Pacific Union College Institutional Review Board (IRB)

Standard Operating Procedures

Responsible Office: Office of the Vice President for Academic Administration
Committee: Institutional Review Board
Chair: Dean of the School of Sciences
Contact: irb@puc.edu
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Approved By: *TBD*

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1. Purpose

The Pacific Union College Institutional Review Board (IRB) protects the rights and welfare of human participants involved in research conducted at or associated with Pacific Union College.

These Standard Operating Procedures establish how the PUC IRB receives, reviews, and acts on human-subject research proposals and how it oversees approved research.

The IRB considers research proposals submitted by PUC faculty, staff, and students, as well as proposals from external researchers seeking to conduct research involving PUC faculty, staff, or students.

2. Institutional Authority and Administration

The IRB is administered through the Office of the Vice President for Academic Administration as part of Pacific Union College's Human and Animal Protections program.

The IRB is not part of the College governance structure and uses ongoing membership rather than the College governance nomination process.

The Dean of the School of Sciences serves ex officio as Chair of the IRB.

The IRB has authority to determine whether proposed activities require IRB review and to approve research, require modifications necessary to secure approval, or withhold approval.

Research requiring IRB review may not begin until the investigator receives written authorization from the IRB.

Institutional officials may impose additional requirements on research approved by the IRB. However, research that the IRB has not approved may not proceed through administrative override.

3. Ethical and Regulatory Framework

The PUC IRB evaluates research according to generally accepted ethical principles for the protection of human research participants and applicable federal requirements.

The IRB's review is guided by the principles of respect for persons, beneficence, and justice. In applying these principles, the IRB considers whether participation is voluntary and appropriately informed, risks are minimized, risks are reasonable in relation to anticipated benefits and the importance of the knowledge expected to result, selection of participants is equitable, privacy and confidentiality are appropriately protected, and additional safeguards are provided when participants may be vulnerable to coercion or undue influence.

When federal regulations or other requirements apply to a particular project, the IRB will conduct its review in accordance with those requirements.

4. Scope of IRB Review

Research involving human participants conducted by PUC faculty, staff, or students must be submitted for IRB consideration when required by these procedures.

The IRB also reviews requests from external researchers seeking to conduct research involving PUC faculty, staff, or students.

For purposes of IRB review, human-subject research generally involves a systematic investigation involving living individuals from whom investigators obtain information through interaction or intervention or obtain identifiable private information.

Investigators should contact the IRB when uncertain whether a proposed activity requires review. The IRB, rather than the investigator alone, makes the institutional determination when the status of a project is unclear.

No recruitment, consent, data collection, intervention, or access to identifiable research information may begin until required IRB review has been completed and authorization to proceed has been received.

5. Classroom Projects

Certain classroom activities involving people may be conducted without formal IRB review when they are educational exercises rather than human-subject research.

At PUC, IRB review is not required for a classroom project only when **all** of the following conditions are satisfied:

1. The activity is limited to surveys, questionnaires, interviews, or observations of public behavior directly related to topics studied in an official PUC course.
2. The activity contains no sensitive personal questions or information that could stigmatize participants.
3. Identifying information is not recorded in a manner that could reasonably expose participants to harm to reputation, employability, or financial standing, or create a risk of criminal or civil liability.
4. Participants do not include vulnerable or special populations, such as minors, prisoners, pregnant women, or cognitively impaired individuals.
5. Data remain within the classroom setting and are not disseminated or published.
6. No PUC employee or student receives financial compensation for collecting, organizing, analyzing, or reporting the data.

If any of these conditions is not met, the project must be submitted to the IRB before activities involving human participants begin.

Faculty supervising classroom projects are responsible for determining whether a proposed activity meets these criteria and for referring questionable activities to the IRB.

6. IRB Membership

The PUC Faculty Handbook establishes the membership of the Institutional Review Board.

The IRB consists of:

- the Dean of the School of Sciences, ex officio;
- three faculty members with experience in ethics and/or human research; and
- one science faculty member as specified by the Faculty Handbook.

Membership is ongoing rather than based on fixed terms.

