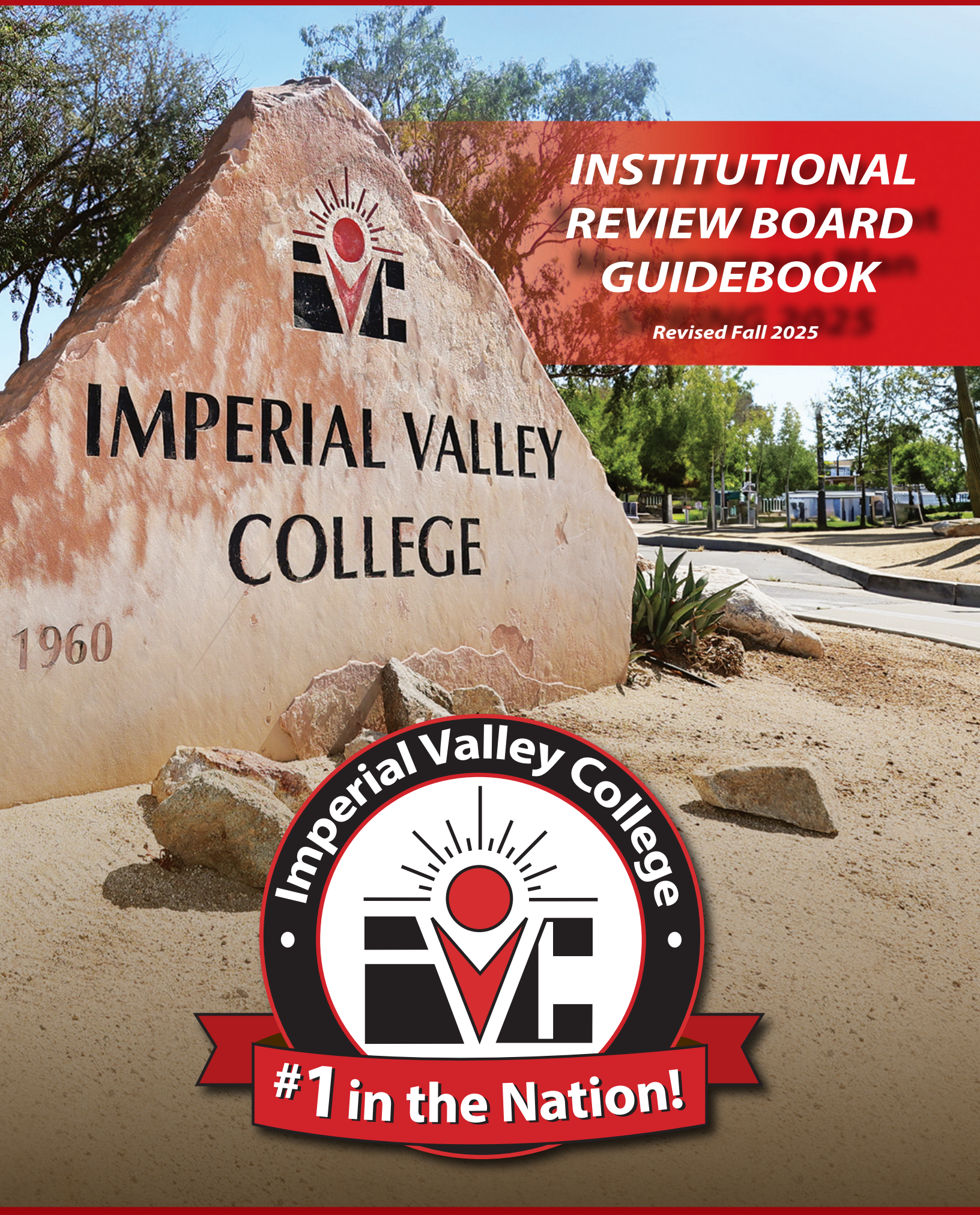

INSTITUTIONAL REVIEW BOARD GUIDEBOOK

Revised Fall 2025

Imperial Valley College
Institutional Review Board (IRB):
Process and Guidelines for Human Subject Research

