations of human Research activities on behalf of the IRB;
- is involved in assessing and processing post-approval event reports, including but not limited to reports of adverse events, protocol violations or incidents, safety reports, and concerns and complaints;
- refers any reports of unanticipated problems involving risks to study participants or others as well as incidents or allegations of serious and or continuing noncompliance to the IRB for review and management;
- responds to PI requests for the emergency use of an investigational drug or device;
- refers legal issues to UCLA Legal Affairs which may seek the advice of the UC General Counsel;
- routinely reviews the review activities of the IRBs as well as the OHRPP;
- develops and conducts quality improvement activities to improve human Research protections.

OHRPP Education and Training Unit (EPP):

- develops, coordinates and provides presentations on issues in Human Subjects protection
- delivers education and training for departments, investigators and their Research staff and IRB members and their support staff;
- responds to requests for clarification and provides guidance regarding ethical issues in biomedical and behavioral Research involving Human Subjects;
- maintains, promulgates, and updates educational and institutional review guidance materials.

Principal Investigator (PI) must submit an application to the IRB for review and approval before initiating, modifying, or extending any Research project using Human Subjects.

The PI for a study must either meet the criteria for PI eligibility as defined in UCLA Policy 900 or identify on the application and include in the project a faculty sponsor who meets the criteria for a PI. Any exceptions to this requirement are also described in UCLA Policy 900, section III.C., Exceptions.

The Principal Investigator:

- will consider racial, cultural, and gender diversity among the subject populations and be sensitive to community attitudes in both the design and conduct of Research involving humans;
- has the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of Human Subjects involved in the Research, and strict adherence to any stipulations imposed by the IRB;
- is responsible for ensuring that all personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol;
- will implement no changes in the approved protocol or consent without prior IRB

approval, except in an emergency if necessary to safeguard the well-being of Human Subjects;

- will assure that adequate resources to protect Research subjects are in place before implementing the Research project and that the Research project will stop if adequate resources become unavailable;
- will report to the IRB any serious or unexpected adverse event on-site related to Research participation experienced by a subject within 10 working days of having become aware of the event. The PI also must report any problems or incidents related to the conduct of a study or patient participation, including those in the recruitment or consent process;
- will report to the IRB any violation of an experimental protocol or any use of subjects not approved by the IRB;
- is responsible for identifying and complying with all additional institutional and sponsor requirements for the conduct of Human Subject Research.

Department Chair is responsible for reviewing the activities within the department to determine that proper reviews and approvals have been obtained and appropriate resources area available to conduct the Research.

University of California (UC) assures the federal government that the campus is in compliance with federal regulations as described in Section III.B.2., above, for the use of Human Subject Research and that no Research involving Human Subjects is conducted without prior review and approval. The UC may provide treatment and compensation for injured Research subjects.

The UC is legally responsible for the acts and omissions of its employees acting in the course and scope of their University duties. In the event of a suit against an employee in connection with an IRB-approved Research activity using Human Subjects, the University assumes the employee's defense and indemnification.

V. REFERENCES

1. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 4/18/1979;
2. DHHS Code of Federal Regulations: (45 CFR Part 46): Protection of Human Subjects, Subparts A, B, C, and D;
3. FDA Code of Federal Regulations - Food and Drugs (Title 21): Protection of Human Subjects (21 CFR Part 50); Institutional Review Boards (21 CFR Part 56); Investigational Device
   Exemptions (21 CFR Part 812); Investigational New Drug Application (21 CFR Part 312);
4. Protection of Human Subjects (45 CFR Part 46); Office of Civil Rights Health Insurance Portability & Accountability Act (HIPAA) (45 CFR Parts 160 and 164);
5. California Health and Safety Code: Human Experimentation (Section 24172);
6. Federalwide Assurance of Compliance with DHHS, Institutional Review Boards (see OHRPP Web site http://www.ohrpp.research.ucla.edu);
7. UCLA Faculty Handbook and Resource Guide - Section III, http://www.apo.ucla.edu/facultyhandbook/3.htm;
8. UCLA Office of the Vice Chancellor for Research Web site www.ovcr.ucla.edu/ovcr;
9. UCLA Office of the Human Research Protection Program Web site http://ohrpp.research.ucla.edu;
10. Human Research News: November 11, 2004: "Vice Chancellor Roberto Peccei on the responsibilities of faculty, staff, administration, the IRBs, ARC and OPRS" (see

OHRPP Web site http://www.ohrpp.research.ucla.edu);

11. Office for Human Research Protections (OHRP) policy guidance, "Guidance on Engagement of Institutions in Human Subjects Research" (https://www.hhs.gov/ohrp/regulations-and-policy/index.html);
12. UCLA Policy 900 - Principal Investigator Eligibility.

Issuing Officer

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Questions concerning this policy or procedure should be referred to the Responsible Department listed at the top of this document.