



## Guidance: Requirements for IRB Review and Approval

(updated April 14, 2021)

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## 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.

All clinical investigations are reviewed in accordance with FDA regulations at 21 CFR 50 and 56 and with any IRB-related provisions of the investigational drug and device regulations at 21 CFR 312 and 812. UCLA IRBs follow International Conference on Harmonization Guideline E6 (R2) to the extent it comports with the FDA regulations.

## 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. Provisions to maintain confidentiality of data are adequate – when appropriate.
8. 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
9. If multi-site research study management of information relevant to protection of subjects is adequate.
10. 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.
11. The IRB shall set a continuing review period at intervals appropriate to the degree of risk.
  - Continuing review periods for research reviewed by the convened IRB will be not less than once per year.
  - Continuing review periods for research reviewed using Expedited Review procedures will be set when an Expedited Reviewer provides justification why continuing review would enhance protection of research participants.
  - Greater than minimal risk research that has reached certain milestones on or after January 21, 2019 may be eligible for no further continuing review.

## 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)

- a. Disclosure statement that informs participants that investigator(s) may have a conflict of interest (financial interests and/or dual physician-research roles).
- b. 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 [Bill of Rights](#) in participants' own language to keep.
- c. Required UCLA boilerplate sections for tissue/blood samples, establishment of cell lines, genetic testing.

### 5. 2018 Revised Common Rule

In addition to the above requirements, federally-funded studies that are approved by the UCLA IRB for the first time on or after January 21, 2019 must also comply with the following informed consent requirements:

- a. **Key Information Summary.** Informed consent documents that are longer than four pages must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or their legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Generally, the beginning of an informed consent should include a **concise** explanation of the following:
  - The fact that consent is being sought for research and that participation is voluntary
  - The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;

- The reasonably foreseeable risks or discomforts to the prospective subject;
  - The benefits to the prospective subject or to others that may reasonably be expected from the research; and
  - Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject.
- b. **Basic Elements [45 CFR 46.116(b)]**: Consent forms about any research that involves the collection of identifiable private information or identifiable biospecimens must include one of the following statements:
- i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; OR
  - ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- c. **Additional Elements [45 CFR 46.116(c)]**: Consent forms must include the following when applicable to the research:
- i. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - ii. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; AND
  - iii. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

## 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 \(Behavioral\)](#)

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**Change history:**

04/14/2021: Added information re: ICH.

2/26/2019: Updated continuing review and informed consent requirements to reflect Revised Common Rule.