

Sierra College

ADMINISTRATIVE PROCEDURE

AP 4620

Human Subjects Research

Date Adopted: 5/12/2017

Date Revised:

Date Reviewed:

References: Office for Human Research Protections,
U.S. Department of Health and Human Services;
Federal Educational Rights and Privacy Act; BP 4030

Research is an integral part of forwarding the advancement of knowledge within a field and is regularly part of the responsibilities of faculty within institutions of higher education. Although Sierra College is not primarily a research college, Sierra College faculty and students, outside organizations, and individuals, such as graduate students, may have a desire or need to conduct research at Sierra College. As such, Sierra College has a responsibility to ensure that any research conducted using Sierra College students or employees as research subjects is conducted in a manner that is consistent with current professional and legal standards of participant protection.

For the purposes of this policy and in accordance with the Office for Human Research Protections, research is defined as: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (OHRP, §46.102 Definitions). For the purposes of this policy, research does not include activities that are normally associated with classroom instruction—such as grading and testing, program evaluation, or those responsibilities normally associated with the regular duties of an office (for example, the Factbook by the Office of Planning, Research, and Resource Development or faculty evaluations by division offices).

External Individuals and Organizations

In order for individuals and organizations (investigators) who are external to Sierra College (the college) to conduct research on college employees or students (participants) they must submit the following documents to the Dean of Planning, Research, and Resource Development for review:

1. A copy of the investigator’s IRB/HSRB approval letter that shows the degree of risk from the investigators parent organization.
2. A copy of a short summary of the research proposal, which must include:
 - a. An approximate timeline of research activities

- b. A list of data or resources the investigators are requesting from the college
 - c. A description of the potential participants
 - d. Any perceived risk to the participants
 - e. A description of the likely benefit of the research
3. A copy of any survey or assessment instruments to be used in the research.
 4. A copy of the informed consent document that will be provided to participants.

The Dean of Planning, Research, and Resource Development will review the submitted documentation to ensure the investigators are meeting the minimum standards of human subjects' protection, that any data being requested is done in compliance with the Federal Educational Rights and Privacy Act (FERPA), and public information request regulations. The Dean of Planning, Research, and Resource Development may consult with other campus experts. A decision will be issued within 10 working days after receipt of all materials.

Internal Individuals and Groups

Sierra College supports the right of faculty to conduct research that is free from political control or authority provided that research is conducted "in line with the tools of their discipline...except the controls of professional ethics or the authority of the rational methods by which truths and conclusions are established in the disciplines involved" (BP 4030). Sierra College recognizes that students may conduct research at Sierra College as part of normal classroom activities under the guidance of a course instructor, who may request an additional review for human subject protection. At this time, Sierra College does not have a formal Institutional Review Board (IRB) or Human Subjects Review Board (HSRB). Until such a board is established, Sierra College employees and referred students who are engaged in human subjects' research should submit the following to the Dean of Planning, Research, and Resource Development:

1. A copy of a short summary of the research proposal, which must include:
 - a. An approximate timeline of research activities
 - b. A list of data or resources the investigators are requesting from the college
 - c. A description of the potential participants
 - d. Any perceived risk to the participants
 - e. A description of the likely benefit of the research
2. A copy of any survey or assessment instruments to be used in the research.
3. A copy of the informed consent document that will be provided to participants.

The Dean of Planning, Research, and Resource Development will review the submitted documentation to ensure the employee investigator or the referred student is meeting the minimum standards of human subjects' protection and will offer an *opinion* as to whether the study meets the standards of an exempt study, or whether there are sufficient protections to the participant in order to meet the standards of minimal risk as defined by the Office for Human Research Protections. The Office of Planning and Research will help the employee investigator or student develop any areas of human subjects' protection that are necessary to minimize risk to participants. Students who wish to conduct research outside of a course must have an instructor sponsor and are expected to submit the listed documents for review.

In the event a research proposal does not meet the standards of minimal risk, the Dean of Planning, Research, and Resource Development will confer with the Vice President of Instruction, Academic Senate President, and employee investigator or supervising faculty to determine next steps.