

## HRPP Contacts

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### *Did you know?*

To ensure that the rights and welfare of research participants are protected, all research team members are required to disclose their financial interests with outside entities at the time of initial IRB submission and at the time of continuing review.

See [IRB COI Disclosure Requirements](#) for more information.

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# UNIVERSITY of CALIFORNIA • IRVINE

## Human Research Protections Program

### News Brief

### Criteria for IRB Review and Approval (§46.111 and §56.111)

For research that qualifies as **minimal risk** (Expedited review) and **greater than minimal risk** (full Board review) the IRB must determine that the research meets the following criteria prior to granting approval:

1. **Risks to subjects are minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, **and** whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
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.
  - ◇ Potential risks are weighed against the probability of the risk occurring and the magnitude of harm that may result. It is then judged whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the risks.
  - ◇ Only those risks and benefits that may result from the research are considered. This is distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. Also, the IRB does not consider the possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy).
3. **Selection of subjects is equitable**. The purposes and the setting in which the research will be conducted are considered, as well as the special problems of research involving **vulnerable populations**, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
  - ◇ When vulnerable populations likely to be susceptible to coercion or undue influence are involved, additional safeguards should be included in the study to protect the rights and welfare of these subjects.
4. **Informed consent will be sought from each subject** or the subject's legally authorized representative, in accordance with, and to the extent required by regulations.
5. **Informed consent will be appropriately documented**, in accordance with regulations.
6. **When appropriate**, the research plan makes **adequate provision for monitoring the data collected to ensure the safety of subjects**.
7. When appropriate, there are **adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data**.
8. When appropriate, **additional safeguards are included to protect the rights and welfare of vulnerable populations**.

### Human Research Records Retention

Researchers are required to retain all study records for **a minimum of three years** past the close of the study. This includes approved IRB documents, as well as case-report forms, tapes or transcripts, and all other data-collection instruments and source documents.

UC General Counsel recommends longer retention periods for certain research records:

- Research records involving the generation, disclosure, and/or use of **Protected Health Information (PHI)** should be retained for **six years**.
- When children are research participants research records must be retained for **seven years after** all children enrolled in the study reach the **age of majority** [age 18 in California].
- Research records involving pregnant women must be retained 25 years.
- Investigators conducting FDA-regulated studies are required by regulation to retain records for periods which may be significantly longer than six years after study closure of the IRB protocol at UCI. See [Records Retention Requirements](#) for more details.

## Investigator Responsibilities when Conducting Human Subjects Research

### Investigator Responsibilities When *Conducting* Human Subject Research:

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB.

Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include:

- **Obtaining and documenting informed consent of subjects** or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB ([45 CFR 46.116](#); [45 CFR 46.117](#));
- **Obtaining prior approval from the IRB for any modifications to the previously approved research**, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects ([45 CFR 46.103\(b\)\(4\)](#)). Modifications should be submitted via the UCI [electronic modification request \(e-MOD\)](#) and;
- **Ensuring that [continuing review applications \(e-CPA\)](#) ([45 CFR 109\(e\)](#)) are submitted to the IRB in a timely manner to avoid a lapse in approval.** Investigators should submit their e-CPA and the required hard copy documentation to ORA at least 60 - 90 days prior to expiration for full Committee studies and 30 days prior to expiration for expedited studies.
- **Investigators also would be responsible for meeting additional regulatory requirements by promptly providing the following to the IRB:**
  - ◇ Reports of any **unanticipated problems involving risks to subjects or others** [45 CFR 46.103\(b\)\(5\)](#) through the [electronic Adverse Events/Unanticipated Problems \(AE/UP\)](#) reporting process;
  - ◇ **Reports of serious or continuing noncompliance** with the regulations or the requirements or determinations of the IRB ([45 CFR 46.103\(b\)\(5\)](#)); and
- **Finally, Investigators should submit a [closing report \(e-Closing\)](#) report when the research concludes and retain the research records** for at least three years after completion of the study ([45 CFR 46.115\(b\)](#)).

### IRB Protocol Submission Deadlines for April Meetings:

- IRB-B: March 25
- IRB-C: April 2
- IRB-A: April 9

## Vulnerable Populations—Children

### Why Children are considered a "vulnerable" population:



- **Their intellectual and emotional capacities are limited**
- **They are legally incompetent to give valid informed consent.**

Federal Regulations regarding "children" (both 45 CFR 46 and 21 CFR 50) state, "Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Thus, who qualifies as a "child" depends on local laws for consent. In California, 18 is the usual age when people can consent to treatments or procedures, but there are important exceptions, such as when seeking medical care related to the prevention or treatment of pregnancy.

When reviewing research involving children, in addition to ensuring adherence to the general regulatory requirements of the Common Rule ([45 CFR 46 Subpart A](#)), the IRB also must consider the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion.

In assessing the risks and potential benefits, the IRB considers the circumstances of the children to be enrolled in the study such as their health status, age, and ability to understand what is involved in the research. The IRB will also consider the potential benefits to subjects, other children with the same disease or condition, and society as a whole.

Research involving children can be approved by the IRB if it satisfies the categories of research involving children as required by the federal regulations. Requirement for permission by parents or legal guardians and for assent by children will be determined by the IRB, based on the level of risk.

Investigators interested in enrolling children are required to complete **Appendix D** when completing the electronic IRB Application or when requesting a modification to an IRB-approved study. Investigators should describe in the protocol narrative if and how assent will be obtained and documented, taking into account the ages, level of maturity and psychological state of the children involved.

**To learn more about Children as human research participants check out the [Requirements When Children are Research Participants](#) web page.** Also review the Office for Human Research Protections (OHRP) guidance documentation on [Children](#).