Membership should collectively provide the experience and perspectives necessary to evaluate the ethical, scientific, behavioral, and social considerations associated with research reviewed by the committee and must satisfy applicable regulatory requirements for IRB composition.

The IRB will maintain an accurate membership roster.

7. IRB Chair

The Dean of the School of Sciences serves as Chair of the IRB.

The Chair is responsible for the effective operation of the committee, including coordinating review of submissions, determining or assigning appropriate review pathways, convening and conducting meetings, managing conflicts of interest, communicating IRB determinations, and ensuring that IRB records and procedures are maintained.

The Chair may designate qualified IRB members to conduct reviews or perform other IRB responsibilities when permitted by applicable requirements.

8. Training

IRB Chair

The IRB Chair must complete human-subject protection and IRB Chair training before assuming responsibility for the IRB and renew the training every three years.

IRB Members

IRB members must complete foundational human-subject protection training upon appointment and refresher training every three years.

Training should provide members with sufficient familiarity with ethical principles, federal requirements, informed consent, privacy and confidentiality, vulnerable populations, conflicts of interest, and IRB review responsibilities to perform their duties.

Faculty Researchers

Faculty conducting human-subject research should complete Social-Behavioral-Educational (SBE) human-subject protection training before submitting a protocol. Refresher training is required every three years.

Student Researchers

Students participating in human-subject research should complete foundational human-subject protection training appropriate for Social-Behavioral-Educational research before beginning recruitment, data collection, or access to identifiable participant information.

When external training or certification is not available, appropriate instruction may be incorporated into PUC research-methods courses. Such instruction should address ethical principles, applicable requirements, informed consent, privacy and confidentiality, and responsible data handling.

Training records will be maintained as appropriate to document compliance with these requirements.

9. Submission of Applications

PUC provides separate application processes for:

PUC Students. Student investigators use the designated student IRB application and work under appropriate faculty supervision.

PUC Faculty and Staff. Faculty and staff investigators use the designated faculty/staff IRB application.

External Researchers. Investigators who are not affiliated with PUC and wish to conduct research involving PUC faculty, staff, or students use the designated external-researcher application.

Applications must provide sufficient information for the IRB to evaluate participant protections. Depending on the project, required materials may include the research protocol or project description, recruitment materials, informed-consent materials,

surveys or interview instruments, descriptions of the participant population, data-management and confidentiality procedures, and evidence of required training.

Incomplete submissions may be returned to the investigator before substantive review.

10. Approved Survey Platforms

Research requiring IRB approval that uses electronic surveys must use an institutionally approved survey platform.

Approved platforms are:

- Microsoft Forms;
- LimeSurvey; and
- Qualtrics.

Google Forms and SurveyMonkey should not be used for IRB-approved research unless an exception has been granted.

Requests to use another survey platform must be submitted to **irb@puc.edu** and must identify the proposed platform and explain why an approved platform is not appropriate for the project.

Approval of an alternative platform must be obtained before the platform is used to collect research data.

11. Submission and Review Schedule

During the Fall, Winter, and Spring quarters, the IRB normally provides three review cycles per quarter.

The regular submission schedule is:

Application Deadline	Target IRB Decision
Week 3, Friday at 5:00 p.m.	Week 4, Friday at 5:00 p.m.
Week 5, Friday at 5:00 p.m.	Week 6, Friday at 5:00 p.m.
Week 9, Friday at 5:00 p.m.	Week 10, Friday at 5:00 p.m.

The IRB does not normally accept new submissions during summer break.

Investigators should generally allow two to four weeks for review during the academic year. Additional time may be necessary when an application is incomplete, revisions are required, or a proposal presents issues requiring additional committee consideration.

12. Initial Administrative Review

Upon receipt, an application is reviewed for completeness and to determine the appropriate review pathway.

The initial review may identify missing documents, incomplete responses, inconsistencies, missing training documentation, or other matters that must be corrected before substantive IRB review.

Applications that are not ready for review may be returned to the investigator with instructions for revision.

Administrative review does not constitute IRB approval.

13. Determination of Review Pathway

The IRB determines the appropriate review pathway based on the nature of the activity, participant population, level of risk, and applicable requirements.

A submission may be determined to be:

Not Human-Subject Research/IRB Review Not Required. The activity does not constitute human-subject research requiring IRB oversight.

