



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM
FACT SHEET

Student Activities in Research Methods Courses
in the Social and Behavioral Sciences

The UCSD Human Research Protections Program (HRPP) is providing this information to help UCSD Instructors and students determine whether activities undertaken as part of research methods courses in the social and behavioral sciences require review by HRPP and an Institutional Review Board (IRB).

The term "human subjects research" is one with a specific meaning according to Federal regulations and guidance and UCSD policies. Many activities that involve obtaining data about living persons constitute human subjects research (see https://irb.ucsd.edu/Human_Research_or_Not.pdf). It is the responsibility of anyone affiliated with UCSD who intends to obtain such data to determine whether the planned activities constitute human subjects research *before beginning any work*. Engaging in human subjects research without IRB/HRPP review and approval may result in serious sanctions, including a request to destroy all data and a prohibition on any use including publication. However, not all activities that involve obtaining data about living persons constitute human subjects research. Some scholarly, investigative, and other professional activities are commonly referred to as "research" although they do not constitute "human subjects research" in the narrower meaning of the applicable regulations and policies. In addition to the guidance provided by instructors in research methods courses, HRPP assists all members of the UCSD community in determining whether planned activities constitute human subjects research.

The UCSD HRPP Standard Operating Policies and Procedures define activities designed to develop or contribute to generalizable knowledge as those that are "designed (with intent) to collect information about some individuals to draw general conclusions about other individuals that are predictive of future events and that can be widely applied as expressed in theories, principles, and statements and that enhance scientific or academic understanding."

Many course activities in research methods classes *do not* involve human subjects research in that they are undertaken for educational purposes only: in other words, these are "practice runs," and there is no intent to use data collected to develop or contribute to generalizable knowledge. The data collected in this type of training-only coursework may never be used for purposes of human subjects research, either during or after the course. Data collected in research methods courses that result from activities that are *not* undertaken with the intent to develop or contribute to generalizable knowledge may, however, be used or re-used for purposes that do not constitute human subjects research.

In some research methods courses, one or more students might plan to go beyond the practice-only aims of the course and actually engage in human subjects research. If a student's activities in a research methods course *do* involve human subjects research, then no activities may be undertaken without IRB/HRPP approval. *No work with human subjects may be done until this approval is received*. It is therefore critical for students and their instructors to carefully consider the factors involved in determining whether or not student activities constitute human subjects research. If a student's planned activities would constitute human subjects research, the student should immediately seek IRB/HRPP approval.

It is important to note that, if human subjects research is involved, IRB/HRPP can only rarely issue approvals covering all student activities undertaken in connection with a research methods course. The IRB/HRPP may only approve research where it has fully considered all aspects of a proposed investigation; this is often not the case in research methods classes. Approval for studies that do involve human subjects research may be granted for course activities only where all investigators/students are following the same protocol (i.e., investigating the same questions, using the same methods, working with the same pool of human subjects, analyzing data using the same procedures, addressing and minimizing the same risks, using the same procedures and documentation for obtaining informed consent, etc.).

Instructors' responsibilities include the following:

1. The instructor must inform students that data from activities which are intended to be for training and practice only may never be used or subsequently re-used for human subjects research.
2. The instructor must inform students that if they intend to go beyond the training aims of the course and collect data for an investigation that does constitute human subjects research, they must obtain IRB/HRPP approval *before* engaging in any research activities.
3. The instructor must take reasonable efforts to inform students about how to protect the rights, welfare, and interests of human participants in course-related training activities in research methods, including the importance of obtaining informed consent, ensuring confidentiality, providing contact information to participants, and using other ethical procedures. The instructor should emphasize that *ethical obligations toward human participants apply even to activities that do not constitute human subjects research*.
4. The instructor, as part of the normal supervision of student coursework, should monitor students' data collection plans and activities; when it appears that any student intends to engage in human subjects research, the instructor should require the student to seek IRB/HRPP approval immediately and advise the student about how to obtain that approval.
5. Wherever appropriate according to UCSD HRPP policies, the instructor should ensure that data collected in connection with the course are securely destroyed in order to prevent unauthorized use or re-use for human subjects research.

Students' responsibilities include the following:

1. Students should consult with instructors and/or HRPP to determine whether planned activities constitute human subjects research.
2. If a student determines that planned activities would constitute human subjects research, the student should immediately seek IRB/HRPP approval before conducting any activities with human participants.

Instructors and students are encouraged to contact the HRPP Office at hrpp@ucsd.edu or 858-657-5100 for assistance.