

**PALO ALTO COLLEGE
COLLEGE PROCEDURES**

Procedure Number: A 26.0
Procedure Title: Institutional Review Board Standard Operations
Relevant Board/SACSCOC Policy: SACSCOC Standard 13.5 Control of Sponsored
Research/External Funds
Code of Federal Regulations (CFR) 46.107
Originating Unit: Institutional Research and Planning
Maintenance Unit: Vice President of College Services

- I. Purpose: To oversee research at the College that involves human subjects for data collection and analysis. Consistent with federal mandates, the College's Institutional Review Board (IRB) will review and approve research proposals that involve human subjects and ensure the rights and safety of human subjects are protected.

II. Procedure Statement:

Palo Alto College is committed to the protection of the rights and welfare of human research participants recruited to participate in research conducted under its auspices. To comply with federal and state law and regulations, all human-subjects research, including student research, conducted under College auspices must receive appropriate review and approval. In its Federal Wide Assurance, on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, the College assures compliance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46), including subparts B, C and D. No distinctions in the monitoring of research will be drawn between funded and nonfunded research, or between research conducted by faculty, students, other university personnel or affiliated researchers.

- A. The responsibilities of the Institutional Review Board are to safeguard the rights and welfare of human subjects involved in research. The responsibilities of the IRB shall include, but not be limited to, the following:

- Determining which research requests involving human subjects require review;
- Approving requests for research involving human subjects;
- Conducting initial and continuing reviews of human subjects research;
- Reporting findings and actions to the investigator and the institution;
- Ensuring reporting of changes and unanticipated problems involving risks or noncompliance.

B. Palo Alto College will adhere to the criteria laid out in 45 CFR 46.107 regarding the composition of the IRB. The membership of the IRB shall include at least five individuals, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall include a chair, at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. Alternate members may be used if they are formally appointed as alternate members.

1. Appointment of Chair and Vice Chair

a. The Chairperson of the IRB will be appointed by the Vice President of College Services in concert with the Vice President of Academic Success and Vice President of Student Success. Training will be provided to the Chairperson of the IRB. The IRB Chairperson can resign or be removed by the Institutional Official following written notification.

2. Delegation of Authority

- a. Authority is delegated to the Vice President of College Services to handle all matters regarding human subject research, in compliance with federal and state regulations and the ethical considerations set forth in The Belmont Report.
- b. The Director of Institutional Research, Planning, and Effectiveness is delegated the authority to administer the day to day operations of the program. The IR Director is to document and disseminate comprehensive standard operating procedures detailing criteria for review and other procedures used in the review process.
- c. The IR Director is to support the Institutional Review Board of Palo Alto College. The Chair of the IRB is to have independent authority to institute and approve all procedures related to the review of research.
- d. The IR Director will additionally support and assist the research community as needed. Support is to include outreach and education to faculty, staff, students and research subjects.
- e. The IR Director serves as a non-voting member of the IRB. The IR Director cannot serve as IRB Chair.

C. Consistent with federal guidelines defined in Title 45 Code of Federal Regulations Part 46, the following research activities are EXEMPT from IRB review:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: a) research on educational instructional strategies; b) research on the effectiveness of instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public

behavior, unless: a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the collection or study of existing, data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
4. Taste and food quality evaluation and consumer acceptance studies: a) if wholesome foods without additives are consumed, or b) if a food is consumed that contains a food ingredient at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the requirement for ensuring that the welfare of subjects is protected and that methods used to gain subject consent are appropriate. Questions regarding whether a research activity may be exempt from IRB review should be directed to the Chair of the IRB and/or Director of IR for determination.

D. The above exemptions do NOT apply - and research activities will require IRB review - in any case when:

1. Deception of subjects may be an element of the research;
2. Subjects are under the age of eighteen;
3. Subjects are elected or appointed public officials or candidates for public office;
4. Subjects are under federal statutes which require, without exception, that the confidentiality of personally identifiable information will be maintained throughout the research and after;
5. The activity may expose the subjects to discomfort or harassment beyond levels encountered in daily life; or
6. Fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

E. The IRB shall review non-exempt research proposals involving human subjects to ensure that:

1. The rights and welfare of human subjects used in research studies are protected;
2. Risks have been considered and minimized;
3. Benefits have been identified and maximized;
4. All human subjects volunteer to participate in research after being provided with legally effective informed consent; and
5. Research is conducted in an ethical manner and in compliance with established standards.

Attachment: [Office of Human Protections Decision Charts](#)

Date Created: July 22, 2020

Date Updated/Approved: September 1, 2020

Approved:

(signed: Katherine Doss)

Vice President of College Services

(signed: Elizabeth Tanner)

Vice President of Academic Success

(signed: Gilberto Becerra)

Vice President of Student Success

(signed: Dr. Robert Garza)

President