Exempt, when applicable. The activity meets the requirements of an applicable exempt category.

Eligible for Expedited Review. The activity is eligible for expedited review under applicable requirements and presents no more than minimal risk.

Convened IRB Review. Research that does not qualify for another pathway or that the Chair determines warrants consideration by the full committee is reviewed by the convened IRB.

Investigators should not independently designate their research as exempt or otherwise determine that IRB review is unnecessary when an institutional determination is required.

14. Expedited Review

Research eligible for expedited review may be reviewed by the IRB Chair or by one or more experienced IRB members designated by the Chair.

The expedited reviewer may approve the research, require modifications necessary to secure approval, or refer the proposal to the convened IRB.

An expedited reviewer may not disapprove research. A proposal that may warrant disapproval must be referred to the convened IRB.

Expedited actions will be documented in the IRB records, and IRB members will be kept appropriately informed of research approved through expedited procedures.

15. Convened IRB Review

Research requiring full committee consideration is reviewed at a convened meeting of the IRB.

Before the meeting, IRB members receive sufficient materials to evaluate the proposed research. These normally include the application or protocol and, as applicable, consent materials, recruitment materials, survey or interview instruments, data-security information, and other documents relevant to participant protection.

The committee may request additional information from the investigator before or during its review.

Investigators or other individuals may be invited to attend a portion of the meeting when their participation would assist the committee. Individuals who are not voting IRB members may provide information but do not vote.

16. Quorum and Voting

Formal action by the convened IRB requires a quorum as defined by applicable federal requirements.

A quorum consists of a majority of the voting membership and must include at least one member whose primary concerns are in nonscientific areas.

If quorum is lost during consideration of a proposal, discussion may continue, but no vote may be taken until quorum is restored.

Only voting members or properly designated alternates participating in the review may vote.

IRB actions and vote counts will be documented in the meeting minutes.

17. Conflicts of Interest

IRB members must disclose any actual or potential conflict of interest related to research under review.

A member may not participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest except to provide information requested by the committee.

A member with a conflict will not vote on the proposal and will not be counted toward quorum while the proposal is under consideration.

The meeting minutes will document the member's recusal.

Investigators must likewise disclose conflicts that could affect participant rights or welfare. The IRB may require appropriate management of a conflict as a condition of approval.

18. Criteria for IRB Approval

The IRB may approve research only when it determines that appropriate protections for participants are in place.

The IRB considers whether:

1. risks to participants are minimized;
2. risks are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge reasonably expected to result;
3. participant selection is equitable;
4. informed consent will be appropriately obtained unless an applicable waiver or alteration has been approved;
5. informed consent will be appropriately documented unless documentation has been waived;
6. participant safety will be appropriately monitored when necessary;
7. adequate provisions exist to protect participant privacy and confidentiality; and
8. appropriate additional safeguards are provided when participants may be vulnerable to coercion or undue influence.

The IRB may request additional information when it cannot make these determinations from the submitted materials.

19. Informed Consent

Unless an applicable waiver or alteration has been approved, investigators must obtain informed consent from prospective research participants before participation.

The consent process must provide sufficient information for an individual to make a voluntary and informed decision about participation. Information must be presented in language understandable to the intended participant population.

The IRB reviews both the content of the consent materials and the proposed consent process.

When appropriate, the IRB may consider requests for waiver or alteration of informed consent or waiver of documentation of consent in accordance with applicable requirements.

Research involving individuals who do not read or understand English must provide an appropriate means of communicating study information and obtaining consent in a language understandable to the participant.

20. Vulnerable Participants

The IRB gives additional consideration to research involving participants who may be vulnerable to coercion or undue influence or for whom additional regulatory protections apply.

The IRB will determine whether the research includes safeguards appropriate to the population, research procedures, and risks involved.

Research involving children, prisoners, pregnant women, individuals with impaired decision-making capacity, or other populations requiring additional protection must comply with applicable requirements.

21. IRB Review Outcomes

Following review, an application will receive one of the following determinations.

Approval

The IRB has determined that the research satisfies the criteria for approval.

The investigator may begin the research after receiving written approval and satisfying any other applicable institutional requirements.

