

Guidance: Requirements for IRB Review and Approval

(last updated August 19, 2011)

Overview

Criteria for IRB Approval of a Human Research Study

Criteria for IRB Approval of Informed Consent

References and Regulations

Overview

UCLA researchers and IRB members share responsibility for ensuring that human research conducted under UCLA's jurisdiction meets the ethical principles of the [Belmont Report](#) and federal criteria for IRB approval of research and informed consent. These criteria are outlined below.

Criteria for IRB Approval of a Human Research Study

To be approved, a study must meet the criteria listed below.

1. Risks to subjects are minimized.
 - Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
 - Study utilizes procedures already performed for diagnosis/treatment -- when appropriate.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
 - Inclusion/exclusion criteria are adequate.
 - Research purpose and setting are appropriate.
 - Recruitment process is fair.
 - Special requirements for vulnerable populations are addressed.
4. Informed consent will be sought or waived in accordance with 45 CFR 46.116— and 21 CFR 50.25 for FDA-regulated research.
5. Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117—and 21 CFR 50.27 for FDA-regulated research
6. Provisions for monitoring collected data are adequate to ensure the safety of subjects – when appropriate.
7. Provisions to protect privacy of subjects are adequate – when appropriate.

8. Provisions to maintain confidentiality of data are adequate – when appropriate.
9. Vulnerable populations are adequately protected by additional safeguards.
 - Children
 - Prisoners
 - Pregnant women, fetuses and neonates
 - Cognitively impaired persons
 - Economically and educationally disadvantaged persons
 - Non-English speaking persons
10. If multi-site research study management of information relevant to protection of subjects is adequate.
11. For continuing review or review of modifications, new information that might affect the willingness of participants to continue to participate will be provided – when appropriate.
12. The IRB shall set a continuing review period at intervals appropriate to the degree of risk, but not less than once per year,

Criteria for IRB Approval of Informed Consent

To be approved, an informed consent document must meet the criteria listed below.

1. General Requirements

- Information is in language understandable to participants or representatives
- There is no exculpatory language through which participants or representatives are made to:
 - Waive or appear to waive any legal rights or
 - Release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2. Basic Required Elements

- Statement that the study involves research.
- Explanation of the purpose(s) of the research.
- Expected duration of the participant's participation.
- Description of the procedures to be followed.
- Identification of any procedures which are experimental.
- Description of any reasonably foreseeable risks or discomforts to the participant.
- Description of any benefits to the participant or to others which may reasonably be expected from the research.
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. If study is FDA-regulated, add statement that FDA may inspect the records.
- If research poses greater than minimal risk, information on availability and nature of compensation or medical treatment available if injury occurs.
- An explanation of whom to contact in the event of a research-related injury to the participant.
- Contact information for the research team for questions, concerns, or complaints.
- Statement that participation is voluntary.

- Statement that participant may refuse or discontinue participation at any time with no penalty or loss of benefits to which the participant is otherwise entitled.

3. Additional Elements, when Appropriate

- The approximate number of participants involved in the study.
- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
- Statement that significant findings during the course of the research which may relate to participant's willingness to continue participating will be provided to the participant.
- Anticipated circumstances under which PI may terminate participation without participant's consent.
- Consequences of a participant's decision to withdraw from the study.
- Procedures for orderly termination of participation by the participant.
- Any additional costs to the participant that may result from research participation.
- The amount and schedule of payments to the participants.

4. Other Requirements (State Law, University Policy)

- Disclosure statement that informs participants that investigator(s) may have a conflict of interest (financial interests and/or dual physician-research roles).
- If the study has a real or foreseeable risk of biomedical harm, statement that participants will be given a copy of the consent form and a copy of the Experimental Subject's Bill of Rights in participants' own language to keep.
- Required UCLA boilerplate sections for tissue/blood samples, establishment of cell lines, genetic testing.

References and Regulations

DHHS Regulations & Guidance

- Criteria for IRB Approval of Research: [45 CFR 46.111](#)
- General Requirements for Informed Consent: [45 CFR 46.116](#)
- [The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

FDA Regulations

- Criteria for IRB Approval of Research: [21 CFR 56.111](#)
- General Requirements for Informed Consent: [21 CFR 50.20](#)

UCLA OHRPP Guidance and Checklists

- [Commensurate Protections for Non-Federally Funded Human Subjects Research](#)
- [Criteria Required by Federal Regulations for IRB Approval of a Human Research Study](#)
- [Criteria Required by Federal Regulation to Approve Informed Consent](#)
- [Criteria for IRB Approval of Research \(Biomedical\)](#)
- [Criteria for IRB Approval of Research \(Behavioral\)](#)