

HUMAN SUBJECTS RESEARCH

It is the policy of the Sequoias Community College District ("District") to act in an ethically responsible manner when conducting research involving human subjects. To that end, an Institutional Review Board (IRB) at COS has been established to provide a process to ensure that the normal and prudent policies established for the protection of human subjects are followed at the District.

This policy applies to any and all human subjects research (i.e., activities that are procedures, demonstrations, and/or experiments which use human subjects) conducted by District faculty, staff, or students as well as to any non-District entities performing research upon District faculty, staff, or students with the expressed consent of the District. Persons conducting such research are known, for the purpose of this document, as "investigators."

Here, *research* means a *systematic investigation* designed to develop or contribute to *generalizable knowledge* (per 45 CFR 46). Data collection and analysis activities occurring at the District that do not meet this definition of research would not be subject to this policy.

Institutional Authority

This Board Policy and associated Administrative Procedure establishes and empowers the District Institutional Review Board. The District IRB will be registered with the Federal Office of Human Research Protections (OHRP).

Basic Principles

The basic principles adhered to by the District are drawn from the Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

1. **Respect for Persons:** Individuals should be treated as autonomous agents. That is, individuals should be treated as capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to an individual person's considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

2. **Autonomy:** The investigator has an obligation to each participant to treat them as a person fully capable of making an informed decision regarding his or her participation in the research. Each participant must be given a full disclosure of the nature of the study, including any risks or benefits. To ensure the autonomy of the participant, the District requires a signed informed consent form from each participant in the study unless the study meets the exception criteria outlined in the sections on “consent” (i.e., Specific Requirements, subsection (e) – “Consent”) or “exemptions.”
3. **Beneficence:** The investigator has an obligation to each participant to attempt to maximize benefit for each participant and/or society, while minimizing the risk of harm to each participant.
4. **Justice:** The investigator has an obligation to provide for equitable selection of participants, i.e., avoiding unfair coercion. The investigator is also obligated to provide for equitable distribution of benefits and burdens among the selected population. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. As an example, the burdens of serving as research subjects should not fall largely upon the poor, infirm, or upon particular racial or ethnic minorities, while the research benefits likewise should not fall largely and exclusively upon, for example, the rich and/or healthy populations.

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