Approval applies only to the research described in the approved materials.

Modifications Required to Secure Approval

The IRB has identified specific changes or clarifications necessary before approval can be granted.

The investigator must address the requested changes and submit revised materials. Research may not begin while required modifications remain outstanding.

When the required changes are limited and clearly specified, the convened IRB may authorize the Chair or another qualified reviewer to confirm that the investigator has satisfactorily completed them.

When the requested revisions are substantive or require additional committee judgment, the revised submission will return to the convened IRB.

Withhold Approval

The convened IRB has determined that the research cannot be approved as submitted.

The investigator will receive the reasons for the decision and will be provided an opportunity to respond. PUC will provide feedback and guidance when appropriate to assist the investigator in developing a revised proposal.

Research for which approval has been withheld may not proceed.

22. Communication of IRB Decisions

The IRB communicates its findings and actions to the investigator in writing.

The communication identifies the determination and, when applicable, required modifications, clarifications, or additional information.

When revisions are required, the investigator must respond to the IRB's requirements and submit revised materials. The IRB or authorized reviewer will determine whether the response adequately addresses the requirements.

An investigator may begin research only after receiving written authorization to proceed.

23. Changes to Approved Research

Investigators must conduct research according to the IRB-approved protocol and supporting materials.

Proposed changes to approved research must be submitted to and approved by the IRB before implementation. This includes changes affecting recruitment, consent, participant populations, research procedures, research instruments, data collection, privacy, confidentiality, or participant risk.

The exception is a change necessary to eliminate an apparent immediate hazard to participants. An investigator may make such a change when necessary to protect participants but must report the change promptly to the IRB.

Minor modifications that meet applicable requirements may be reviewed through an expedited process.

Substantive modifications that materially affect participant risk, informed consent, participant populations, or other significant aspects of the approved research will be reviewed by the convened IRB when required.

24. Continuing Review and Ongoing Oversight

The IRB conducts continuing review when required by applicable regulations or when the IRB determines that continuing review is necessary for adequate oversight of a project.

When continuing review is required, the IRB establishes an appropriate review interval based on the nature of the research, level of risk, participant population, and other relevant circumstances.

Investigators are responsible for submitting required continuing-review materials before approval expires.

When continuing review is not required, investigators remain responsible for complying with all other IRB requirements, including obtaining approval for modifications and reporting problems, noncompliance, and study completion when required.

25. Unanticipated Problems and Participant Safety

Investigators must promptly report events or information that may constitute an unanticipated problem involving risks to participants or others.

A report should describe the event or problem, its relationship to the research, its effect on participants, actions already taken, and measures proposed to prevent recurrence when appropriate.

The Chair will determine the appropriate initial response and review pathway. Matters presenting significant new risk or requiring committee action will be referred to the convened IRB.

The IRB may require protocol or consent changes, additional participant notification, additional monitoring, suspension of research activities, or other measures necessary to protect participants.

Qualifying events will be reported to appropriate institutional officials and regulatory agencies when required.

26. Noncompliance

Investigators, faculty mentors, research staff, and students are expected to comply with IRB requirements and conduct research according to the approved protocol.

Potential noncompliance includes conducting research without required approval, implementing unapproved changes, departing from the approved protocol, failing to obtain consent as required, failing to protect participant information, or failing to comply with IRB reporting requirements.

Reported or discovered noncompliance will be evaluated to determine its seriousness, effect on participants, whether it represents serious or continuing noncompliance, and what corrective action is appropriate.

Corrective actions may include education or additional training, protocol modification, increased monitoring, restrictions on research activities, participant notification, suspension, termination, or other actions appropriate to the circumstances.

27. Suspension or Termination of Approval

The IRB may suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

When research is suspended or terminated, the IRB will consider the rights and welfare of participants already enrolled and determine what actions are necessary for their protection.

The investigator will receive written notification of the action and its basis.

Suspensions or terminations will be reported to appropriate institutional officials and regulatory agencies when required.

28. Participant Questions, Concerns, and Complaints

Research participants may contact the PUC IRB with questions about their rights as research participants or concerns about a research project.

Questions and complaints should be directed to **irb@puc.edu**.

