



Santa Clarita Community College District - Institutional Review Board

Frequently Asked Questions about Human Subject Research at College of the Canyons

Adapted from Sinclair Community College Grants Development Office

1. What is the IRB?

The Institutional Review Board (IRB) is a committee, comprised of faculty and staff from diverse backgrounds and a community member, that reviews research protocols involving human subject participants to ensure that the rights of the participants are protected, that they are not subject to unreasonable harm (physical and emotional), and that information about them is kept confidential.

2. What is research?

Research means a systematic investigation, including pilot research, testing and evaluation, *designed to develop or contribute to generalizable knowledge*. This includes investigations carried out by faculty, students, staff, or outside investigators for publication and/or presentation and the collection of scholarly materials for theses and dissertations.

3. Why should I submit anything to an IRB? I'm not conducting clinical trials.

An IRB is a federal requirement covering all types of research involving human subjects, including medical, psychological, and educational. Faculty and staff often engage in educational research—testing new curricula, new modules, new courses, assessing faculty development workshops, assessing student success resulting from program improvements, etc.

4. How do I know if I should submit a research protocol to the IRB?

If your project meets the definition of research (including observation, interviews, and surveys) and involves human participants, it must be reviewed by the IRB.

5. My research with human subjects is not externally funded with grant money. Do I still have to submit an application to the IRB?

Yes. All research that involves human subject/participants must be reviewed and approved by the IRB.

6. If I begin my activity that involves human subjects before I receive IRB approval, what action may be taken against me?

Any study can be terminated by the IRB, which could result in loss of funding.

7. Can the IRB stop me from conducting my research?

Yes. The IRB has the authority to disapprove, suspend, or terminate research that is not carried out according to its requirements or may be associated with unexpected serious harm to subjects. The IRB can require you to destroy all data.

8. Do student projects that are part of a class requirement have to be submitted to the IRB?

It depends, but typical assignments for a class that are not for generalizable knowledge do not typically need IRB review. Of course, the faculty needs to be aware of the types of information being collected and communicate to students the ethics that guide the collection of information by the students. If there is any question, it is best to contact the IRB co-chairs for guidance before the project is initiated.

9. Do I need IRB approval if my activities will be conducted someplace other than College of the Canyons' campuses? Do I need IRB approval if my protocol is already approved by another IRB?

Yes. College of the Canyons is still responsible for the activities of its researchers and must comply with federal and college regulations and policies. It is important that the IRB be aware of where and by whom such activities are being conducted, even in another country. The IRB form can be used to designate that an IRB from another institution will be responsible for oversight but a proposal must also be filed with the SCCCD IRB.

10. Who should I contact if I have questions?

Contact the IRB Co-Chairs, Daylene Meuschke, Office of Institutional Research at College of the Canyons (661-362-5329) or Miriam Golbert, Chair of Biological Sciences (661-362-5927). College of the Canyon's website also contains helpful information at the [Institutional Review Board website](#).

11. What is informed consent?

Informed consent is usually obtained through a document that fully discloses the nature of the research, explains the risks (both physical and psychological) and benefits and allows the individual to voluntarily decide whether to participate in the research study or not.

12. What is the difference between anonymous and confidential?

Anonymous means that the data collected by the researcher cannot be linked to the participant. Confidential means that the researcher may be able to identify a participant's data but will not reveal the participant's identity to anyone else. Person-to-person interviews, for example, are never anonymous.

13. Does the IRB serve as a scientific review panel?

No, but if a proposed project appears to lack scientific merit or rigor, or duplicates existing work with more than minimal risk to subjects, the IRB is required to consider whether the benefits to individual subjects and society outweigh the potential for harm to them.

14. Who is responsible for reporting any problems that may occur during the conduct of approved human subject research activities?

Principal Investigators are responsible for reporting promptly to IRB Co-Chairs, Daylene Meuschke (661-362-5329) or Miriam Golbert (661-362-5927) at College of the Canyons any serious or continuing noncompliance with federal regulations, college policies, injuring to subjects, unanticipated problems, or changes in research activities. However, anyone who becomes aware of any serious or continuing noncompliance in the conduct of approved research should bring this to the attention of the IRB Co-Chair.

15. What should I do if I know of research that has violated ethics?

You should notify the IRB Co-Chairs, Daylene Meuschke (661-362-5329) or Miriam Golbert (661-362-5927). If you have any concerns or are uncertain about what constitutes a violation, contact the IRB Co-Chairs.

16. May deception or misrepresentation be used in studies with human subjects?

Yes, if the benefits outweigh the risks to the subjects for participating in such a study, and if the researcher provides a compelling scientific justification for such experimental manipulation. The participants must be informed that some information is being withheld until the end of their participation. For research where deception or misrepresentation is involved, the subjects must receive an explanation (a debriefing) about the nature of the experiment and why such manipulation was critical to its success. Such a form should be included with the materials submitted for IRB review and approval. All research that involves deception must be approved by the IRB.

17. Does the IRB continue to review research once it has been approved?

Yes. The IRB conducts annual/continuing reviews of applications at one year intervals for projects that continue for longer than one year.

18. If I make changes in my protocol, does the IRB have to review and approve it again?

Yes. Any changes must be reviewed and approved by the IRB.

19. When do projects require consent?

Consent is required from any human subject in research unless informed consent has been specifically waived by the IRB. The IRB may waive consent if the project involves no more than minimal risk; the waiver does not adversely affect subjects; the research could not practicably be carried out without the waiver; and, where appropriate, subjects are given information about the project afterwards.

20. Do all projects require written consent?

The IRB may waive written consent if:

- Signed consent is the only record linking the subject to the research and the greatest risk of the research is a breach of confidentiality; or
- The research presents no more than minimal risk and involves procedures for which consent would not normally be obtained outside of the research context.

21. What consent materials are required for research with minors?

Research activities with minors require completion of a parental consent form and an assent form.

22. What is assent and is it always required?

Assent refers to the agreement by the minor to participate. Assent must be accompanied by consent from a parent or guardian and must be written in the simplest terms possible. Assent must be sought from a child unless: (1) the child is incapable of providing assent (due to age or condition), or (2) the intervention holds out the prospect of direct benefit to the child and the intervention is available only in the context of the study. In these two situations, consent from parent(s) is sufficient.

23. I have a project that involves evaluating data collected about human subjects from databases. The databases I intend to use do not contain any identifiable information (i.e., the identity of the subjects may not be readily ascertained by the investigator or associated with the information) and I am not going to have any intervention or interaction with human subjects. What type of IRB review would this need?

This is not considered human subject research and does not need to be submitted to the IRB for review. It is important to realize that if you conduct a research project that is considered human subject research and you have not had your project reviewed and approved by the IRB before you start your research project, it may be considered scientific misconduct. In addition, scholarly journals are unlikely to publish your study. If there is any question, it is always best to contact the IRB Co-Chairs to verify whether you need to have your project reviewed.

24. What should I be concerned about regarding the recruitment flyer for my research project?

The recruitment flyer or advertisement is meant to interest prospective participants but it must provide a rudimentary amount of information that will give a person an understanding of what is to be expected and who is conducting the study, without hype that raises false expectations.

25. Is human subject training required to conduct research approved by the IRB?

All individuals conducting research with human subjects are required to complete training through the CITI program regardless of prior IRB or research experience. New regulations or changes to existing regulations are reflected in the training so it is important that all investigators be knowledgeable of the latest information regarding the protection of human subjects in research.

College of the Canyons' IRB training is online and can be accessed through the College's [IRB website](#). It's important to remember that you do not have to complete the modules in one sitting. You can go in and out of the training at your leisure.