

Using Human Subjects in Research

Why is a review of my research needed?

Federal regulations state that all research involving human subjects is subject to review and approval by an Institutional Review Board (IRB). The IRB at CSUDH must review all proposals that:

- Will be conducted by, or under the supervision of, staff, faculty or students at CSUDH
- Will involve CSUDH staff, faculty or students
- Will be performed on the CSUDH campus or involve CSUDH equipment or facilities

What about classroom activities?

Classroom projects that are used exclusively for instructional purposes need not undergo IRB review. However, if the data will be disseminated outside the university, a clearance form must be submitted.

How do I submit a protocol for review?

The Office of Research and Funded Projects is located in Welch Hall D-445, (phone) 310.243.3756 (fax) 310.516.4410 and has available the clearance forms and instructions. This information can also be obtained at the IRB website: <http://www.csudh.edu/RF/r&fpro3.html>. Three copies of the completed forms should be submitted.

Human Subjects Protection Certificate

Beginning in August 2004, all principle investigators must successfully complete one of three options to become certified in human subjects protection research:

- Online training program offered by the National Institute of Health at <http://cme.cancer.gov/c01/>
- Training program offered by the Harbor-UCLA Research Education Institute
- Training program offered by the University of Rochester Medical Center

Submission of a completion certificate will be required prior to IRB approval of research protocols.

What are the deadlines for submission?

The IRB meets once per month to review protocols. Your protocol must be received by the deadline date indicated below: to be covered at the meeting.

<i>Deadline Date</i>	<i>Meeting Date</i>
February 19, 2004	March 4, 2004
March 18, 2004	April 8, 2004
April 22, 2004	May 6, 2004
May 20, 2004	June 3, 2004

When can I expect to hear the results of the review?

IRB determinations are received approximately one week after the IRB has met, discussed and voted on your proposal. Letters are mailed to the address provided on the application.

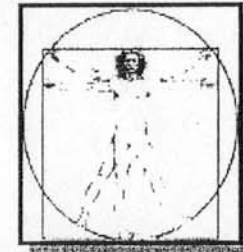
The Function of the Institutional Review Board

The IRB:

- Determines and certifies that all projects conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights and privileges of human subjects
- Assists the investigator in complying with DHHS regulations in a manner that permits accomplishment of the research activity

What is the definition of "human subjects" research?

Human subjects research includes any research that involves humans, human tissue, or records and data gathered on humans.



Subject recruitment and data collection may not be initiated prior to formal written approval from the CSUDH Institutional Review Board for the Protection of Human Subjects