



California Health Sciences University

CHSU POLICY FOR HUMAN SUBJECTS RESEARCH

I. POLICY SUMMARY and SCOPE

This Policy describes the responsibilities of California Health Sciences University in protecting the rights and welfare of human subjects who participate in research in which the University is engaged. This applies to all CHSU Colleges, CHSU faculty and staff who are conducting research involving human subjects within the course and scope of their University duties, and CHSU students who are conducting research involving human subjects within the course and scope of their studies.

II. INTRODUCTION

California Health Sciences University is committed to the ethical principles of 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 that underlie relevant federal regulations. The principles include:

Respect for Persons involves the 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 benefits, 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, and others--places them in a vulnerable or dependent position.

III. POLICY STATEMENT

1. In order to safeguard the rights and welfare of human subjects in research, CHSU follows



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- the ethical principles of the Belmont Report and the Revised Common Rule. CHSU 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.
2. CHSU holds a current Federalwide Assurance (FWA) filed with the U. S. Department of Health and Human Services Office of Human Research Protections (OHRP) for the protection of human subjects.
 3. CHSU's commitment to protecting human subjects applies to all human subject research in which it is engaged, regardless of funding source or the institution that provided the IRB review. See below, under Revised Common Rule for the updated OHRP regulation on Single IRB review process (sIRB).
 4. Under the sponsorship of OHRP, CHSU is to establish CHSU-Institutional Review Board (CHSU-IRB). CHSU-IRB must comply with HHS and FDA regulations in 45 CFR Part 46 and 21 CFR parts 50 and 56, respectively, when reviewing research subject to those regulations. CHSU-IRB is charged with the review and continuing oversight of research involving human subjects, in accordance with CHSU policies and federal regulations. CHSU-IRB has the authority and the responsibility to the following:
 - Conduct initial and continuing review of research and report findings and actions to the investigator and the institution;
 - Approve, disapprove, or require modifications and/or clarification to research protocols;
 - Suspend or terminate approval of human subject research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects;
 - Determine which projects require review more often than annually and determine which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
 - Ensure prompt reporting to the IRB of proposed changes in a research activity and ensure that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except where necessary to eliminate immediate hazards to the human subjects;
 - Ensure prompt reporting to the IRB and institutional officials for research conducted of any:
 - Unanticipated problems involving risks to human subjects or others;
 - Instance of serious or continuing noncompliance with the HHS and FDA regulations or the requirements or determinations of the IRB;
 - Suspension or termination of IRB approval.



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5. Revised Common Rule. The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule).

The revised Common Rule is effective July 19, 2018.

The HHS press release encompasses the most significant changes adopted in the Final Revisions to the Common Rule.

Final Rule changes include:

- Improving the informed consent document and process to increase subject understanding;
- Requiring that consent forms for certain federally funded clinical trials be posted on a publicly available federal website;
- Requiring single Institutional Review Board (sIRB) review for cooperative research for some studies. When IRB review is performed by another institution and before the human subject research is underway, CHSU investigators are required to submit all application materials to CHSU-IRB and to receive a Letter of Endorsement from CHSU-IRB;
- Allowing the use of broad consent for future research for secondary studies on stored identifiable data or identifiable biospecimens;
- Eliminating continuing review for certain minimal risk research;
- Establishing new exempt categories of research based on level of risk posed to subjects;
- Adopting the definition of “clinical trial” that includes behavioral health-related outcomes.

IV. DEFINITIONS

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)



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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 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.”

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)).

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