



Institutional Review Board (IRB) Policies and Procedures Manual

Foothill-De Anza Community College District

Table of Contents

1. [Mission and Authority](#)
 2. [Ethical Principles](#)
 3. [Scope of Review](#)
 4. [IRB Membership and Structure](#)
 5. [Categories of Research Review](#)
 6. [Application and Review Process](#)
 7. [Researcher Responsibilities](#)
 8. [Appendices: Forms and Templates](#)
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1. Mission and Authority

1.1 Purpose

The primary purpose of the FHDA Institutional Review Board (IRB) is to protect the rights, welfare, and privacy of human subjects participating in research conducted within the district. The IRB ensures that research aligns with:

- **Federal Regulations:** The "Common Rule" (45 CFR 46).
- **State Laws:** California laws regarding privacy and human experimentation.
- **District Policy:** Specifically, **Board Policy 4180 (Research and Publications by Staff)** and **Board Policy 3121 (Standards of Ethical Conduct)**.

1.2 Authority

The FHDA IRB is authorized by the Chancellor and the Board of Trustees to review, approve, require modifications to, or disapprove of all research activities involving human subjects conducted by district faculty, staff, students, or external researchers.



Note: IRB approval is required *before* any data collection begins. Retroactive approval is not permitted under federal guidelines. IRB approval does not indicate the study is approved to continue. Final approval by the respective campus Offices of Institutional Research and Planning is required before the research can begin.

2. Ethical Principles

The FHDA IRB adheres to the principles outlined in the **Belmont Report** (1979):

1. **Respect for Persons:** Treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., minors, students with cognitive disabilities). This is primarily operationalized through **Informed Consent**.
2. **Beneficence:** Minimizing harm (physical, psychological, social, economic) and maximizing benefits to participants and society.
3. **Justice:** Ensuring the burdens and benefits of research are distributed equitably (e.g., not targeting De Anza students solely because they are a convenient population).

3. Scope of Review

3.1 What Requires Review?

Any activity that meets the federal definition of "**Research**" involving "**Human Subjects**":

- **Research:** A systematic investigation designed to develop or contribute to *generalizable knowledge*.
- **Human Subject:** A living individual about whom an investigator obtains data through intervention/interaction or identifiable private information.

3.2 What is Generally Excluded?

- **Classroom Projects:** Activities designed solely for pedagogical purposes (learning research methods) that will *not* be published or presented outside the classroom.
- **Institutional Research:** Routine data collection for internal administrative use (e.g., course evaluations, program review) mandated by the district.



- **Faculty Inquiry of Their Classes:** A faculty member trying a new instructional method and looking at differences in outcomes of the students for internal classroom improvement with no plans for broader dissemination.

4. IRB Membership and Structure

In accordance with **45 CFR 46.107**, the FHDA IRB will consist of at least five members with varying backgrounds:

- **Chair:** Executive Director for Foothill-De Anza Office of Institutional Research and Planning.
- **Scientific Member:** A faculty member with experience in scientific research (e.g., Psychology, Sociology, Biology).
- **Non-Scientific Member:** A member whose primary concerns are in non-scientific areas (e.g., Humanities, Ethics, English).
- **Community Member:** An individual *not* affiliated with FHDA (not an employee or immediate family member of an employee).
- **Prisoner Representative:** Required only if research involves incarcerated populations (rare in community colleges).

5. Categories of Research Review

The IRB Chair determines the category of review. Researchers *cannot* self-determine exemption.

5.1 Exempt Review

Research involving very little risk to participants.

- **Examples:** Anonymous surveys on non-sensitive topics; analysis of existing, de-identified data; normal educational practices (comparing two teaching methods).
- **Reviewer:** Reviewed by the IRB Chair or a designee.
- **Timeline:** 1–2 weeks.

5.2 Expedited Review

Research involving "no more than minimal risk" but does not qualify for exemption.



- **"Minimal Risk":** The probability of harm is not greater than that encountered in daily life or routine physical/psychological exams.
- **Examples:** Focus groups; non-anonymous surveys; recording voice/video; collection of biological specimens by non-invasive means.
- **Reviewer:** Reviewed by the Chair and one designated IRB member.
- **Timeline:** 1–2 weeks.

5.3 Full Board Review (requests not qualifying for exempt or expedited)

The full FHDA IRB committee will review requests that fall within this category. Any request deemed as such by the Chair will be put forward to the full committee. If determined that the request involves greater than minimal risk or vulnerable populations, the Principal Investigator (PI) will be asked to adjust and resubmit their research request.

- **Examples:** Studies involving sensitive topics (illegal behavior, sexual history, mental health); studies involving minors (under 18); studies involving deception.
- **Reviewer:** Reviewed by a quorum of the full IRB committee through online interaction.
- **Timeline:** 2-3 weeks.

6. Application and Review Process (applies to all requests)

Step 1: Preparation

- Complete the Human Subjects Research course or NIH equivalent. Certificates must be submitted with the application ([U.S. Department of Health and Human Services](#) (HHS) free training)
- Prepare all instruments (surveys, interview guides) and the **Informed Consent Form**.

Step 2: Submission

- External researchers outside of FHDA must first obtain a FHDA Employee **Sponsor** who will serve as the liaison between the district/college and PI. For example, a faculty sponsor could offer their course as the research site, or a program director could send an email requesting participation on behalf of the PI.



- Submit the **FORM A: REQUEST FOR CERTIFICATE OF EXEMPTION** or **FORM B: APPLICATION FOR EXPEDITED REVIEW** to the FHDA Office of Institutional Research.

Step 3: Review Criteria

The IRB Chair evaluates:

1. Are risks to subjects minimized?
2. Are risks reasonable in relation to anticipated benefits?
3. Is the selection of subjects equitable?
4. Is informed consent adequate and documented?
5. Are there adequate provisions to protect privacy and confidentiality?

Step 4: Decision

Principal investigators will be notified of their IRP decision. If IRB approval is granted, all research requests must then additionally be approved at the district or college site in which the research is to be conducted. Site approval is granted by the Director of Institutional Research and Planning at the respective site.

- **Approved:** Research is approved by the IRB and must seek district/college approval.
- **Conditional Approval:** IRB approval will be granted after specific minor changes are verified by the Chair.
- **Deferred/Tabled:** Major issues must be addressed; the proposal must be resubmitted to the full board.
- **Disapproved:** Research cannot proceed.

7. Researcher Responsibilities

7.1 Informed Consent

Unless waived by the IRB, researchers must obtain informed consent. Informed consent can only be obtained by those 18 years of age or older. Those under 18 must secure parent/legal guardianship approval to give consent.

- "You are being asked to participate in a research study..."



- Description of procedures and time commitment.
- Risks and benefits.
- Statement that participation is **voluntary** and can be withdrawn at any time without penalty.
- Contact information for the PI and the FHDA IRB Chair.

7.2 Modifications

Any change to the study design, instruments, or recruitment must be submitted to the IRB Chair and approved *before* implementation.

7.3 Adverse Events

Any unexpected harm to a participant (e.g., extreme emotional distress during an interview) must be reported to the IRB Chair within **24 hours**.

7.4 Record Keeping

Researchers must maintain signed consent forms and data in a secure location (e.g., encrypted drive, locked cabinet) for at least one quarter or after the study closes.

8. Appendices: Forms and Templates

- **Form A:** Request for Exempt Status
- **Form B:** Application For Expedited Review
- **Form C:** Policy on FHDA Class Assigned Research Projects
- **Form D:** Instructor Review Form for Class Assigned Research Projects
- **Form E:** Classroom Project Consent Script