LOS ANGELES COMMUNITY COLLEGE DISTRICT

INSTITUTIONAL REVIEW BOARD

Educational Programs & Institutional Effectiveness

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The following is meant to provide an introduction to the IRB's role and how to submit a proposal to conduct research at the LACCD. This presentation includes information on:

- The purpose & role of the IRB
- How to determine the level of IRB review (Exempt, Expedited, or Full Review)
- Steps to submit a proposal to conduct research at LACCD

IRB Purpose & Role

- The primary purpose of the IRB is to protect the rights and welfare of human subjects who participate in research conducted by the LACCD Colleges and Educational Service Center.

- The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality.

History of Human Research Protection

- Institutional Review Boards exists as a reaction to past research abuses, most notably the human experimentation done by the Nazis during World War II and the Syphilis Study at Tuskegee (U.S. Public Health Service).
  - Other incidences include: the Willowbrook Hepatitis Experiments (Krugman, New York University School of Medicine), the Tearoom Trade Study (Humphreys, Washington University), the Stanford Prison Experiment (Zimbardo), and the Milgram Obedience Study (Yale University).
- From these and other incidents came various important responses, which include:
  - The Nuremburg Code, Belmont Report, and the Common Rule

Basic Principles of the Nuremburg Code

(https://history.nih.gov/research/downloads/nuremberg.pdf)

1. Voluntary consent of the human subject
2. Experiment should yield a benefit for society, unattainable by other methods of study
3. Anticipated result should justify the experiment
4. Avoid all unnecessary physical and mental suffering and injury
5. No *a priori* reason that death or disabling injury will occur
6. Degree of risk should never exceed the humanitarian importance of the problem being studied
7. Provide protection for human subjects again even the remote possibilities of injury, disability, or death
8. Experiment to be conducted by scientifically qualified persons
9. Subjects have the liberty to stop the experiment at any stage
10. The scientist must terminate the experiment if it is likely to result in injury, disability, or death

Basic Principles of the Belmont Report

(https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf)

The Belmont Report (1979) identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects

1. **Respect for Persons**
   - Treat individuals as autonomous agents, allow people to choose for themselves, and provide extra protections to those with diminished autonomy (i.e., prisoners, children, cognitively impaired, etc.)
   - Rules Derived: Informed consent and respect for privacy

2. **Beneficence**
   - Do no harm & maximize benefits and minimize risks
   - Rules Derived: Good research design, Competent investigators/researchers, and favorable risk-benefit analysis

3. **Justice**
   - Treat people fairly and have an equitable distribution of research burdens and benefits
   - Rules Derived: Equitable selections of subjects

The Common Rule

(https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)

- The “Common Rule” is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report. The regulations are established under the Department of Health and Human Services, Office for Human Research Protections.
- Mechanisms established: Institutional assurances of compliance, review of research by an IRB, and the informed consent of research subjects.

Determining Level of IRB Review

The requirements for submitting a proposal depend on the levels of IRB review required for your protocol; this is determined by the type of research being conducted (e.g., the population being sampled, the type of data being collected) and the level of risk for the participant.

The following slides contain important definitions, criteria, and resources that will help guide you in determining the appropriate type of IRB review for your research.

Important Definitions

Research

Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (See 45 CFR 164.501)

Human Subject

A human subject means, “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.”

Important Definitions

Minimal Risk

"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

(See 45 C.F.R. § 46.102(i))

Types of IRB Review

- Exempt
- Expedited
- Full Board Review

It may also be determined that no IRB review is required.

Decision trees can also be found on:
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

Determining if IRB Review is Required

- IRB review and approval is required for projects that:
  - Meet the definition of research,
  - Involve human subjects, and
  - Include any interaction or intervention with human subjects or involve access to identifiable private information.

- If you are unsure if your project requires IRB review, please consult with Office of Institutional Effectiveness on your campus or contact our office: esc-irb@email.laccd.edu

Exempt Review

- Must be minimal risk research
- Fits one of six categories
- Review is typically conducted by a designated IRB member
- Exemptions are not granted for research involving prisoners of for some types of research activities involving children.

Minimal risk

Categories of Exemption

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording.
4. 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.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads.
6. Taste and food quality evaluation and consumer acceptance studies.

Expedited Review

- Must be minimal risk research
- Fits one or more of the seven categories
- Rigor same as full committee review
- Decision may be rendered by a designated IRB member or by a majority of the assembled quorum, depending on the level of risk and time sensitivity of the project

Research Eligible for Expedited Review

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(4)).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full Board Review

- Any study that does not meet the Exemption or Expedited Criteria or research involving vulnerable populations, sensitive topics, or complex research designs
- A full quorum is assembled
- Decision is rendered by a majority of the assembled quorum
- No member with a conflict of interest can participate in the decision
- All members participate in the discussion and comments

Steps to Submitting a Research Proposal

To submit a proposal, the researcher must complete the following steps:

1. Complete Required Human Subjects Research Training
2. Obtain Institutional Approval
3. Submit an IRB Application
4. Maintain Research Protocol

Step 1: Complete Human Subjects Training

Anyone wishing to conduct research within the District must complete Human Subjects Research Training, which provides information about issues that may arise in the context of conducting research, with a focus on the protection of human subjects. The training is provided by CITI Program (https://about.citiprogram.org/en/homepage/).

- Go to the website and register as an affiliate of the “Los Angeles Community College District” organization
- Create a username and password
- Enroll in and complete the training

Step 2: Obtain Institutional Approval

To obtain approval to conduct your investigation, you must complete the research review process conducted by College Institutional Effectiveness Office or the District Research Committee (DRC), if research is proposed across more than one LACCD campus. The review process includes:

- Determining the level of review required for your research protocol and completing the appropriate application
- Submitting the completed application to the Institutional Effectiveness Office at your campus, who will review the application
  - If the research is approved, the office will complete an “Institutional Approval Form” and you can proceed to step 3
  - If it is not approved, the IRB will not review the proposed project

Step 3: Submit an IRB Application

The IRB application, along with supporting documents, may be submitted electronically to the IRB office (esc-irb@email.laccd.edu).

- Applications will not be reviewed unless the Principal Investigator has completed their Human Subjects Training, obtained institutional approval to conduct their research, and has a complete IRB application (there is a submission checklist on the first page of the application)
- Researchers will be notified electronically regarding the disposition of their application
- Research may only be conducted once IRB approval has been obtained

Step 4: Maintain Research Protocol

Once your IRB application has been approved, your research protocol is **valid for one year**. Researchers are responsible for maintaining their research protocol current; this is accomplished by submitting necessary updates and forms to the IRB. These include:

- Amendment Application – used when an investigator wants to make changes to the already approved research protocol
- Adverse Event Reporting Form – used when an adverse event occurs and is submitted within 72 hours of the event
- Continuing Review Application – used to renew the research protocol for another year
- Final Report Form – used to share information about your study and its findings and is completed once your research has concluded

Questions?

Please contact our office:

esc-irb@email.laccd.edu