SAN DIEGO
Community College District

Institutional Review Board (IRB) *Ins and Outs*

College Flex/CCE Flex: 30527/38169

Natalia Córdoba-Velásquez Alarcón

IRB Chair

SDCCD Institutional Effectiveness and Research Director

nalarcon@sdccd.edu

Welcome!

- ✓ Introduce yourself on the chat
- ✓ Share if any experience with IRB
- ✓ In one word, share what you are hoping to learn today?

Contents

- ✓ IRB Role and Purpose
- ✓ Types of Review
- ✓ SDCCD Process
- ✓ Ethical practices
- ✓ Becoming part of the IRB

Session Learning Outcomes

1. Understand the purpose and role of the SDCCD Institutional Rev… Board (IRB) in promoting ethical research practices.

2. Determine which types of research require IRB review and recognize the basic criteria for exemption.

3. Navigate the IRB submission process, including key components like informed consent and risk assessment.

4. Apply ethical principles and district policies to ensure compliance when conducting or supporting research involving human subjects.

What is the IRB

- Guided by the principles of The Belmont Report.
- Acts as advocate of humans subjects.
- Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- SDCCD IRB reviews all human research protocols to ensure protection of human subjects in accordance with federal regulations, State laws, and District policies.

Why Ethics matter in Research?

Respect

Beneficence

Justice

Case Examples of Wrongful Practices

- Historical Ethical Breaches
- Consequences of Misconduct
- Importance of Safeguards and Community Protection
- Four examples. More info here

1. J. Marion Sims' experiments on enslaved women (1840s)
2. The Tuskegee Syphilis Study (1932-1972)
3. The Cincinnati Radiation Experiments (1940-1970s)
4. The Willowbrook Hepatitis Experiments (1956-1971)

When is IRB needed?

- Types of research that require IRB review
- Examples of student, faculty, and staff research
- SDCCD Regulations and Operations

Board Policy 0400
Administrative Procedure 0400
Standard Operational Procedure

SDCCD BP and AP

Board Policy 0400 (5/2019)

SAN DIEGO COMMUNITY COLLEGE DISTRICT

Board of Trustees Policy

Chapter 3 – GENERAL INSTITUTION

BP 0400 RESEARCH INVOLVING HUMAN SUBJECTS

The Board of Trustees recognizes that the involvement of human subjects (i.e., students and employees) in research is an integral part of the advancement of educational and scientific research. This policy guides the review and approval of requests to involve human subjects from the San Diego Community College District (SDCCD) institutions in such research. While the District will make every effort to accommodate investigatory endeavors, ethical conduct and the safety of its students and employees is the District's central priority.

RESEARCH INVOLVING DISTRICT STUDENTS AND EMPLOYEES

All research by external investigators must be reviewed by the District Institutional Review Board (IRB). External investigators are those who conduct research for the purpose of a report, or study requested by an individual or an institution or agency other than the San Diego Community College District expecting to approach SDCCD populations for external use (e.g., dissertations, theses, articles).

INSTITUTIONAL REVIEW BOARD

1. Each college, Continuing Education, and the District will designate one to two Institutional Review Board (IRB) members for the Districtwide IRB whose primary goal is to protect student and employee participants from harm.

   a. The IRB will be comprised of faculty, staff, administrators and Research Analysts from the colleges, Continuing Education and the District Office. The designation of members will rotate annually to a) allow diversity of perspectives and b) ensure broad participation.

   b. The primary responsibility of the IRB is to judge whether there is more than minimal risk of harm to participants in accordance with FERPA, HIPPA and Title 45 Code of Federal Regulations Part 46, *Protection of Human Subjects* and whether those risks could be further minimized. Dependent on the findings of the members, the IRB will either negotiate changes in the research methods, or disapprove the research proposal entirely.

   c. The objective of the IRB is to act as advocates for the safety of students and employees in accordance with federal, state, and local laws and regulations for research involving human subjects.

Administrative Procedure 0400 (3/2017)

SAN DIEGO COMMUNITY COLLEGE DISTRICT

Administrative Procedure

Chapter 3 – GENERAL INSTITUTION

AP 0400.1 PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The Board of Trustees defines, authorizes and regulates the involvement of students and employees in accordance with the stated policies in Board of Trustees Policy *BP 0400, Research Involving Human Subjects*. This policy is operationalized through the procedures and requirements outlined in these procedures. The *Investigator Guidelines for Research Using Human Subjects* are used as a guideline for implementing these procedures.

1) All research involving or pertaining to students and employees conducted by individuals or groups outside of SDCCD is subject to review by the District and/or campus designated IRB regardless of approval by an Institutional Review Board from another institution or agency. No proposals will be reviewed prior to IRB approval from the investigator's institution or agency responsible for the research evaluation or study.

2) Proposals are to be submitted to the chair of the SDCCD IRB according to the pre-determined submission and review timetable established by the IRB. The IRB will make its recommendation to the campus president or designee.

3) SDCCD employees who are seeking to conduct research and/or use existing data and information for publication or public presentation purposes (e.g., doctoral dissertations or master's degree thesis) are considered external investigators and must go through the SDCCD IRB review process in order to gain approval prior to conducting research even if they are SDCCD employees with access to the information as part of their work responsibility.

