Informed Consent

Obtaining the informed consent of the project participants is one of the more regulated parts of doing Human Subjects Research. Typically consent must be documented via a consent form. The consent form should include:

- The purpose of the research, duration, and what to expect
- A description of the risks in participating
- A description of the benefits
- A description of alternate procedures (if treatment is involved)
- A description of how confidentiality will be maintained
- A statement of whether compensation for harm is available
- Contact information for the researcher and the Director of ORSP
- A statement that the participant is free to withdraw at any time

Guidance regarding consent forms and examples are posted on the ORSP website.

Note: University policy requires that all Human Subjects Research be reviewed by the IRB to protect the subjects, but a review also protects the investigator. If a subject is injured, becomes overly emotional, or decides later that they are unhappy they participated, an IRB approval shows that federal protection regulations were followed.

Whom to Contact:

CSUEB Institutional Review Board
Kevin Brown, Chair
kevin.brown@csueastbay.edu

Office of Research and Sponsored Programs
Anne Wing, IRB Coordinator
California State University, East Bay - ORSP
Hayward, California 94542
anne.wing@csueastbay.edu
510.885.4212

To Learn More:

CSUEB Office of Research and Sponsored Programs
www.csueastbay.edu/orsp

Office for Human Research Protections
www.hhs.gov/ohrp

Office of Research on Women's Health
www4.od.nih.gov/orwh

President's Council on Bioethics
www.bioethics.gov

A Guide to Understanding Informed Consent
www.cancer.gov/clinicaltrials/conducting/informed-consent-guide

IRB Forum
www.irbforum.org

Are you conducting research using human subjects?

The CSUEB Institutional Review Board can help!

CALIFORNIA STATE UNIVERSITY
EAST BAY

Human Subjects Research

The CSUEB Institutional Review Board (IRB) is responsible for protecting the interests of human subjects participating in research projects conducted by CSUEB faculty, staff, and students or research conducted by others on the CSUEB campuses or using CSUEB faculty, staff, and students as their subjects.

In order to fulfill this charge, the IRB reviews all research involving human subjects before the research begins. Federal Regulations 45 CFR 46, Protection of Human Subjects defines:

Research – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

At CSUEB, the IRB considers any research intended for publication to be research. This includes journal articles, conference presentations or masters theses. In general, class projects are not considered research (unless they may be published).

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains

1) data through intervention or interaction with the individual,

or

2) identifiable information.

Is my research Human Subjects Research? Some examples:

No:

- Journalism (not generalizable)
- Research using publicly available data such as Census data (no intervention and not private data)
- Research on business practices, construction methods, etc. (not regarding an individual)
- Research on a historical figure (individual is no longer living)
- Anonymous observation (no interaction or identity determination)

Yes:

- History/Ethnic Studies - Collecting oral histories
- Teacher Education – Evaluating new teaching techniques in K-12 classrooms
- Psychology – Determining student attitudes through questionnaires
- Women's Studies – Studying women's health issues through surveys and interviews
- Communicative Sciences – clinical studies, e.g. "Computer-based interventions for Alzheimer's sufferers"
- Anthropology/Sociology – surveys, e.g. "Urban reactions to rural accents in Japan", "Attitudes of native employees of call center in India"

If you are unsure whether your research is Human Subjects Research, please contact the chair of the IRB (contact information on the reverse).

If my proposed research is Human Subjects Research, what should I do next?

Before beginning your research, submit a research protocol to the IRB. The research protocol should include descriptions of:

- The proposed project
- The subject population
- The possible risks to the participants
- The methods used to reduce possible harm and
- The form which will be used to document the consent of the participants
- Any survey instruments or questionnaires

Guidance on writing research protocols is provided on the ORSP website.

The IRB will screen the protocol to determine if Human Subjects Research is being conducted. If so, certain categories of research (low risk) may be found to be exempt from IRB review. Only the IRB, however, may make this determination. Research in other categories may undergo expedited review, and the rest undergo full board review. The IRB may then request modifications if necessary to protect the subjects, after which approval may be granted.

IRB approval lasts up to one year. For multi-year projects, continuation review is completed at least once per year.