Institutional Review Board Process and

Guidelines for Human Subjects Research

Imperial Valley College

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Office of Institutional Research
Supporting Decision-Making

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INTRODUCTION

The role of the Office of Institutional Research (OIR) at Imperial Valley College (IVC) is to support the colleges mission by centering a data and research. Historically, the OIR defines research through a holistic approach that involves gathering of enrollment and student outcomes statistics (e.g. retention, transfer, and completion rates). More, recently, with the adoption of our new Imperial Valley College 2030 Vision Comprehensive Master Plan (2030), the institution has committed to be more data-driven for all intents and purposes. As a result of these changes and updates to current process at IVC has determined the need for the OIR to create an Institutional Review Board manual for in support of the expansion of research activities and to ensure that the rights of human research subjects are protected.

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 established at the college to ensure that each project evaluated complies with ethical standards concerning issues such as informed consent, confidentiality, and risk to participants.

OVERVIEW OF INSTITUTIONAL REVIEW BOARD (IRB)

The purpose of the IRB at Imperial Valley College is to ensure the well-being of participants who may volunteer for or participate in research studies or investigative inquiries.The IRB assists researchers and members of the institution:

- Comply with state and federal regulations that may apply to their studies or investigative inquiries
- Protect them from potential liability from which they may be exposed
- Protect Imperial Valley College from any liability it may be exposed

PURPPOSE 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 and as stated in the Code of Federal Regulations, 45 CFR §46, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role of 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. At Imperial Valley College, the main

purpose of the IRB is to ensure compliance with state and federal laws and the protection of faculty, staff, students, and administrators when research related to the institution is being conducted.

Authorizing Regulations:

- 1. Federal Register 56 (June 18, 1991): 28002-28032 [Federal Policy for the Protection of Human Subjects; Notices and Rules] (The Common Rule)
- 2. Title 45 Part 46 of the Code of Federal Regulations a. Codification of the Federal Policy for each of the departments and agencies adopting it is as follows:
    - i. CFR Part 1c [Department of Agriculture]
    - ii. 10 CFR Part 745 [Department of Energy]
    - iii. 14 CFR Part 1230 [National Aeronautics and Space Administration]
    - iv. 15 CFR Part 27 [Department of Commerce]
    - v. 16 CFR Part 1028 [Consumer Product Safety Commission]
    - vi. 22 CFR Part 225 [International Development Cooperation Agency] [Agency for International Development]
    - vii. 24 CFR Part 60 [Department of Housing and Urban Development
    - viii. 28 CFR Part 46 [Department of Justice]
    - ix. 32 CFR Part 219 [Department of Defense]
    - x. 34 CFR Part 97 [Department of Education]
    - xi. 38 CFR Part 16 [Department of Veteran's Affairs]
    - xii. 40 CFR Part 26 [Environmental Protection Agency]
    - xiii. 45 CFR Part 46 [Department of Health and Human Services]
    - xiv. 45 CFR Part 690 [National Science Foundation]
    - xv. 49 CFR Part 11 [Department of Transportation]
- b. FDA regulations pertaining to research with human subjects are codified at:
    - i. 21 CFR Part 50 [Protection of Human Subjects]
    - ii. 21 CFR Part 56 [Institutional Review Boards]

DEFINING HUMAN SUBJECTS

A human subject is defined by Federal Regulations as **"a living individual <u>about whom</u> an investigator conducting research obtains (1) data through intervention orinteraction with the individual, or (2) identifiable private information."**

Living individual- The specimen(s)/ data/ information must be collected from <u>live</u> subjects. Cadavers, autopsy specimens or specimens/ information from subjects now deceased are not human subjects.

"About whom" - a human subject research project requires the data received from theliving individual to be <u>about</u> the person.

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.

Identifiable private information "includes information about behavior that occurs in acontext 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).

IDENTIFYING HUMAN RESEARCH STUDIES

Studies based on data that are individually identifiable but are also publicly available may not constitute human subjects 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 subjects research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are three categories to be considered:
Studies that <u>are</u> human subjects research
Studies that <u>may be</u> considered human subjects research (gray area)
Studies that <u>do not</u> qualify as human subjects research

STUDIES THAT <u>ARE</u> HUMAN SUBJECTS RESEARCH

1. Studies that produce generalizable knowledge about categories or classes ofsubjects 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 riskybehaviors or attitudes that contribute to generalizable knowledge.

3. Studies using 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 on the web at: (http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf).

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.

STUDIES THAT ARE <u>NOT</u> HUMAN SUBJECTS RESEARCH

Studies that fit any of the categories below typically do not need IRB review.

1. **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.

2. **Service surveys** issued or completed by college personnel for the intent and purposes of improving services and programs of the college or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or the college. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge; IRB review may be required before the data could be released to the new project.*

3. **Information-gathering interviews** where questions focus on things, 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]"*

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

6. **Independent contract for procedures** carried out for 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. Please contact the IRB for further information.*

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 particular individuals, or when the 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 or not 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 or not they are contributing to generalizable 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 as long as 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 determination. These projects require verification from the IRB liaison or their designee. (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1)*

13. Some examples of **Non-Engagement in Research** 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. (http://www.hhs.gov/ohrp/policy/cdebio.pdf)*

IMPERIAL VALLEY COLLEGE IRB PROCESS

Research projects that gather data from human subjects should undergo, at least, some review by a *faculty member, administration, or department* to determine if the project 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.

IVC IRB Review Members			
Name	**Role**	**Email**	**Extension**
Yolanda Cataño	Interim Associate Dean of Institutional Effectiveness, Equity, and Student Success	yolanda.catano@imperial.edu	X5710
Jose Carrillo	Director of Institutional Research	jose.carrillo@imperial.edu	x
Oliver Zambrano	Research Analyst	oliver.zambrano@imperial.edu	x
Dr. Christina Tafoya	Vice President of Academic Services	christina.tafoya@imperial.edu	x
Faculty Designee	TBD	TBD	TBD

*Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should submit an email to jose.carrillo@imperial.edu.

The IRB staff, associate dean, director, VP, and faculty designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

SUBMITTING AN IRB REQUEST TO IMPERIAL VALLEY COLLEGE

Any researcher who wants to request IRB at Imperial Valley College should submit the form below. Please submit this form and project summary and pertinent documentation to Imperial Valley College Office of Institutional Research to jose.carrillo@imperial.edu.

Petitions will be reviewed, and investigators will be notified about the acceptance of the petition within 14 business days. If you have received IRB approval from another institution, please attach the approval letter along the petition.

PETITION FOR IVC IRB APPROVAL FORM

Before you submit the form to the Department of Institutional Research, 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

Once you have reviewed the checklist above, please proceed to fill out the form using this link: https://forms.imperial.edu/view.php?id=747108

*If you have any questions, please feel free to contact Jose Carrillo at jose.carrillo@imperial.edu or Yolanda Cataño at yolanda.catano@imperial.edu or visit our IVC Institutional Research webpage at https://www.imperial.edu/about/institutional-research/.