Developed by:

Office of Institutional Effectiveness
Supporting Decision - Making

Table of Contents

Section 1 – Introduction & Roles

A. Introduction

IVC's Institutional Review Board (IRB) was developed to review human subject research proposals to ensure that the rights and welfare of students are protected by minimizing risks and ensuring informed and voluntary participation. The Institutional Review Board at IVC is responsible for overseeing the procedures and for establishing at the college to ensure that each project that is being evaluated is following ethical standards regarding issues such as informed consent, confidentiality, and risk to participants.

B. Role of the Office of Institutional Research

The role of the Office of Institutional Research (OIR) at Imperial Valley College (IVC) is to support the college mission by centering data and research. Historically, the OIR defines research through a holistic approach that involves gathering of enrollment and student outcome statistics (e.g., retention, transfer, and completion rates). With the adoption of IVC's Comprehensive Master Plan-Vision 2030, the institution if fully committed to becoming more data-driven in every aspect. As a result, revisions to existing processes identified the need for an Institutional Review Board manual. The Office of Institutional Research was charged with creating said manual in support of the expansion of research activities and to ensure that the rights of human research subjects are protected.

Section 2 - Purpose, Overview & Scope of IRB

A. Purpose of IRB

The purpose of the IRB at Imperial Valley College is to secure the well-being of participants who may participate in research studies or investigative inquiries.The IRB assists researchers and members of the institution with, but not limited to, the following:

- Comply with state and federal regulations that apply to institutional studies or investigative inquiries
- Mitigate potential liability from which all parties may be exposed
- Protect Imperial Valley College from exposure to potential liability

B. Overview and scope of IRB

Under Food and Drug Administration (FDA) regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. In accordance with the Office of Human Research Protection (OHRP) guidelines and FDA regulations, an IRB has the authority to approve, disapprove or require modifications of research scope. The review process plays an important role in the rights and welfare of human subjects. The purpose of an IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.

To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to insure protection of the rights and welfare of human subjects of research. An essential component of the IRB is to ensure compliance with state and federal laws and the protection of faculty, staff, students and management when research related to the institution is being conducted.

Section 3 – Defining and Identifying Human Subject Research

A. Defining Human Research Studies

Studies based on data that are individually identifiable but are also publicly available may not constitute human subject research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor or educational statistics. An investigator should not assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

Certain studies may have the characteristics of human subject research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are 3 categories to consider:

- Studies that qualify as human subject research
- Studies that possibly qualify as human subject research
- Studies that do not qualify as human subject research

B. Defining Human Subject Research

1. Human Subjects - A human subject is defined by Federal Regulations as "a living individual" about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

2. Living Individual - The specimen, data and/or information must be collected from living subjects. Cadavers, autopsy specimens or specimens/ information from subjects who are now deceased are not human subjects.

3 "About whom" - a human subject research project requires the data received from the living individual to be about the person.

4. Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail,and phone interaction as well as other modes of communication.

5 Identifiable private information -includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, (such as a public restroom)" and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).

Section 4 – Studies that Qualify as Human Subject Research

Studies that meet the criteria of the categories below require IRB review.

1. Studies that produce general knowledge about categories or classes of subjects from individually identifiable information.

2. Studies that collect data through intervention or interaction with individuals. Examples of this type of research include in-person and online surveys, open-ended interviews, studies that involve deception, and research involving risky behaviors or attitudes that contribute to generalizable knowledge.

3. Studies that use private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.

4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded, and the investigator does not have access to the coding systems. Guidance on research involving coded private informationor biological specimens is available online at: (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html)

5. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space ortest chamber.

6. Studies that utilize test subjects for new devices, products, drugs, or materials.

Section 5 – Studies that Do Not Qualify as Human Subject Research

Studies that meet the criteria of the categories below typically do not need IRB review.