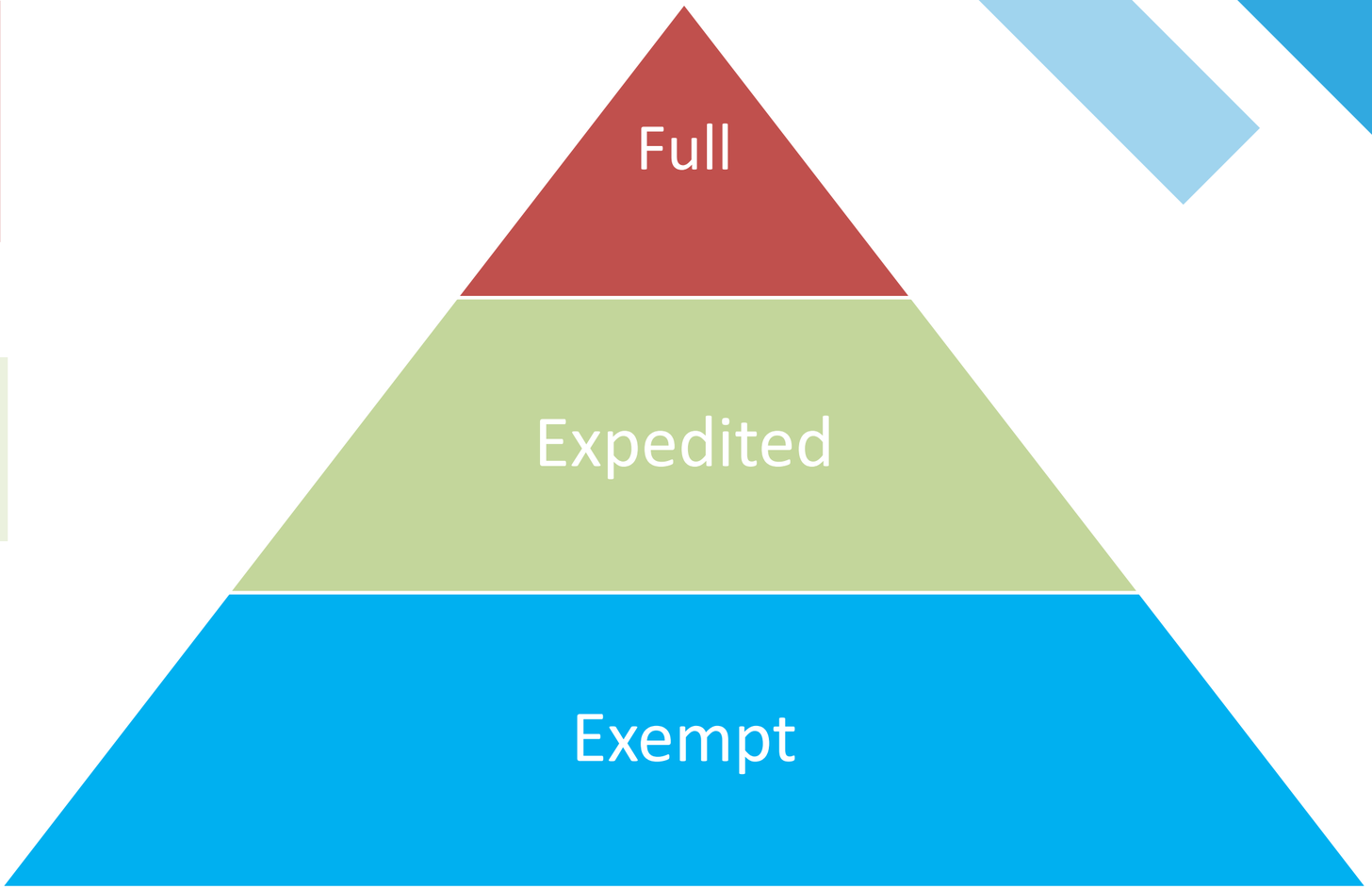
4) Any research that claims exemption will need to be reviewed by the SDCCD

What type of Research is review by IRB?

Example: clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures

Example: collection of bio specimens by noninvasive means.

Example: Research with de-identified records



SDCCD IRB Process

Required Submission Materials:

- SDCCD IRB Proposal Form
- Attestation Form for each Investigator
- IRB approval letter from your institution
- Verification of Training in Human Subjects Research
- Informed consent forms (per 45 CFR § 46.116)
- Data collection instruments (e.g., surveys, interview guides)
- Recruitment materials (e.g., email scripts)

SDCCD IRB Process

- Proposals must be submitted after receiving IRB approval from sponsoring institution.
- SDCCD IRB reviews proposals monthly (no meetings during summer).
- Deadlines and decision dates are posted on the IRB website
- All materials are reviewed to ensure that ethical practices are in place to protect human participants.

Submission Deadlines

IRB Submission Deadline And Review Dates

IRB Submission Deadline Dates	IRB Decision Expected
Friday, January 10, 2025	Friday, March 14, 2025
Monday, February 10, 2025	Friday, April 11, 2025
Monday, March 17, 2025	Friday, May 16, 2025
Monday, September 8, 2025	Friday, October 10, 2025
Monday, October 6, 2025	Friday, November 14, 2025

Becoming Part of IRB

1. Interest Form
2. Human Subjects Certification (Department of Health
3. PHRP, CITI)
4. Attend to New Members Orientation (by Invitation)

SAN DIEGO
Community College District

Thank you
and
Workshop Evaluation

SAN DIEGO CITY COLLEGE
SAN DIEGO MESA COLLEGE
SAN DIEGO MIRAMAR COLLEGE
SAN DIEGO COLLEGE OF CONTINUING EDUCATION

Institutional Innovation and Effectiveness