HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD PROCEDURES

The Institutional Review Board (IRB) is a college committee whose task is to review all research conducted by Cañada College students, faculty, and staff that involves the use of human subjects, and to make sure that this research is being done in compliance with federal policy 45CFR46, and other applicable regulations.

Criteria for Determining When IRB Review is Required

1. The activities are considered research. Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g., publication - including a thesis or dissertation - or presentation or use outside the specific instructional setting).

2. The activities involve human subjects. Research is considered to involve human subjects if it involves living individuals about whom an investigator obtains data through intervention or interaction with the individual(s) or obtains identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

   There is human subjects involvement when:

   - Human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material.

   - People are asked to participate through interaction that solicits personal information (surveys, interviews, observation).

   - Information concerning specific, individually identifiable human beings is asked for from third parties - whether through access to files, data banks or other means - or through direct inquiry of third parties concerning the individuals in question.

Who Needs to Submit an IRB Protocol

1. Cañada faculty, students, or staff planning to conduct human subjects research.

1. Outside investigators must register their protocol with the Office of Planning and Research prior to collecting data at Cañada College by filling out an IRB application and submitting a copy of the protocol that was reviewed by their home institution as well as a copy of the IRB approval letter.

Types of IRB Review

There are three types of IRB review:

1. Expedited Review (protocol approval is determined by a single reviewer).

2. Full Review (protocol approval is determined by every member of the IRB).

3. Exempt Review (protocol approval is determined by the Office of Planning & Research). Exemption is not the same as exclusion from IRB review. Exempt status is conferred by the Office of Planning and Research prior to data collection after the investigator has submitted all the required supporting documents. These may include a complete protocol narrative, agreements from participating institutions, data instruments, and information on how informed consent will be obtained, when applicable.

Timeline

Protocols must be submitted and approved prior to data collection or recruitment of human subjects. The stated timelines and dates in the protocol must allow enough time for IRB approval. The IRB cannot retroactively approve data collection and protocols with unrealistic timelines will be withdrawn from consideration. Data collected without IRB approval cannot be used in publication or dissemination.

The investigator submits two copies of a complete IRB protocol to the Office of Planning & Research. Any subsequent documents or revisions that are submitted must contain the researcher's name and a description of the research activity (coded with the tracking number).

If the protocol qualifies for exemption, the IRB coordinator will email the investigator to indicate that the protocol will be registered under an assigned tracking number. The investigator may begin after receiving a second email indicating the registration has been approved (7-10 business days).

. If the protocol does not qualify for exemption, the Office of Planning & Research pre-screens all protocols, generates a tracking number, identifies any necessary preliminary revisions or missing documents, emails the researcher, and sends the protocol to the IRB Board(time varies, but typically 1-7 days).

The IRB Board will be informed of the preliminary revisions that were requested. If the requested revisions are minor, the investigator may wait until the reviewer has made a recommendation before submitting the corrections.

. The IRB Board examines the protocol, identifies any required revisions, and returns the protocol to the Office of Planning & Research (7-25 days). The IRB Board can either:

1. Approve the protocol.

2. Provisionally approve the protocol, pending the submission of revisions, additional documents, or information. The revisions are submitted to and reviewed by the Office of Planning & Research.

3. Request a Full IRB Review. Cases when this may occur:

    * The research involves greater than minimal risk to participants.

    * The subjects are a protected/vulnerable group (e.g., prisoners).

The IRB meets once a month during the Fall and Spring semesters. Full Reviews are scheduled as needed for the next available monthly meeting. Investigators are notified by the Office of Planning regarding the date, time, and location of the Full Review.

4. Ask the investigator to re-submit a new protocol. Cases when this may occur:

    * The protocol is poorly written or lacks the information needed to make a recommendation.

Once the protocol is approved by the reviewer, and the investigator has submitted any requested revisions, it is forwarded to the Office of Planning & Research for final approval. The Office of Planning & Research notifies the researcher of IRB approval via email.

DOCUMENTS NEEDED FOR A COMPLETE CAÑADA IRB PROTOCOL

To ensure compliance the IRB requires that all investigators submit a standard set of documents designed to procure all of the essential information about a particular study prior to initiation of the research. All of the documents and materials that are submitted to the IRB are what constitute the **IRB protocol.**

Training Verification

Investigator or sponsoring professor (if applicant is a student) has completed a mandatory IRB training. If the sponsoring professor has previously submitted a certificate of completion from the IRB training to the Office of Planning & Research, it is not necessary to include the certificate with every student application.

Application

The IRB application is two pages and includes a Request to Use Human Subjects in Research as well as a Request to Determine Eligibility for Exemption. Please fill out the second page of the application only if you believe that your research may qualify for exempt review. Exempt status is conferred by the Office of Planning & Research once the protocol has been evaluated to ensure that the research entails only minimal risk to participants, does not involve a vulnerable population, and falls into at least one of the six prescribed categories of exemption.

If the investigator is a student, a sponsoring professor must read and approve the student's IRB protocol and sign the first page of the application where indicated.

Protocol Narrative

In addition to the IRB application, the investigator should attach an Abstract, Statement of Purpose, and a complete description of the methods and procedures of the research that adequately explains:

. Who the subjects are.

. How subjects will be recruited and what they will be asked to do.

. The kinds of materials and/or devices that will be used, including:

1. How the investigator will recruit and get information from participants (e.g., the use of recruitment flyers/advertisements, surveys, questionnaires, interview questions, tests).