1. Data collection for administrative or departmental purposes does not require IRB review. Examples: teaching evaluations, customer service surveys.

2. Service surveys are issued by college personnel for the purpose of improving services and programs of the college or for developing new services or programs for students, employees, or alumni. If the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This includes surveys by professional groups or the college. *Note: If an opportunity arises to contribute previously collected identifiable or coded survey data to a new study, IRB review would potentially be required before the data can be shared with the new project.*

3. Information gathering interviews where questions focus on products or policies rather than people or their thoughts regarding themselves. Examples: canvassing librarians about their libraries' inter-library loan policies or periodical purchases or interviews with company engineers or managers about how a product is made.

4. Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement but are not intended for use outside of the classroom. Example: instruction on research methods and techniques. *Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject,[4] or "engaged in research."*

5. Biography or oral history research involving a living individual that is not generalizable beyond that individual.

6. Independent contracts for procedures carried out by an external agency. Examples: personnel studies, cost-benefit analysis, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

7. Research involving cadavers, autopsy material or biospecimens from now deceased individuals. *Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review.*

8. Innovative therapies except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to individuals, or when innovative therapy is investigational.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*

9. Quality Improvement projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. Case History or Case Study which are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. *Note: Investigators should contact the IRB if they are uncertain as to whether they are contributing to general knowledge.*

11. Publicly Available Data Do Not require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available."*

12. Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review if the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not independently allowed to make this decision. These projects require verification from the IRB liaison or their designee.*

13. Non-Engagement in Research examples include when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research.

Note: the examples above are not an all-inclusive listing.

Section 6 – Institutional Review Board Members and Processes

A. IRB Member Requirements

Federal policy provides that IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. IVC's Review Board Structure is illustrated below.

IVC Review Board Members	
Position	**Role**
Associate Dean of Institutional Effectiveness	Chairperson
Research Analyst	Voting Member
Vice President of Academic Services	Voting Member
Vice President of Student Services	Voting Member
Faculty Member (area of expertise)	Voting Member

B. IVC-IRB Review Requirements

Research projects that gather data from human subjects should undergo review by a faculty member, administration or department to determine if the activity requires IRB review. Thus, all members of the campus community who are involved in collecting data from must review their research according to the IRB guidelines and submit their research proposal(s) for review if deemed necessary by the guidelines, even if the research is being conducted off campus. Additionally, members outside the campus community who wish to use or collect data from the campus, or its students must undergo IRB review.

Section 7 – Submitting an IRB Petition to Imperial Valley College

A. IRB Petition and Instructions

Any researcher who intends to submit an IRB request to Imperial Valley College should submit a petition through the IVC website by using the link below:
https://www.imperial.edu/about/institutional-research/irb-request-form.html

B. IRB Petition Checklist

Before submitting a final petition, please consider the following checklist items:

- ✓ Research plan/proposal
- ✓ Name of principal investigator and/or co-investigators
- ✓ Duration of project
- ✓ Samples of informed consent
- ✓ Outline of information to be provided prior to subject's agreement to participate.
- ✓ Instruments, protocols, surveys, questionnaires, etc.
- ✓ Any other pertinent information

C. IRB Contact Information

Please submit a complete IRB petition, project summary and all other required documentation to the Office of Institutional Research. Questions can be directed to Institutional Research Staff at the link below. If an investigator is unsure of whether a proposal constitutes "human subject research", the investigator should submit an inquiry email to the IRB Chairperson or Associate Dean of Institutional effectiveness at jose.carrillo@imperial.edu or reference the OIR staff directory at https://www.imperial.edu/about/institutional-research/staff-directory.html
The Chairperson, staff or designee will determine if a study requires IRB review; Federal regulations do not allow investigators to make this determination themselves.

Complete petitions will be reviewed upon receipt, and investigators will be notified of the petition status within 14 business days.