Conducting Research at Cochise College

Institutional Review Board Handbook

Direct all questions concerning this manual and the human subjects review process to:

Executive Director of Institutional Research
Cochise College, Downtown Center
2600 E. Wilcox Drive
Sierra Vista, AZ 85635
Phone: 520-515-3602
Email: ie@cochise.edu

Contents

Introduction and Overview

For Institutional Review Board (IRB) purposes, research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Anyone proposing to conduct research at Cochise College, including analysis of institutional data, surveys, interviews, and/or focus groups, must first seek administrative approval from their Dean, and from the Office of Institutional Research. Additionally, college staff who are conducting research in the community must also have their research projects reviewed.

The review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality. Further, the intent of the Cochise College IRB process is to ensure compliance with federal guidelines by assuring that human subjects exposed to any research procedures are adequately protected. Compliance is regulated by the Office for Human Subjects Protection (OHRP) at the U.S. Department of Health and Human Services (DHHS). Protection of Human Subjects Regulations can be found under the Code of Federal Regulations, Title 45 (45 CFR Part 46), and on the Web at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Exempt from Review

Research projects that do not include direct contact with human subjects may be exempt from full IRB review if they are conducted by a college instructor in their class(es), by departmental personnel within their own department, and/or if the data collected does not contain individually identifiable information. However, the investigator may **not** self-determine if their project is exempt, and must submit the appropriate paperwork for review and approval before beginning project work. Secondary analysis projects, where Cochise College student or institutional data is to be accessed and analyzed, must be submitted for review.

Procedure

1. **Submit paperwork.**

All researchers must complete the Project Description Form (Appendix A) and include all supporting research materials (survey questions, consent forms, etc.). Researchers should also include an IRB Approval Form (Appendix B) signed by the appropriate Dean (or the Executive Vice President of Academics if the researcher is a Dean). Additionally, if research is part of a dissertation, thesis, or educational project a Faculty Advisor Attestation Form (Appendix C) must be completed.

Completed, signed forms, should be routed to the Executive Director of Institutional Research (EDIR).

Any and all additional materials should be submitted as a single Word or PDF file. Email submissions are strongly encouraged and should be sent to ie@cochise.edu. Proposals may be submitted for review at any time, and are reviewed as they are received.

2. **Project Review**

Once the EDIR receives the proposal submission, the project's risk level will be determined. If the project is deemed to have minimal risk, the EDIR will forward the request to the Dean of Academic Affairs for a final review and signature. If a project is deemed to have moderate or substantial risk, the EDIR and Dean of Academic Affairs will determine if the project can proceed, or if a Human Subjects Review Committee needs to be formed to review the project. Research in this risk category would include studies with vulnerable populations, studies that employ deception, international studies, and studies where information may be disclosed that could require mandatory legal reporting. These studies are rare at Cochise College.

3. **Response**

The EDIR will notify the researcher when the project is approved, not approved, or if the project needs to be reviewed further. Once a researcher has approval, the researcher may begin conducting the research. If the research project is being conducted at a facility other than Cochise College, the researcher has the responsibility of also complying with that organization's guidelines.

Appeal of Review Decision

To appeal an initial review decision, the researcher must email the EDIR within 10 business days of receiving the decision. If the initial decision was rendered solely by the EDIR and Dean of Academic Affairs, a Human Subjects Review Committee will be called to review the project. Their decision is final. If the initial decision was rendered by a Human Subjects Review Committee, the decision may be appealed to the Executive Vice President for Academics, whose decision is final. Following the completion of any additional review, the decision will be communicated in writing to the researcher.

Citi Training

Certain research projects may require the primary investigator to complete formal Human Subjects Protection Program (HSPP) training. An HSPP certificate that is less than four years old (and may have been obtained from another college or university) is acceptable evidence of training completion. Researchers will be notified if they need to complete HSPP training following the review of the project proposal. HSPP training will comprise completion of online CITI training, with assistance from the EDIR.

