



COMPTON COMMUNITY COLLEGE DISTRICT
BOARD OF TRUSTEES POLICIES

**AR 3226 Procedures for
Institutional Review Board (IRB)**

**Issued: June 16, 2020
Revised: November 17, 2020**

References:

Code of Federal Regulations (CFR), Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP), National Science Foundation (NSF);
Title 45 part 46; Title 45 part 690;
45CFR part 690 §.107; 45CRF46.102;
[The Belmont Report](#);
BP 3226 - Institutional Review Board.

Investigators who would like to conduct human subject research must apply to the Institutional Review Board (IRB) at Compton College. The Director of Institutional Effectiveness, serving as the chair of the IRB, will collect the required information from applicants and convene the Institutional Review Board monthly during the fall and spring primary terms to review applications and provide a decision about Compton College participation.

The IRB at Compton College is charged with the responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, any risk to the participants, and evaluating the alignment of the study with the College's Mission.

The IRB role, guided by the Belmont Report, will include the following:

1. Review proposed research studies that involve the use of human subjects;
2. Ensure that all research subjects are treated ethically;
3. Ensure that all research subjects are provided with substantial information, consent, and debriefing;
4. Ensure that research subjects' private information will be handled confidentially;
5. Ensure that each research study complies with ethical standards;
6. Ensure that approved research studies align with the College's Mission Statement;
7. Be an active resource to the campus regarding research ethics;
8. Guide the research ethics progress and process for the College;
9. Develop timelines and recommend policies and procedures for conducting human research projects at Compton College; and,

10. Coordinate training for faculty, staff, and management about research ethics standards, policies, and procedures.

IRB Make-up

The IRB will be chaired by the Director of Institutional Effectiveness. The IRB is an ethics committee composed of at least five individuals who serve as advocates for human subjects involved in research and who have varying expertise and diversity including at least one individual from the community and one nonscientist as outlined in regulations (45CFR part 690 §.107).

Members whose training, background, and occupation would incline them to view scientific activities from a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from outside a biomedical or behavioral scientific discipline should be considered a nonscientist. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments about the acceptability of the research in terms of Compton College's mission, regulations, relevant law, ethical standards, and standards of professional practice. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the educational research that it reviews. External or internal consultants may be used to review proposals for which additional expertise is needed. Further, the IRB may call on external or internal consultants to support special populations, such as students with disabilities, formerly incarcerated students, or foster youth.

The gender and ethnic makeup of the members should be taken into consideration, as well as representation of the college employees and students. There is to be one member from the community.

Due to federal regulations set forth regarding the preferred expertise and training of committee members, members will be recommended by the District as well as the Academic Senate for appointment with the number of faculty appointed to be *three*. Compton Community College Federation of Employees (*Classified*) may appoint two nonscientists to the IRB.

All members will be required to complete Human Subject Protection training and maintain an active certification throughout their service on the Compton College IRB.

Member list

Chair- Director of Institutional Effectiveness
Administrator Representative (scientific or non-scientific)
Three (3) Academic Senate Representative (at least one scientific and one non-scientific representative)
Two (2) Federation of Employees (Classified) Representative (non-scientific)
Community Member

IRB Review Process

The IRB Chair will conduct an initial review all petitions for research projects and evaluate them relative to the criteria set forth by the committee. Each application will identify a Primary Investigator (PI). The Chair will communicate with the PI on behalf of the IRB and the College. The projects could be categorized into one of the following: exempt from review; requires an expedited review; or requires a full board review by the IRB.

Exempt

In the Compton College IRB Application Form, applicants will suggest if their research is eligible for exempt or expedited review if there is no or minimal risk. The Chair of the IRB will review to determine if the application shows acceptable evidence of no or minimal risk. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified. Under federal regulations, certain types of research qualify as exempt unless the appropriate federal agency has determined otherwise

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>), such as:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained identifies human subjects, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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 and which are designed to study, evaluate, or

otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The IRB Chair, not the investigator, shall make the recommendation as to whether a project is or is not exempt. The IRB determines if a study is exempt and reports on all approved exemptions to the President/Chief Executive Officer (CEO).

Expedited Review

Under federal regulations, certain types of research qualify for an 'expedited' review(see<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>). These are activities that: (1) present no more than minimal risk to human subjects; and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

1. Clinical studies of drugs and medical devices.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens (e.g., hair and nail clippings) 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. Where medical devices are employed, they must be cleared/ approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review including studies of cleared medical devices for new indications.)
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).
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. (Note: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where the above categories two (2.) through eight (8.) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB Chair may recommend a protocol to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full Board. The IRB Chair cannot “disapprove” of a protocol but may table action pending further information/clarification. The IRB Chair will inform the Principal Investigator (PI) of its actions. Any disagreement between the PI and the IRB Chair must be resolved by the full IRB. The PI may request a Full Board Review of any denied research request. The IRB authorizes the Chair to approve an expedited review research projects at the College and reports on all approved requests to the President/CEO.

Full Board Review

If there is considered to be significant risk to the participants of the study, that is inherent in the study, then it requires a petition to the IRB for full Board review. Compton College discourages research requests of this nature. Studies in this category may be considered by the IRB only if they are clearly in alignment with the mission of the College. The PI must receive formal approval from the IRB, as well as sign appropriate paperwork with the Institutional Effectiveness Department, before engaging in any research activity on campus.

The IRB webpage will contain all documents needed by both the IRB and researchers.

Meetings and Approvals

The IRB will meet monthly during the Fall and Spring semesters. The Co-Chair of the IRB will make decisions and inform the IRB regarding studies that are exempt or expedited, but the IRB shall grant a decision on research studies requiring full Board review. If no external research requests are submitted to the College, the Chair will cancel the meeting. If only Exempt requests, as determined by the Chair, are submitted, the Chair may request a review of materials and approval via email from the IRB members.

Reports

The IRB shall provide an informational report to the Consultative Council, quarterly.

The PI will be required to share the final report with Compton College. Further, if and when deemed appropriate, the IRB can choose to share the results of a particular study in conjunction with the PI.

Compton College will require to be identified by a pseudonym in all reports.