

SOCIAL AND BEHAVIORAL vs BIOMEDICAL RESEARCH	SOP 11.1.01
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1. Purpose & Policy

The purpose of this SOP is to provide guidance regarding the distinction between social and behavioral and biomedical research at Caltech.

2. General Information

The research at Caltech falls into the broad categories of either social and behavioral or biomedical research. Social and behavioral and biomedical research are two distinct fields of research that differ in their focus, methodology, and goals. The goals of social and behavioral research are often to gain insights into human behavior and social interactions, to identify factors that contribute to health or well-being, and to develop interventions or policies that can improve individual's lives. The goals of biomedical research are often to understand the biological mechanisms that underlie diseases, to develop new treatments or interventions, and to improve the overall health of the population.

The IRB will review each protocol and determine if the work is social and behavioral or biomedical. This decision will dictate the necessary training requirements that all researchers working under that protocol will need to take. There are times when the two areas of research intersect. In those circumstances, the IRB will require hybrid training.

3. Training Requirements

There are no specific training requirements associated with determining whether a study is social and behavioral or biomedical; however, researchers should carefully read and follow this guidance when selecting a type of study. Once a protocol is determined to be social and behavioral or biomedical by the IRB, specific CITI training courses are required based upon that determination: Social & Behavioral Research – Basic/Refresher, Biomedical Research – Basic/Refresher, or Hybrid Research – Basic/Refresher. Please refer to the [IRB website](#) for more information regarding training.

4. Procedure

A. Social & Behavioral Research

Social and behavioral research refers broadly to research that deals with human attitudes, beliefs, and behaviors and is often characterized by data collection methods such as questionnaires, interviews, focus groups, direct or participant observation, and non-invasive physical measurements. Social and behavioral studies that involve the use of drugs or devices,

radiation and radiolabeled tracers, and other invasive procedures will be classified as biomedical (e.g., fMRI, electrical stimulation). See section D below for additional detail regarding devices.

Social and behavioral research may be qualitative or quantitative. Social and behavioral research also includes epidemiological or outcomes research and health services research:

Epidemiological and behavioral studies: These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.

Outcomes and health services research: These studies seek to identify the most effective and most efficient interventions, treatments, and services.

Common Types of Social & Behavioral Research

1. Questionnaires, interviews, and focus groups
2. Studies of existing records
3. Observation:
 - a. With or without observer interaction
 - b. Public information (e.g., court records, motor vehicle registration) and/or non-public information (e.g., medical or educational records in which the participants are identified)
 - c. Conducted in public places, labs, or private settings (e.g., a clinic, therapy office, participant's home)

B. Biomedical Research

Biomedical research refers to the study of human physiology and specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons; the design of methods, and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; and/or the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology. This research is typically quantitative and not qualitative.

Common Types of Biomedical Research

1. Studies designed to evaluate the safety, effectiveness, or usefulness of an intervention.
 - a. Therapies (e.g., exercise, or medical devices)

- b. Diagnostic procedures
 - c. Preventative measures
- 2. Research on normal human functioning and development.
 - a. Studies of the human body while exercising, fasting, feeding, sleeping or learning
 - b. Responding to such things such as stress or sensory stimulation
- 3. Research on specific disease processes is often needed before improved methods of prevention, diagnosis, and treatment can be developed (e.g., research on the neurological changes associated with Alzheimer’s Disease).
- 4. Research on the human genome and genetic markers.
- 5. Clinical Trials
- 6. Social and behavioral studies that involve the use of drugs or devices, radiation and radiolabeled traces, and other invasive procedures.

C. Hybrid Training

Hybrid training is available for researchers whose labs perform both Social & Behavioral and Biomedical research or for protocols that are social behavioral studies that involve the use of drugs or devices, radiation and radiolabeled tracers, and other invasive procedures (e.g., fMRI, electrical stimulation).

Social & Behavioral protocols require researchers to complete the Social & Behavioral Research – Basic/Refresher or the Hybrid Research – Basic/Refresher course. Biomedical protocols will require researchers to complete the Biomedical Research – Basic/Refresher or the Hybrid Research – Basic/Refresher course.

Protocol Designation	Acceptable CITI Training Course
Social Behavioral Protocol	Social & Behavioral Research – Basic/Refresher
	Hybrid Research – Basic/Refresher
Biomedical Protocol	Biomedical Research – Basic/Refresher
	Hybrid Research – Basic/Refresher

D. Biomedical v Social and Behavioral Devices

Biomedical devices are those commonly used in biomedical research (e.g., at medical schools) and social and behavioral devices are those commonly used in psychological/behavioral

research (e.g., in psychology departments). Generally, biomedical devices are more invasive or introduce energy into participants, whereas social and behavioral devices do not. Social and behavioral devices observe participants and the data collected is a dependent variable. The below lists are examples of the devices that may fall within each category.

Biomedical Device Examples:

- MRI
- Intracranial readings
- PACT
- Ultrasound imaging
- Ultrasound neuromodulation
- Transcranial Magnetic Stimulation (TMS)
- Transcranial Direct Current Stimulation (tDCS)
- Electrical Simulator

Social & Behavioral Device Examples:

- Eye-tracker
- Computer and peripherals (mouse, keyboard, joystick)
- Skin-conductance response devices (EEG, ECG, EOG, and any other measures that involve placing patches on the surface of the body to measure electrical resistance)
- Respiration belt or pulse oximeter to monitor breathing
- Any video of parts of the body, in addition to eye-tracking
- Any audio recording of voice, heart, breathing or anything else in the body as long as it is non-invasive