Students as Research Subjects

Students play an integral role as subjects in teaching and learning focused research. However, it is critical that students' participation is voluntary. The classroom environment, by its very nature, creates unintentional coercion due to the relationship between the student and instructor. Faculty who wish to involve their own students as subjects must note this in the project proposal and provide sound scientific reasoning for doing so. Convenience does not constitute sound scientific reasoning. Participation in research should be part of the learning experience for the students. In instances where researchers have justified involving their own students in their research, someone other than the primary investigator (instructor) shall obtain informed consent, collect the data, and de-identify the data before sharing with the primary investigator.

Termination of the Research Authorization

Human subjects approval is valid for one year or for a shorter interval determined by the EDIR based on the risks involved. If the research continues beyond a year, a Periodic Review Form must be submitted to extend approval for the next year.

In addition to the routine periodic review, researchers are obligated to keep the EDIR informed of unexpected findings involving risks and to report any occurrence of harm to subjects. Problems of these types must be reported without delay. Failure to comply with periodic review requirements, or failure to immediately report problems involving risks to human subjects not foreseen in the approved protocol, will be cause for suspension or termination of the study. To the extent that the study is an integral part of any funded research project, the project scope may need to be formally altered should a study be terminated or suspended. This suspension notice will be reported to the researcher, institutional officials, and external funding sources.

Site Authorization

Researchers must receive authorization from all appropriate instructional deans whose students or employees are to be subjects. If the research is to be conducted with students or employees district-wide, then approval must be obtained from the Executive Vice President for Academics. If the research includes subjects from organizations outside Cochise College then authorization from those organizations is also required. Authorization granted by the administrator of the area involved in a research project does not provide clearance to begin the research nor does that authorization guarantee the cooperation of faculty, staff, or students in the research project.

Changes in Research Design

Any proposed change, amendment, or addendum to a previously approved protocol or consent form must be reviewed and approved by the EDIR prior to implementation. The researcher will provide a letter via email describing the change, amendment, or addendum including:

- a description of current procedures/study design
- proposed changes in procedures/study design
- any anticipated change in risk and/or benefit to subjects
- any/all revisions necessary to the consent form

The EDIR has the authority to determine whether or not a proposed change, amendment, or addendum will increase risk to the subjects and to approve proposed changes that do not involve increased risk.

Data Management

The researcher is solely responsible for ensuring privacy and confidentiality to all research subjects and therefore must develop and implement processes and procedures to secure all data. The following represents reasonable guidelines for researchers to observe.

- When a computer database with research-related information is kept, the privacy and security procedures must be documented on the Project Description form.
- Procedures must describe physical security of the computer and memory devices, specifically designated (and limited) personnel access, and use of software security codes to permit data access and entry only to authorized research personnel.
- Information obtained from computer databases must only be used for research or to ensure subject safety.
- Hard copies containing confidential subject information must be stamped as confidential with access limited to persons with a designated "need to know" authority.
- All documentation gathered during the course of the research project must be destroyed at the end of the applicable retention period. The data may not be used for non-protocol purposes without each subjects' written permission and may not be shared with non-involved researchers.
- At the conclusion of the research project, data stored on a computer shall be removed from the computer and any storage copies kept in a secure locked site as outlined in the original protocol.
- Electronically stored data must be destroyed as specified in the original Project Description Form

Advertising for Subjects

Advertising for prospective volunteer subjects must be documented in the Project Description Form. Compensation may be mentioned but no dollar amount should be indicated in any advertising. The level

of compensation must be commensurate with the time and inconvenience involved and must not be in amounts which could be construed as economically coercive. The college's Executive Vice President for Administration should be consulted for acceptable processes to disburse any payments.

Liability Statement

Liability for research related injury is a legal issue and is not covered by the policies set out in this document. The contractual relationship between the sponsor, the researcher, and the institution will provide details of liability. The consent form should contain standard information as set out in the sample forms.

