HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD PROCEDURES

What is the Institutional Review Board (IRB)?

The college IRB is responsible for reviewing all research conducted by Cañada College students, faculty, and staff that involves the use of human subjects, and making sure that the research is being done in compliance with federal policy 45CFR46, and other applicable regulations. IRB review is under the office of Planning, Research, and Institutional Effectiveness (PRIE).

Who Needs to Submit an IRB Protocol?

1. Any Cañada faculty, students, or staff planning to conduct human subjects research.

Definition of research. Research means a systematic investigation—including research development, testing and evaluation—designed to develop or contribute to generalizable knowledge. The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g., publication—including a thesis or dissertation—or presentation or use outside the specific instructional setting).

Definition of human subjects. Research is considered to involve human subjects if it involves living individuals about whom an investigator obtains data through intervention or interaction with the individual(s) or obtains identifiable private information.

2. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

There is human subject involvement when:

Human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material.

People are asked to participate through interaction that solicits personal information (surveys, interviews, observation).

Information concerning specific, individually identifiable human beings is asked for from third parties—whether through access to files, data banks or other means—or through direct inquiry of third parties concerning the individuals in question.

3. Outside investigators must register their protocol with PRIE prior to collecting data at Cañada College by filling out an IRB application and submitting a copy of the protocol that was reviewed by their home institution as well as a copy of the IRB approval letter.

What are the requirements of an IRB Protocol?

1. First, determine whether your research is eligible for exemption by following the decision tree provided by <u>HHS</u>.

- 2. If your research is eligible for exemption, determine whether you need a signed consent form from each subject. <u>Chart 11</u> provides guidelines to help you and the IRB determine whether you need an active consent form.
- 3. If your research is eligible for exemption, it could qualify for expedited review. Complete the IRB protocol and submit to the PRIE office.
- 4. If your research is not eligible for exemption, you may need to apply for approval from an external IRB. Please contact the PRIE office for more details.

What happens after you submit an IRB Protocol for Internal Review?

Once the PRIE office has a completed IRB Protocol Form, you may expect the initial review to take about 2-4 weeks.

What happens after you submit an IRB Protocol for External Review?

There is a cost associated with an external IRB review, and you will receive an invoice from the external IRB and are expected to cover the cost of the review. You will work directly with the external IRB to meet all IRB requirements.