The IRB will review concerns in a manner appropriate to their nature and seriousness. Information will be shared only as necessary to investigate the concern, protect participants, and satisfy institutional or regulatory responsibilities.

Complaints involving potential noncompliance or risks to participants may be referred for formal IRB review.

29. Study Completion and Closure

Investigators must notify the IRB when an approved study has been completed when closure reporting is required.

Closing a study does not eliminate the investigator's responsibility to maintain research records, confidentiality, or data security in accordance with the approved protocol and applicable institutional requirements.

The IRB will maintain appropriate records of completed and closed studies.

30. IRB Meeting Minutes

Minutes will be maintained for convened IRB meetings.

Minutes will document attendance, establishment and maintenance of quorum, actions taken by the IRB, vote counts, recusals resulting from conflicts of interest, required modifications, and the basis for requiring changes or withholding approval when appropriate.

Minutes will also document other determinations required by applicable regulations.

Minutes constitute official IRB records.

31. IRB Records

The IRB will maintain records sufficient to document its operations and decisions, including as applicable:

- applications and protocols;
- consent documents;
- recruitment materials and research instruments;
- correspondence with investigators;
- determinations and approval records;
- modifications and continuing-review materials;
- reports of unanticipated problems and noncompliance;
- records of suspension or termination;
- meeting agendas and minutes;
- membership records;
- training records; and
- other materials necessary to document IRB activities.

IRB records will be stored securely with access limited as appropriate to the sensitivity of the information.

Records will be retained for at least three years after completion of the research, or longer when required by applicable regulations, funding requirements, or institutional record-retention requirements.

32. Confidentiality of IRB Materials

IRB submissions may contain confidential, proprietary, or sensitive information.

IRB members, staff, consultants, and others receiving research materials for IRB purposes must protect those materials and use them only for legitimate IRB or institutional purposes.

Electronic and physical IRB records will be maintained with access appropriate to the sensitivity of the information.

33. External and Cooperative Research

External researchers seeking to conduct research involving PUC students, faculty, or staff are subject to PUC's IRB requirements.

Approval by another institution's IRB does not by itself authorize an external investigator to recruit PUC participants or use PUC records, facilities, or resources.

When research involves another institution, the PUC IRB will determine whether separate PUC review or an appropriate cooperative or reliance arrangement is required.

34. Administrative Responsibilities

Administrative responsibilities of the IRB include receiving applications, maintaining IRB records, coordinating reviews, scheduling meetings, communicating committee decisions, maintaining current forms and guidance, tracking approved research when necessary, and supporting the Chair and committee in carrying out their responsibilities.

Questions concerning human-subject research or IRB procedures should be directed to:

Pacific Union College Institutional Review Board
Office of the Vice President for Academic Administration
irb@puc.edu

35. Review of These Procedures

These Standard Operating Procedures will be reviewed periodically and revised when necessary to reflect changes in federal requirements, institutional policy, or PUC IRB practices.

The current approved procedures will be maintained by the College and made available to IRB members and investigators.

Appendix A. IRB Review Outcomes

Outcome	Meaning	Next Step
Approval	The IRB has determined that the research meets the requirements for approval.	The investigator may begin after receiving written authorization.
Modifications Required to Secure Approval	Specific changes or clarification are necessary before approval can be granted.	The investigator modifies the application or supporting documents and resubmits them. Research may not begin.
Withhold Approval	The convened IRB has determined that the research cannot be approved as submitted.	Research may not proceed. The investigator may respond to the IRB's concerns and submit a substantially revised proposal or new application as appropriate.

Appendix B. Investigator Responsibilities Following Approval

IRB approval applies only to the research described in the approved application and supporting documents.

Following approval, investigators are responsible for conducting the research as approved; obtaining and documenting informed consent as required; protecting participant privacy and confidentiality; using approved data-collection systems; maintaining appropriate research records; obtaining IRB approval before implementing changes; promptly reporting problems or noncompliance; completing continuing review when required; and notifying the IRB when the research is complete.

An investigator may depart from the approved protocol without prior IRB authorization only when an immediate change is necessary to eliminate an apparent immediate hazard to a participant. Such changes must be reported promptly to the IRB.