Research Reports and Publications

At the conclusion of the study, the researcher is required to provide Cochise College with copies of documents such as annual or final reports to granting agencies, papers presented at professional meetings, and publications based on the research conducted through permission of Cochise College. In addition, human subjects involved with the study should be provided with final results or publications should they request them.

Informed Consent

Informed consent is a fundamental requirement to research involving human subjects. After having been informed about the goals of the research, how they will be involved, and the level of risk involved, participants must be **willing** to participate. A consent form must be signed by each participant involved in the study. If research data is obtained from human subjects via online surveys, the researcher must include an "accept" or "decline" option in lieu of a signed consent form for each subject participating in the survey.

The consent form must be written in language easily understood by the subject. Technical terms should be avoided or if needed, explained thoroughly in simple language. The following elements should be addressed in an informed consent form:

- Nature and purpose of the research
- Nature of the subject's involvement - what activities and for how long
- Potential risks or discomforts for the subject
- Potential benefits of the research for society and for the subject
- Indication that the subject's participation is voluntary
- Indication that subject may withdraw at any time without prejudice
- Procedures for maintaining confidentiality/anonymity
- Name and phone number of the contact person(s) for questions or concerns about the research

- An explanation of whom to contact about research subjects' rights using the following language: "*If you have questions about your rights as a research subject, please contact the Cochise College IRB Administrator at 520-515-3602."*
- Statement of liability, including indication that the subject does not waive any legal rights by signing the form

Informed consent forms should be written in plain language at a reading level appropriate for the age or maturity-level of the participants. The informed consent form should be written in second person for clarity and readability (i.e., there is minimal risk to you; you will be required to perform a certain procedure; etc.).

For additional information or for help creating consent forms, talk to the EDIR.

Vulnerable Populations

It is important for researchers to keep in mind that risks may vary for particular groups, depending on the nature of the research being conducted. The U.S. Department of Health and Human Services has additional protections for subgroups (pregnant women and fetuses, prisoners, and children). Researchers should identify if their research includes vulnerable populations, especially if they are including students who are under the age of 18. Additional information can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

For additional information or for help determining how to conduct research involving vulnerable populations, talk to the EDIR.

Consent and Assent for Children

There must be adequate provisions made for soliciting the assent of children, when the children are capable of providing assent. It is recommended that assent be sought for children ages seven and older, but may be appropriate for younger children depending on their aptitude. In some cases assent is not required.

When assent is required, the child will sign the assent form for documentation.

In addition to the children's assent, researchers are required to solicit consent of each child's parents or legal guardian.

Parents must be consented. One parent's signature is sufficient for research that is minimal risk or greater than minimal risk with the prospect of direct benefit to the participant.

For additional information or for help creating consent or assent forms, talk to the EDIR.

Appendix A: Project Description Form

Institutional Review Board

Project Description

Primary Researcher:

Name:	Title:
Department:	
Phone number:	
Email address:	
Is the project funded? Y___ N____ If Y, from where?_____ If N, have you applied for funding? Y ____ N _____ Where?	

List any co-researchers and their title, department, phone number, and email address:

Title of Study

Anticipated Project Start and End Date

Purpose of Research Project:

In lay language, summarize the objectives and significance of the research.

Special Classes

Does your research involve any participants from special classes (children, prisoners, pregnant women, cognitively impaired persons, etc. Read more here.)? If so, please describe.

Data Collection and Access

Describe the data you will collect or obtain.
Describe how you will obtain or access the data. Please specify if you will be submitting a request to Cochise College IR.

Confidentiality & Data Storage Procedures:

Explain whether or not participants will be identifiable:
Will the data you collect be anonymous or confidential (check the one that applies)? *Note: research is only anonymous if the researcher does not know the identity of the participants and there are no identifiers linking the participant to the research. Confidential is where study participants (or participant responses) could be identified by the researcher, but every effort has been taken to protect that identity from being revealed to anyone else.* Anonymous_____ Confidential _____
Explain the procedure that will be used to protect privacy and confidentiality:
How and where will data be stored (may be indefinitely)?
How long will the data, research summary, and applicable paperwork be stored (may be indefinitely)?
Who will have access to the data?