2. How the information will be recorded by the investigator (e.g., written notes, photographs, audio/video recording, transcription). If participants will be recorded or photographed, the investigator should describe how these materials will be used and must state this information on the consent form.

. The risks and benefits of the study.

. A clear description of the kinds of identifiers, if any, that will be obtained and reported, or mechanisms for maintaining confidentiality (e.g., how materials will be kept safe, who has access to the data, and measures the investigator will implement in reporting data, such as the use of pseudonyms or other kinds of coding systems).

· How informed consent will be obtained if participants are adults and how assent will be obtained if participants are minors (see Informed Consent Materials section for more information).

Informed Consent Materials

Attach to the application the appropriate consent form, letter, or script containing all of the elements of informed consent. If a paper copy is to be distributed to participants, it must be on SJSU departmental letterhead.

The purpose of informed consent procedures is to:

1. Inform participants of the research and what it will entail, including the risks and benefits of the research.

2. Inform participants of their rights (e.g., participation is voluntary).

3. Provide participants with information on who to contact if they have any questions.

The following is an outline of what kind of informed consent materials should be submitted for IRB review:

If the protocol qualifies for exemption and data is being sought directly from participants, the investigator may obtain informed consent either in writing or verbally. Documentation of informed consent is not required; however, the Office of Planning & Research recommends providing participants with information that addresses the above three items in writing whenever applicable. For anonymous surveys, for example, signature lines on the standard consent form are replaced with a statement such as "Your completion of the survey indicates your willingness to participate. Please keep this information for your records and do not write any information that could identify you on the survey."

. If the protocol does not qualify for exemption, the investigator must submit a document that solicits the informed consent of participants (e.g., consent form, script). Written consent may be waived under certain circumstances. For example, when participants come from a culture that has an oral rather than written tradition, investigators may submit an informed consent script, outlining the manner in which informed consent will be obtained verbally. Investigators must explicitly request that written consent be waived in their protocol narrative, and must document alternative procedures for obtaining informed consent. Requests to waive the need for written consent will be considered on a case by case basis.

. If the research involves minors, the investigator must always submit a consent form that solicits the permission of a parent or guardian, as well as information on how assent will be obtained from the minor (either verbally or in writing depending on the age group).

. If the research involves minors who are wards of the state, the investigator must submit written permission from the judge assigned to the youth for their participation.

If the research involves the evaluation of student records in which the investigator has access to individually identifying student information, the investigator must submit a consent form that solicits the permission of the student, or a parent/guardian if the student is a minor, to access the records. Permission from a participating institution is also required when applicable (see Permissions from Participating Institutions section for more information).

. If the research involves evaluation of employee records in which the investigator has access to individually identifying employee information, the investigator must submit a consent form that solicits the permission of the employee to access the records. Permission from a participating institution is also required (see Permissions from Participating Institutions section for more information).

If the research involves evaluation of medical records in which the investigator has access to individually identifying patient information, the investigator may be required to submit a consent form that solicits the permission of the patient to access the records. Permission from a participating institution is also required (see Permissions from Participating Institutions section for more information).

Refer to the IRB website for consent form templates for adults and parents/guardians of minors, cover letters, and instructions for online surveys

Data Instruments

Attach to the application all data instruments, and other materials to be distributed to participants (e.g., surveys, questionnaires, interview questions, description of physical interventions or tests, data intake sheets).

Permissions from Participating Institutions

If applicable, obtain permission from outside institutions or agencies that either serve as a source of subjects, a source of records and information, or on whose facilities your project will be conducted. Participating institutions may include:

Schools, hospitals, government agencies, community organizations

Be aware that other institutions may have their own IRBs; if so, you must make your project known to them and go through the proper channels to get permission.

Permission from participating institutions must be on their letterhead and must include: the title of the study, the inclusive dates for which the permission is granted, and the title and type written name of the individual with the authority to grant such permission, in addition to their signature.

FUNDAMENTAL RULES

Investigators conducting research in accordance with Cañada policy must:

Obtain HS-IRB approval prior to soliciting subjects or collecting data. This includes projects that may qualify for exemption. Exempt status is determined by the Office of Planning and Research and not by the researcher. NOTE: Exemptions from HS-IRB review will not be granted for research involving protected classes of subjects (e.g., pregnant women, prisoners, children, or those institutionalized as mentally disabled) even though the research may appear to belong to an exempt classification.

Provide potential subjects with information necessary to make an informed decision regarding participation in the study.

Protect the confidentiality of all subjects participating in research and all data that may be collected from the subjects, unless the researcher has provided thorough documentation indicating to participants that they will be identified in publication or dissemination.

Provide special safety procedures, as needed, to avoid any harm to subjects. Harm includes psychological trauma, physical injury, and the release of potentially damaging personal information.

Provide additional protection for “at risk” subjects, such as children, pregnant woman, the elderly, the infirm, and any person receiving treatment for a serious psychological or physical problem.

Provide immediate and follow-up care in case of research-related injury, and report any research-related injuries to the Institutional Officer overseeing the IRB.

Federal and California State statutes and University policy require that investigators are knowledgeable about and comply with regulations for the protection of human subjects in research.

CONTACT INFORMATION

The Office of Planning & Research

Administration Building: 8-211

IRB Protocol should be submitted to:

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