

Informed consent and other ethical issues in human subjects research

Hyperlinks accessible through Chrome.

The [Committee for Protection of Human Subjects](#) (CPHS) and the Office for the Protection of Human Subjects (OPHS) have developed two documents to help guide undergraduate-initiated research activities (UIRA).

These documents are on the CPHS/OPHS web site under [CPHS Guidelines](#). The first document, [Ethical Issues in Undergraduate Research Activities with Human Participants](#), walks undergraduate researchers through important ethical considerations that arise in human subjects research: designing the research to minimize risks to participants, creating an environment where participants are informed and are free from coercion, and providing protection for individuals who are members of a vulnerable group.

The second document, [Guidance on Designing Undergraduate-Initiated Research Activities](#), is a practical step-by-step document on how undergraduates should select their population, recruit subjects without undue influence, obtain informed consent, minimize risk, and keep data confidential.

Historically, OPHS has determined that most undergraduate projects do not meet the threshold definition of research (to contribute to generalizable knowledge), because these projects are seen more as an educational tool than truly research. These projects do not require IRB review. There are a few exceptions to this. Undergraduate students who are part of a scholarship program, such as Haas Scholars, McNair Scholars, etc., typically need to submit an IRB application for review. This is because it is a requirement of being part of these programs and many of these programs are tied to federal funding.

However, typically, undergraduate senior thesis projects do not require IRB review.

After reviewing these two guidance documents, [Ethical Issues in Undergraduate Research Activities with Human Participants](#) and [Guidance on Designing Undergraduate-Initiated Research Activities](#), students who believe that they will need CPHS review and approval should work with their instructors to commence the process as soon as possible, and be in contact with the OPHS Analyst of the Day at (510) 642-7461 or email: ophs@berkeley.edu.

If the links don't come through they can be gotten at

<http://news-rac.berkeley.edu/2013/10/cphs-develops-two-guidance-documents.html>