Benefits to Participants:

Describe the indirect research benefits for the participants:

Describe the direct research benefits or state there are no direct benefits to the participants:

Risks to Participants:

This section should include a detailed description of any reasonably foreseeable risks or discomforts to the participants as a result of each procedure, survey, or interview questions. All projects are deemed to involve some level of risk to participants, whether obvious or obscure. Consequently, **proposals must state** that minimal risk is involved even when the proposed research is viewed as involving little or no risk to participants. Risk is minimal where the probability and magnitude of anticipated harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Even when risk is minimal, investigators must still state what the minimal risk is and why it is minimal (example would be potential for embarrassment or boredom).

Describe the risks to participants:

Will your results be published, presented, or publicly shared? If yes, how?

Will your results be generalizable to other populations? If yes, describe.

Will you have direct contact with human subjects? (survey, focus group, interview, etc)

_____ No – Form is complete

_____ Yes – Complete the questions below

Description of Potential Participants:

Age-range and gender:
Describe how the participants will be recruited and/or selected:
Describe the number of participants expected:
Will compensation or incentives be provided for participation? Y____ N_____ IF Y, please describe:
Criteria for exclusion from participant pool:

Procedure:

Description of participants' activities:

What will non-participants do while participants participate? *Note: this only applies when research is conducted in the classroom and some students may participate and some may not.*
What will participants be told about the research project?
Will deception be used? Y ____ N _____ If Yes, please explain why this is necessary, and how debriefing will occur:
Estimated time required for participants:
Where will research take place?
Method of data collection (check one of the following): Qualitative ___ Quantitative___ Mixed Method___
Please describe how and when participants may terminate participation:
Description of equipment to be used on or by participants:

Description of procedure to obtain informed consent or other information to be provided to participant:

How and when will the participants be approached to obtain consent?

Who will be responsible for obtaining consent (check the box that applies)? Project Director _____ Member of Project team _____ (list name or position) Other _____ (Please explain, and include name, affiliation, and title)
How will information be relayed to participant (read to, allowed to read, audio-recorded, video-recorded)?
If children are involved, who will be responsible for obtaining parental consent (check the box that applies)? Project Director _____ Member of Project team _____ (list name or position) Other _____ (Please explain, and include name, affiliation, and title)

Appendix B: IRB Approval Form

Institutional Review Board

Approval Form

Project Title:

Primary Researcher:

I certify that I have reviewed the completed "Institutional Review Board Project Description" form for the above listed project and approve of the research to be conducted.

Cochise College Dean or Executive Vice President of Academics

Printed Name:

Signature: Date:

Cochise College Institutional Research Executive Director

Printed Name:

Signature: Date:

Cochise College Dean of Academic Affairs

Printed Name:

Signature: Date:

Appendix C: Faculty Attestation Form

Institutional Review Board
Faculty Advisor Attestation

Project Title:
Principal Investigator Name:
Faculty Advisor Name:
Faculty Advisor Email:
Faculty Advisor Affiliation:

I am the Faculty Advisor for the Researcher submitting this protocol.

By my signature, I certify that:

- I have reviewed the proposal, including the data management protocol, and determined that all departmental and institutional requirements are met.
- I believe that the researcher has the necessary training, experience, and knowledge to conduct the research in a manner consistent with the regulations governing human subjects research and sound research principles.
- The researcher has adequate resources to conduct the proposed research.
- I acknowledge that I am acting in an advisory capacity on this protocol for the researcher.
- As faculty advisor I will:
    - Oversee and monitor the conduct of this research by communicating regularly with the Principal Investigator
    - Assist with the resolution of any problems or concerns encountered during the research
    - Assure that the Cochise College IRB is notified in the event of an adverse event or unanticipated problem.

_____

Faculty Advisor Signature and Date