W.M. Keck Science Department

Claremont McKenna College • Pitzer College • Scripps College

Information for Students Conducting Research on Human Subjects

1. What is "human subjects research"?

Any scientific research that involves either directly collecting information from living individuals or using previously-collected information in which individuals are directly identified is considered human subjects research. Federal regulations require that research on human subjects must adhere to a basic set of rules designed to protect participants from unnecessary risk and exploitation.

2. What is an Institutional Review Board?

Each college maintains its own Institutional Review Board (IRB), which is responsible for reviewing and approving all studies involving human subjects research. An IRB contains at least 5 individuals, both men and women, and must include at least one scientist, at least one non-scientist, and at least one external member who is not directly affiliated with the college. The IRB reviews each application for human subjects research and determines if it conforms to federal guidelines. The IRB may ask for modifications to a study before approving it.

3. How do I know if my project needs IRB review?

All research projects involving human subjects require some level of IRB review. There are 3 levels of review: exempt, expedited, and full. Most class projects are classified as exempt (see "Guidelines" section) and only require a cursory review by the IRB. Most senior theses qualify for expedited review. However student research projects that involve sensitive topics, special categories of participants, or more than minimal risk, will require review by the full IRB board (see "Guidelines" section).

4. Which IRB should I go through?

Students conducting thesis research should go through the IRB of their home campus, even if their advisor is assigned to a different campus. The only exception is if you will be working on a protocol for which your advisor has or will have IRB approval from their home campus, in which case you would be added as a researcher to her/his IRB protocol. Class projects should be handled as a group by the instructor, who will contact his/her home campus IRB to determine if projects are exempt or need review (see Guidelines).

5. How many IRBs do I need to go through?

In most cases, once an IRB is approved by one of the Claremont Colleges, you do not need additional approval from the other Claremont Colleges. Instead you should email your IRB approval to the Dean of Students office at any campus where you might recruit students. However, if you plan to recruit Pomona students you must contact Pomona's IRB after you have been approved by your home campus.

6. How long does the process take?

Review times differ among the three colleges. In general expect roughly 7-10 days for exempt reviews, 1-3 weeks for expedited reviews, and one month or more for full board reviews. Please note that multiple rounds of review may be required if either the IRB requests modifications or if the original application is not clearly written. Students are encouraged to contact the IRB as they develop their application to discuss the type of review needed and to ensure that the submitted application is correct and complete.

7. For further information:

CMC	https://www.claremontmckenna.edu/irb/	irb@cmc.edu	x18101
Scripps	http://www.scrippscollege.edu/academics/irb	gedwalds@scrippscollege.edu	X79100
Pitzer	http://pitweb.pitzer.edu/irb/	Cece_Manoochehri@pitzer.edu	x78618

Guidelines for ethical student research on human subjects

A class project involving human subjects is most likely to be classified as exempt if it meets all of the guidelines below. All senior theses with human subjects are required to undergo IRB review, but thesis projects that meet these guidelines will typically be classified as expedited. Note that the examples and definitions below are not exhaustive. **Students should contact their IRB to discuss the specific details of their proposed project before submitting an application.**

Guideline	Meaning
Participants do not come from vulnerable or protected populations	• All participants are adults between the ages of 18 and 64 • Studies that include special categories such as children, pregnant women, prisoners, people with cognitive impairments, senior citizens, etc. would require additional IRB review
All participants give informed consent to participate	• The details of the study or experiment are fully explained to participants before they start. • Participants are told they can stop or withdraw from the study or experiment at any time without penalty. • All studies that are not classified as exempt, including senior thesis projects, require a formal written consent form that details this information.

The study or experiment is of minimal risk to the participants	• Participants should not experience any physical, health, or emotional risks beyond those a person normally experiences in daily life.
	• Examples of topics that do not qualify as exempt include:
	  • Surveys and questionnaires that cover sensitive topics such as health status, immigration status, use of illicit drugs, or sexual experiences
	  • Physiological studies that require invasive measurements, such as blood samples
	  • Activities that are not typical of daily life, such as heavy exercise or the ingestion of non-food substances

The collected data are treated in a confidential manner	• Participants are not identified by name in any publications or presentations of the project • Any materials collected from the experiment that include identifying information are stored in a secure manner (e.g., locked file cabinet, password protected-computer file). Note that cloud storage (e.g., GoogleDrive) is not considered secure.